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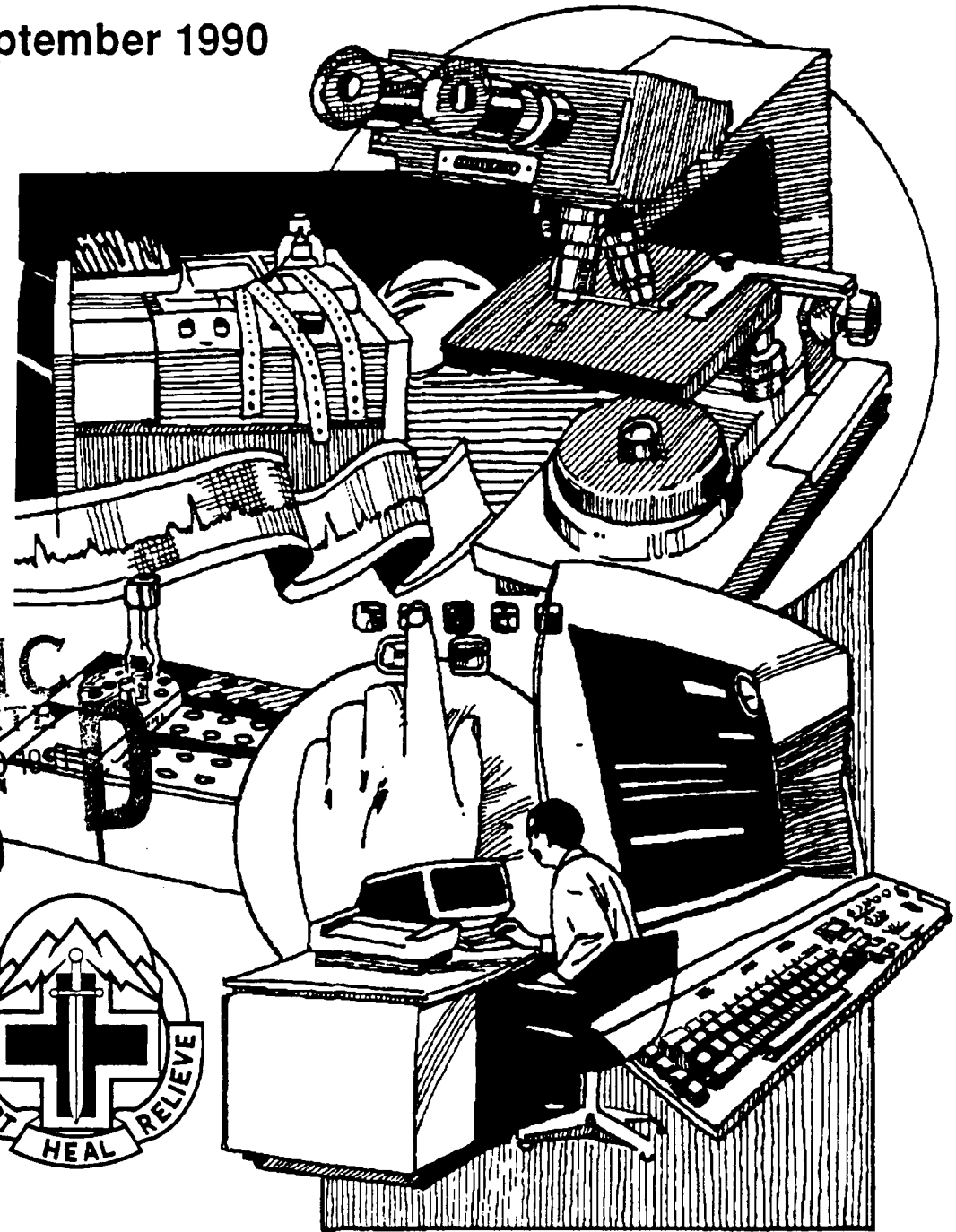
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CLINICAL INVESTIGATION PROGRAM

30 September 1990

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DEPARTMENT OF CLINICAL INVESTIGATION

Fitzsimons Army Medical Center
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ANNUAL PROGRESS REPORT

REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER 26	2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) Annual Research Progress Report (U)		5. TYPE OF REPORT & PERIOD COVERED ANNUAL FY 90
		6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s) SHANNON M. HARRISON, LTC, MC		8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS Department of Clinical Investigation Fitzsimons Army Medical Center Aurora, Colorado 80045-5001		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
11. CONTROLLING OFFICE NAME AND ADDRESS Office of Deputy Commander (HSHG-ZB)		12. REPORT DATE 30 September 1990
		13. NUMBER OF PAGES
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office) U.S. Army Health Services Command ATTN: HSHN-I Fort Sam Houston, TX 78234-6060		15. SECURITY CLASS. (of this report) Unclassified
		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) Approved for public release, distribution unlimited		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report) NA		
18. SUPPLEMENTARY NOTES The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Unit summary; research protocols (objective, technical approach, progress); publications; presentations.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies these individuals who are conducting investigative protocols at Fitzsimons Army Medical Center. An abstract of each protocol giving abbreviated technical approach, objectives, and progress is presented.		

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30 SEPTEMBER 1990

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
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FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1990 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 40-23, as amended, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations. In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is grateful to the Center's Commander, BG Thomas E. Bowen and all of the professional and administrative staff for departments and directorates who have furthered the mission of Clinical Investigation Department at Fitzsimons through their cooperation and extra effort as reflected in this report. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Deputy Chief, LTC Leo A. Andron, the Research Protocol Specialist, Ms. Marcia Bilak, and Ms. Chris Montoya, Secretary, without whose assistance and support beyond the call of duty this year's progress and its report would not have been possible.



SHANNON M. HARRISON
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Chief, Department of
Clinical Investigation

TABLE OF CONTENTS

REPORT NO. 26

	Page
Report Documentation Page	(a)
Reports Control Symbol Med-300	(b)
Foreword	(c)
Table of Contents	(d-bb)
Unit Summary + HMLAC Report + Service Report	i-ix
Publications FY 90.....	1-14
Presentations FY 90	15-30
Detail Summary Sheets	31-442
Investigator's index	443
Key Word Index	451
Distribution	459

DEPARTMENT OF MEDICINE

<u>No.</u>	<u>Status</u>		
80/120	O	Evaluation of Carbohydrate Metabolism in Thyrotoxicosis: Investigations into the Frequency, Type and Mechanisms of Carbohydrate Tolerance	32
81/117	O	The Role of Calcitonin in Osteoporosis (PR) (P)	34
81/118	O	Hypothalamic Pituitary Gonadal Function in Hypothyroidism	36
81/119	C	The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion (P)	37
82/114A	T	Growth of Basal Cell Carcinoma Cells in Defined Medium and Study of their Growth and Immunological Characteristics	39
83/107	O	Use of Isotretinoin in Prevention of Basal Cell Carcinoma (PR) (P)	40
83/113A	O	Growth of Human Keratinocyte (P)	42
83/122	O	The Role of Food Allergy in the Pathogenesis of Migraine Headaches (PR) (P)	44
83/126	O	The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism	46
84/100	O	The Effect of Abnormal Thyroid States on the Metabolism of Theophylline and Methylprednisolone (PR)	48
84/115A	C	Heterotransplantation of Basal cell Carcinomas to Nude Mice (P) (PR)	50

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

84/119	O	Treatment of Graves' Ophthalmopathy with Cyclosporin	52
85/100	O	SWOG #7804 - Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III	53
85/102	C	SWOG 7827 - Combined Modality Therapy for Breast Carcinoma, Phase III	54
85/122	C	SWOG 8221 - Treatment of Advanced Bladder Cancer with Preoperative Irradiation and Radical Cystectomy vs. Radical Cystectomy Alone, Phase III	55
85/132	C	SWOG #8294 - Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer, Intergroup Study	56
85/133	C	SWOG #8300 - Treatment of Limited Non-Small Cell Lung Cancer: Radiation Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III	57
85/136	C	SWOG #8313 - Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of the Breast, Phase III	58
85/139	O	SWOG 8393 - National Intergroup Protocol for Intermediate Thickness Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Margins (2 vs 4cm) Around the Melanoma and Evaluation of Elective Regional Lymph Node Dissection	59
85/141	C	SWOG 8411 - Evaluation of DTIC in Metastatic Carcinoid, Phase II	60
85/142	C	SWOG 8415 - Evaluation of Tamoxifen in Un-resectable and Refractory Meningiomas, Phase II	61
85/147	C	HLA and Gm Genes in Systemic Lupus Erythematosus Antibody Expression	62
85/157	C	SWOG 8590 - Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck	63
85/158	C	SWOG #8591 - NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole Plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon, Phase III-Intergroup	64
85/163	C	The Effect of Theophylline and Nifedipine on Hormone Secretion (P)	65
85/165A	O	An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae Pollens and Mold Spores of the Same or Related Botanical Families (PR) (P).....	67

Ongoing (O), Completed (C), Terminated, (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

85/166	C	Colon Inflammation in Reiter's Syndrome: Response to Sulfasalazine. Results in a Controlled Study (P) (PR)	69
85/167	O	The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test	71
85/174	C	SWOG #8326/27 - Evaluation of Combination Chemotherapy Using High Dose ARA-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III	72
86/10X	T	- Feasibility Study to Determine if Estrogen and Progesterone Affect In-vitro Growth of Cultured Malignant Melanoma (MM) Cell Lines	73
86/103	C	SWOG #8592 - Evaluation of Low Dose Ara-C versus Supportive Therapy Alone in the Treatment of Myelodysplastic Syndromes (ECOG EST 4483)	74
86/107A	O	In-Vitro Drug Sensitivity Utilizing the Guinea Pig Airway Smooth Muscle Model (PR) (P)	75
86/109	O	The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism	77
86/114	O	Natural History of HTLV-III Infection and Disease in a United States Military Community (PR)	78
86/118	C	SWOG #8507 - Maintenance vs. No Maintenance BCG Immunotherapy of Superficial Bladder Cancer (P-PR)	79
86/119	C	SWOG #8514 - Randomized Comparison of Cisplatin + 5-Fluorouracil vs. CBDCA + 5-Fluorouracil vs. Methotrexate in Advance Squamous Cell Carcinoma of the Head and Neck, Phase III	80
86/120	O	SWOG #8516 - A Phase II Comparison of CHOP versus m-BACOD versus ProMaCE-CytaBOM versus MACOP-B in Patients with Intermediate or High Grade Non-Hodgkins' Lymphoma	81
86/123	C	SWOG #8519 - Phase II Evaluation of Methyl-Glyoxal Bis-Guanylhydrazone (MGBG) in Patients with Advanced Bladder Cancer	82
86/124	C	SWOG #8573 - Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy and Intensification with High Dose Cyclophosphamide	83
86/126	T	LCSG #832 - A Prospective Randomized Trial to Determine the Benefit of Surgical Resection of Residual Disease Following Response of Small Cell Lung Cancer to Combination Chemotherapy	84

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

86/12 ³	T	LCSG #853 - A Clinical Trial in Patients with Stage II and III Completely Resected Non-Small Cancer of the Lung Comparing Chemotherapy vs. no Therapy Following Surgery	85
86/132A	C	The Effect of Theophylline on Calcium and Vitamin D Metabolism (P)(PR)	86
87/102	T	Anti-Histone Antibody Production in Procainamide Associated Drug-Induced Lupus Erythematosus: Association of Serologic Patterns and Lymphocyte Subsets	88
87/103	O	Identification of Those at Risk for Osteoporotic Hip Fractures, by a Noninvasive Measurement (P)(PR)	90
87/104	O	SWOG 8600 - A Randomized Investigation of High-Dose Versus Standard Dose Cytosine Arabinoside with Daunorubicin in Patients with Acute Non-Lymphocytic Leukemia, Phase III	92
87/105	C	Pre-operative Cimetidine Therapy in Patients Undergoing Parathyroid Exploration: Efficacy and Mechanisms of Action	93
87/111	O	A Prospective Double Blind Study of Retrovir in Early HIV Infection (PR)(P)	94
87/112	O	SWOG 8598 - (RTOG-85-01) Prospective Trial for Localize Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup	95
87/113	C	SWOG 8624 - A Phase II Randomized Trial of Combination Therapy for Multiple Myeloma: Comparison of (1) VMCP/VBAP to VAD or VMCPP/VBAPP for Induction, (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha -2b Interferon + Dexamethasone for Incomplete or No Responders	96
87/114	O	Patient Evaluation of Physicians' Humanistic Qualities (P)(PR).....	97
87/115	T	A Double-Blind, Multicenter, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Gram-Negative Sepsis	99
87/116	O	Effect of Iodine Containing Water Purification Tablets on Thyroid Function in Man (PR)	100
87/117	T	Analysis of von Willebrand Factor Multimers Before and After Cardiopulmonary Bypass	101

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
88/101	T	LCSG 871 Centralized Non-Small Cell Lung Cancer Specimen Respository and DNA/RNA Bank ..	102
88/102	C	Effect of Chronic Coumadin Therapy on Cortical and Trabecular Bone Density in Man	103
88/103	C	Clinical Efficacy of Phenindamine as Determined by Skin Test Suppression	104
88/104	O	Descriptive Study of Pastoral Care Interventions Designed to Assist HIV+/AIDS Patients in Achieving Their Maximum Quality of Life (P) (PR)..	105
88/106	C	Use of Nifedipine (Gastrointestinal Therapeutic System) in the Treatment of Hypertension (PR)..	108
88/109	O	Methotrexate in the Treatment of Steroid Dependent Asthmatics (PR).....	109
88/110A	O	Biological Investigation of Cutaneous Lupus Employing Athymic Mice as Skin Heterotransplant Recipients	111
88/111	C	The Use of Fibrin Monomer and D-Dimer in the Evaluation of Patients with Chest Pain (PR) ...	112
88/112	C	Long-Term 5-Fluorouracil Infusion for Recurrent Head and Neck Cancer. A Phase II Pilot Study..	114
88/113	O	Methotrexate vs D-Penicillamine in Rheumatoid Arthritis: A Randomized Comparative Study ...	115
88/115	O	The Impact of an Ambulatory Care Rotation on Iterns' Psychosocial Attitudes	116
88/116A	O	Mouse Anti-Chenopod/Amaranth Pollen Monoclonal Antibody Production (PR)	117
88/117	C	A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvant to Opiate Analgesics in the Management of Pain in Cancer Patients	119
88/118	C	(CAP Study 12-21-87) Use of Nifedipine (Gastrointestinal Therapeutic System) in the Treatment of Angina Pectoris (PR).....	120
88/120	O	Ventilatory Effects of Transtracheal Oxygenation	122
88/121	O	Bone Density in Thyroid Extract Treated Patients (PR)	123
88/122	T	LCSG 881 - A Randomized Phase II Study of Preoperative Therapy for Patients with Technically Unresectable Non-Small Cell Lung Cancer	125
88/124	O	Corticosteroids in the Treatment of Stable Chronic Obstructive Pulmonary Disease	126
89/100	O	The Application of Orem's Self-Care Model in Type II Diabetes: An Outcome Study of Diabetic Self-Care Classes and Self-Care Contracting Comparing Self-Care Knowledge, Health Care Benefits, Weight Loss and Metabolic Control ...	127

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
89/102	O	Factors Determining Peak Bone Mass and Subsequent Bone Loss	128
89/103	O	Transient Hypoxia During Sedated Endoscopic Procedures	129
89/104	O	Efficacy of Corticosteroids in the Acute Treatment of Asthma: Is Duration of Symptoms Important?	130
89/105	O	Role of Blood Pressure Control in Progression of Diabetic Nephropathy and Other Microangiopathies	131
89/106	O	Immunologic Criteria for the Cessation of Immunotherapy	132
89/107	T	A Multicentric Observer-Blind, Randomized Study of the Safety, Efficacy and Tolerance of Cefpirome (HR-810) Versus Ceftazidime in the Treatment of Pneumonia	133
89/108	O	Efficacy of Pentoxifylline in Treating Diabetic Impotence	134
89/109	O	The Effect of Percutaneous Endoscopic Gastrostomy Tube Place on Gastric Emptying	135
89/110	O	Cyclic Oxygen Therapy at Rest and During Exercise	136
89/111	O	Multicenter Clinical Evaluation of Penicillin Skin Testing Materials	137
89/112	T	The Use of Megestrol Acetate to Treat Cachexia in Patients with Chronic Obstructive Pulmonary Disease and the Possible Improvement of Pulmonary Function	138
89/113	T	LCSG NC 3 Natural History Registry for Patients with Stage II Non-Small Cell Lung Cancer	139
89/114	O	Response of Arthritis and Microscopic Colitis to Sulfasalazine in Rheumatoid Arthritis Patients	140
89/115	O	The Effect of Congestive Heart Failure (CHF) on the Erythrocyte Sedimentation Rate (ESR) ...	141
89/116	T	Atrial Natriuretic Peptide (ANP) Levels in Patients With VVI Pacing With and Without Ventriculoatrial (VA) Conduction Versus Dual Chamber Pacing	142
89/117	O	Evaluation of Thermography in the Delineation of Late Phase Skin Tests (PR)(P)	143
89/118	T	Bronchoalveolar Lavage in Intubated Patients with the Adult Respiratory Syndrome for the Evaluation of Fat Emulsion Induced Changes in Alveolar Characteristics	144

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
89/119	O	Development of a Cardiopulmonary Resuscitation (CPR) Information Sheet and Assessment of Patient and Staff Exposure	145
89/120A	C	Mediastinal Tamponade Due to Closed Thoracostomy in a Goat	146
90/100	O	Platelet Thromboxane, Aggregation and Whole Blood Prostacyclin Synthesis in Human Thyroid Disease	147
90/101	C	Study of the Efficacy of Influenza Vaccine in Chronic Lung Disease - Serologic Response and Disease Prevention	148
90/102	O	Effect of Prolonged Administration of Iodine Containing Water Purification Tablets in Man	149
90/103	O	The Limulus Amoebocyte Lysate Assay for the Diagnosis of Spontaneous Bacterial Peritonitis in Ascitic Fluid	150
90/104	C	Group C/Treatment Protocol: Levamisole (NSC 177023) Plus 5-Fluorouracil as an Adjuvant to Surgery for Resectable Adenocarcinoma of the Colon. (NCI Protocol 89-0017)	151
90/105	O	Incidence and Prevalence of Hematuria in Patients on Long-Term Anticoagulation	152
90/106	C	Self-Treatment of Anaphylaxis in an Outpatient Population	153
90/107	O	A Double-Blind, Placebo-Controlled Randomized Trial of the Clinical and Hemodynamic Effects of Vasopressin in Patients with Cirrhosis and Acute Variceal Hemorrhage --- A Multi-Center Study	154
90/108	O	Comparison of Impedance Plethysmography, Venogram and Doppler Ultrasound in Diagnosing Deep Vein Thrombosis	155
90/109	O	Altitude Effects on Oxygen Kinetics During Exercise in Acclimatized Fit Troops	156
90/110	O	Effects of Altered Calcium on Blood Pressure ..	157
90/111A	O	Prevention of Pseudomonas Colonization by Saccharomyces boulardii or Lactobacillus acidophilus in Antibiotic Treated Mice	158
90/112	O	Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus	159
90/113	O	Effect of Cold Remedies on Metabolic Control of Noninsulin Dependent Diabetes Mellitus	160
90/114	O	Assessment of Patient Utilities for Health Outcomes: Influence on Aspirin Prophylaxis to Prevent Myocardial Infarction	161

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

		Page
90/115	O Relationship of Blood Flow in Hemodialysis Access to Recirculation with Variable Blood Pump Flow	162
90/116	O Smoking Cessation Enhancement by Estimated Lung Age and Measured Expiratory Carbon Monoxide Levels	163
90/117	O The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions	164
90/118	O Effect of Gymnema Sylvestre on Blood Glucose and Serum Insulin Levels	165
90/119	O Epidemiological and Retrospective Analysis of Patients Consuming L-Tryptophan Containing Products	166
90/120	O Dose Hepatitis-B Vaccine Promote Eosinophilia, Increase Serum IgE Levels or Sensitize Recipients?	167
90/121	O Temporal Course of Altitude Acclimatization ...	168
90/122	O Evaluation of Viral Hepatitis in Patients Infected with the Human Immunodeficiency Virus (HIV)	169
90/123	O Urinary Indices in Acute Renal Failure	170
90/124	O The Effectiveness of Octreotide (Sandostatin*) to Prevent Pancreatitis Caused by Endoscopic Pancreato-Biliary Procedures: A Double-blind, Randomized Study	171
90/125	O SWOG 8697 Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P) TH or CMFH---Intergroup ...	172
90/126	O SWOG 8710 Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III	173
90/127	O SWOG 8737 A Phase III Study, AZQ 24 Hour Infusion Versus BCNU for Adult High Grade Gliomas (Intergroup 0093)	174
90/128	O SWOG 8750 Pilot Study to Examine Cytogenetic Abnormalities in Patients with Acute Leukemia, Ancillary	175
90/129	O SWOG 8814 A Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors	176

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
90/130	O	SWOG 8899 A Prospective, Randomized Trial of Low-Dose Leucovorin + 5-FU, High-Dose Leucovorin + 5-FU, Levamisole + 5-FU, or Low-Dose Leucovorin + 5-FU + Levamisole Following Curative Resection in Selected Patients with Dukes' B or C Colon Cancer	177
90/131	O	VA Cooperative Study No. 316: Efficacy of Passive Immunization in the Prevention of Infection Due to <u>Klebsiella Penumoniae</u> and <u>Psudomonas Aeruginosa</u>	178
90/132	O	Prevention and Treatment of Steroid Induced Osteoporosis	179
90/133	O	The Effect of Terfenadine on Urination	180
90/134	O	Fibrinolytic and Thrombotic Activity in Unstable Coronary Disease	181
90/135	O	Comparison of Liver Biopsy Versus Noninvasive Testing Using Hepatic Ultrasound, Radionuclide Scanning, Erythrocyte Folate Levels and Methotrexate Levels for the Determination of Methotrexate-Induced Hepatotoxicity	182
90/136	O	SWOG 8921 A Phase II Trial of Cyclophosphamide/IL-2, DTIC/IL-2 and DTIC/Cisplatin/Tamoxifen in Stage IV Melanoma	183
90/137	O	SWOG 8312 Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III	184
90/138	O	SWOG 8520 Cis-Diamminedichloroplatinum (II), Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II	185
90/139	O	SWOG 8621 Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III	186
90/140	O	SWOG 8692 Therapy in Premenopausal Women with Advanced ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs the LH-RH Analog, Zoladex Phase III Intergroup	187
90/141	O	SWOG 8711 A Study of Reproductive Function in Patients with Testicular Cancer	188
90/142	O	SWOG 8736 Treatment Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy .	189

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

		Page
90/143	O SWOG 8793 Randomized Phase III Evaluation of Hormonal Therapy VS Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy	190
90/144	O SWOG 8794 Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy	191
90/145	O SWOG 8806 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Advanced Bladder Cancer	192
90/146	O SWOG 8809 A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas	193
90/147	O SWOG 8819 Central Lymphoma Repository Tissue Procurement Protocol	194
90/148	O SWOG 8836 A Study of chest Irradiation Plus Concurrent Daily Low-Dose Cisplatin Followed by High Dose Consolidation for Locally Advanced Non-Small Cell Lung Cancer	195
90/149	O SWOG 8896 Intergroup Phase I Protocol for Surgical Adjuvant Therapy of Rectal Carcinoma: A Controlled Evaluation of (A), Protracted Infusion of 5-Fluorouracil as a Radiation Enhancer and (B), 5-Fluorouracil Plus Methyl-CCNU Chemotherapy	196
90/150	O SWOG 8905 Phase II/III Study of Fluorouracil (F-FU) and Its Modulation in Advanced Colorectal Cancer	197
90/151	O Extrinsic Positive End-Expiratory Pressure (PEEP) Effects on Functional Residual Capacity in Normal Subjects and in Ventilated Patients Experiencing Air trapping (AUTO-PEEP)	198
90/152	O Residual Renal Function in Dialysis Patients ..	199
90/153	O Relationship of Calcium and Glucose Metabolism on Blood Pressure	200
90/154	O SWOG 8326 Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III	201

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

90/155	O	SWOG 8810 Six Courses of 5-Fluorouracil and Cisplatinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck, Phase II Pilot Study	202
90/156	O	SWOG 8812 Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance	203
90/157	O	SWOG 8828 A Phase II Trial of Carboplatin (CBDCA) in Relapsed or Refractory Acute Myeloid Leukemia	204
90/158	O	SWOG 8851 A Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Coladex and Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer.	205
90/159	O	SWOG 8892 A Study of Radiotherapy with or without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III	206
90/160	O	SWOG 8897 Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients and a Natural History Followup Study in Low-Risk, Node Negative Patients	207
90/161	O	SWOG 8910 Evaluation of Low Dose Continuous 5-Fluorouracil (F-FU) and Weekly Cisplatinum (CDDP) in Advanced Adenocarcinoma of the Stomach, Phase II Pilot	208
90/162	O	SWOG 8915 A Phase II Study of 6-Thioguanine Administered as 120 Hour Continuous Infusion for Refractory or Recurrent Small Cell Carcinoma	209
90/163	O	SWOG 8916 Evaluation of Merbarone in Pancreatic Adenocarcinoma, Phase II	210
90/164	O	SWOG 8952 Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid	211
90/165	O	SWOG 8997 A Phase III Chemotherapy of Disseminated Advnaced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide	212

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

90/166A	O	Evaluation of Allergenic Cross-Reactivity Amongst Cockroach Species	213
90/167A	O	Animal Model of Physiologic PEEP (Positive End- Expiratory Pressure)	214
90/168A	O	A Histologic and Immunopathologic Study of the Skin and Internal Organs of MRL+/+Mice	215
90/169	O	The Effect of Steroid Therapy on Recovery After Tonsillectomy	216
90/170	O	SWOG 8744 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Refractory Multiple Myeloma	217
90/171		SWOG 8789 A Randomized Study of Etoposide Plus Cisplatin and Etoposide Plus Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors	218
90/172	O	SWOG 8792 A Phase III Study of Alfa-n1 (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma	219
90/173	O	SWOG 8842 Dihydroxyazacytidine in Malignant Mesothelioma, Phase II	220
90/174	O	SWOG 8900 A Phase II Pilot of VAD and VAD-Verapamil for Refractory Multiple Myeloma .	221
90/175	O	SWOG 8931 Phase III Comparison of Cyclo- phosphamide, Doxorubicin and 5-Fluorouracil (CAF) and a 16-Week Multi-drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer	222
90/176	O	SWOG 8994 Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794	223
90/177	O	National Co-operative rHu Erythropoietin Study in Patients with Chronic Renal Failure: A Phase IV Multi-Center Study	224
90/178	O	The Efficacy and Safety of Orally Administered SQ 32,756 in the Treatment of Acute, Localized Non-Trigeminal Zoster in Immunocompetent Patients	225
90/179	O	A Randomized Prospective Study of Clindamycin or Pyrimethamine Therapy for Prevention of Toxoplasmic Encephalitis in HIV-Infected Individuals with Serologic Evidence of Latent <u>Toxoplasma gondii</u> Infection (CPCRA 001)	226

Ongoing (O), Completed (C), Terminated (T), Published (P) or
Submitted for Publication (SP), Presentations (PR).

DEPARTMENT OF SURGERY

78/20X	O	1-Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats	228
78/20X	O	2-Repair of Femoral Artery by Microvascular Technique in Rabbits and the Rat	229
78/20X	O	3-Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat	230
78/201	O	Clinical Study for Intraocular Lenses, General Leonard Wood Army Community Hospital	231
78/201	O	Clinical Study for Intraocular Lenses, Fitzsimons Army Medical Center (PR)	232
78/201A	O	Clinical Study for Intraocular Lenses, Munson Army Community Hospital	233
78/201C	O	Clinical Study for Intraocular Lenses, Ft. Riley, Ks	234
78/201D	O	Clinical Study for Intraocular Lenses, Ft. Sill, Ok	236
78/201E	O	Clinical Study for Intraocular Lenses, Ft. Carson, Co	237
84/20X	O	001 - Microvascular Arterial and Venous Anastomosis in Laboratory Rats	238
86/200A	O	Treatment of Urinary Tract Trauma in the Porcine Animal Model	239
86/209A	T	Effects of Nonsteroidal Anti-inflammatory Agents on Tendon Healing	240
87/202	O	Improving Cancer Management Through the Tumor Conference	241
87/203	O	Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Disorders Marked by Altered Patterns of Peripheral Blood Flow (PR)	242
87/204	O	Mechanism Based Treatment of Phantom Limb Pain (P) (PR)	243
87/205	O	Etiology of Low Back Pain Due to Muscle Tension (P) (PR)	246
87/206	O	Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain (P) (PR)	248
87/207	O	Determination of Mechanisms of Phantom Limb Pain: Phase 2 (P) (PR)	250

Ongoing (O), Completed (C), Terminated (T), Published (P) or
Submitted for Publication (SP), Presentations (PR).

			Page
88/20X	O	003-Evaluation of the Goat as a Model for Bone Grafting	252
88/20X	O	004-Development of an Animal Model for the Study of Anterior Cruciate Ligament Repairs ...	253
88/200	O	Alcon Surgical Intraocular Lenses Study	254
88/201A	O	Use of Goats for Training in Advanced Trauma Life Support	255
88/202	O	A Comparison of Clinical Features of Ulnar Nerve Compression at the Elbow Before and After Medial Epicondylectomy	256
88/203	O	Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective), Utilizing Anterior Rhinometric Techniques	257
88/206A	T	An Analysis of the Effect of Nonsteroidal Anti-inflammatory Medications on Regeneration of Articular Cartilage in New Zealand White Rabbits Treated by Intermittent Active Motion and Continuous Passive Motion	259
88/208	C	A Retrospective Analysis of the Incidence of Pseudoarthrosis in Posterior Spine Fusion Done Between 1971 and 1986 at St. Anthony's Hospital and Denver Children's Hospital	260
88/209	O	A Comparison of Percutaneous Repair vs Open Repair of Achilles' Tendon Ruptures (PR)(SP) ..	261
88/210A	C	Delayed Repair of Traumatic Intratemporal Facial Nerve Palsy in the Pig (PR)	263
88/211	T	Double Blind Crossover Study of Cyclobenzaprine versus Placebo in Patients with Primary Fibrositis: Correlation of Sympomatic versus Thermographic Criteria of Improvement	264
88/212	T	Prevention of Nosocomial Pneumonia and Gastroduodenal Ulcer Prevention in Mechanically-Ventilated Patients	265
88/213	O	Investigational Plan for the Clinical Study of Silicone Intraocular Lenses Sponsored by Allergan Medical Optics	266
88/214	O	Clinical Investigation of Intraocular Lenses in Minors Sponsored by COBURN Optical IND, Inc/Storz Ophthalmics Inc.	267
88/215	O	Plot Study For: Continuous Environmental Recording Activity, Headache, amd Muscle Contraction Level Among Subjects with Tension, Migraine or No Headache (PR)	268

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

			Page
89/20X	O	001-Microsurgical Training in Free Flap Transfer, and Vessel and Nerve Repair Utilizing the Rat	270
89/202	O	The Effect of Harvesting the Central One-Third of the Patellar Tendon and Reapproximating the Medial and Lateral Edges of Patellofemoral Joint Mechanics in Cadavers	271
89/203	O	Rates of Occurrence of Simultaneous and Independent Low Back Pain and Headache Among Patients with and without Chronic Pain	272
89/204	C	Incidence of Multiresistance in Serial Gram-Negative Isolates from ICU's	273
89/205A	O	Correlation of the Vocal Fold Vibratory Pattern to the Post Operative Surgical Wound in the Porcine Model	274
89/206A	C	The Effect of Liposuction of Mycutaneous Flaps in the Yucata Micro Pig	275
89/207	O	Etiology and Progression of Acute Muscle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercises	276
89/209	T	Clinical Investigation of the Synthes Spinal Spinal Internal Fixator	277
89/210	O	Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers	278
89/211	O	Randomization Study of Transurethral Resection of the Prostate vs Balloon Dilitation of the Prostate for Symptomatic Benign Prostatic Hyperplasia in Men	279
90/20X	O	001-Evaluation of the Goat as a Model for ACL Reconstruction Fixation Studies	280
90/200A	O	Comparison of ACL Graft Fixation Techniques in a Goat Model	281
90/201A	O	Use of Retrograde Cardioplegia in the Pig Model	282
90/202	O	Non-Surgical Treatment of Morton's Neuroma with Injection of Vitamin B-12/Lidocaine/Solumedral Combination (PR)	283
90/203	O	Synovial and Serum Keratan Sulfate Levels and Their Correlation with Arthroscopically Determined Articular Damaged Chronically Deficient Cruciate Ligament Knees	284
90/204	O	A Clinical Comparison of a Hydroxylapatite Coated versus Porous Coated Total Hip Implant for Use in Arthritic Human Hips	285

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

90/205	C	Investigation of the Radiology and Anatomy of the Origin of the Anterior Cruciate Ligament ..	286
90/206	O	Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electromagnetic Fields	287
90/207A	O	Patellar Tendon Healing and Strength Following Patellar Tendon Autograft Harvest in Goats	288
90/208A	O	Development of an Implanted, Hydroxyapatite Coated, Titanium Limb Prosthetic Through Tests in Tissue Culture, Then in Goats, and Finally in Humans	289
90/209	O	Reliability of Psychophysiological Measures Used to Evaluate Pain	290
90/210	O	Effectiveness of Treatments for Reflex Sympathetic Dystrophy	291
90/211A	O	Effects of Coumadin and Methotrexate on Bone Ingrowth and Fixation in Hydroxyl Apatite Coated Porous Implants in a Goat	292
90/212A	O	The Evaluation of Bone Ingrowth in Hydroxyl Apatite and in Non-Hydroxylapatite Porous Implants in a Goat	293
90/213	O	Eaton Trapezial Implant Long-Term Follow-Up ...	294

DEPARTMENT OF CLINICAL INVESTIGATION

77/300	O	Immunologic Disorders in Children and Adults. I. Correlation of Immune Function in the Immuno-deficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies (PR)	296
82/302	O	The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory (P)(PR)	298
86/300	O	Early Identification of <i>Borrelia burgdorferii</i> Antibody in Human Sera	300
88/30X	O	Veterinarian & Veterinary Support Personnel Training in Emergency Care Procedures for Lab Animals	301
89/300A	C	The Effect of the Topical Application of Minoxidil on Hair Growth in the "Nude" Mouse ..	302
89/301	O	Biology of Cutaneous Lupus: I Skin Lesion Examination (P)(PR)	303
89/302	O	Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus	305

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

89/303	O	Biology of Cutaneous Lupus: III The Study of the Effects of Ultraviolet Light on the Skin of Lupus Erythematosus Patients	306
89/304	O	Evaluation of the Protofluor-Z as a Screening Tool for Lead Intoxification in Children (P)(PR)	307
90/300	O	Videx (2',3'dideoxyinosine, ddI) Treatment IND Protocol No. 454-999-001. (Bristol-Myers Co.)	308
90/301	O	Videx (2',3' dideoxyinosine, ddI) Open Label Study Protocol No. 454-999-001. (Bristol-Myers Co.)	309
-----		Training Support Summary	310

DEPARTMENT OF OB-GYN

80/351	O	GOG #26 - Section A: Master Protocol for Phase II Drug Studies in the Treatment of Advanced Recurrent Pelvic Malignancies	313
80/352	O	GOG #26 - Section C: A Phse II Trial of Cis-Platinum	314
80/359	O	GOG #26 - Section S: A Phse II Trial of VM26..	315
80/378	O	GOG #72 - Ovarian Tumors of Low Malignant Potential A Study of the Natural History and a Phase II Trial of Melphalan and Secondary treatment with Cisplatin in Patients with Progressive Disease	316
80/379	C	GOG#74 - Early Stage I Vulvar Cancer Treated with Ipsilateral Superficial Inguinal Lymphadenectomy and Modified Radical Hemivulvectomy (Phase III)	317
80/380	O	GOG #73 - A Clinical Pathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy	318
82/35X	T	-001 - Repair of Femoral Artery and Fallopian Tube of Rabbit and Rat	319
83/351	T	Danazol in the Treatment of Premenstrual Syndrome	320
87/351	C	GOG 85 - Comparison of Hydroxyurea versus Cisplatinum and 5FU as an Adjunct to Radiation Therapy in Patients with Advanced Carcinoma of The Cervix	321
87/353	O	GOG 90 - Evaluation of Cisplatin, Etoposide, and Bleomycin Induction Followed by Vincristine, Dactinomycin and Cyclophosphamide Consolidation in Advanced Ovarian Germ Cell Tumors (O)	322

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

87/354	O	GOG 95 - Randomized Clinical Trial for the Treatment of Women with Selected Stage IAi & IAii & IBii Ovarian Cancer (Phase III)	323
87/356	C	GOG 97 - A Phase III Randomized Study of Cyclophosphamide and Cisplatin in Patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma Comparing Intensive and Non-Intensive Schedules	324
87/358	O	GOG 93 Evaluation of Intraperitoneal Chromic Phosphate After Negative Second-Look Laparotomy in Ovarian Carcinoma	325
87/359	O	GOG 99 Adjunctive Radiation Therapy in Intermediate Risk Endometrial Carcinoma	326
88/350	O	GOG 92 Radiation Therapy vs No Further Therapy in Selected Patients with Stage IB Invasive Carcinoma of the Cervix	327
88/351	O	GOG 94 A Phase II Study of the Treatment of Stage III and IV Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serious Carcinoma and Clear Cell Carcinoma of the Endometrium with Total Abdominal Radiation Therapy	328
88/355	O	GOG 104 Intraperitoneal (SWOG 8501) Intraperitoneal Cis-Platinum and Cyclophosphamide IV vs Intravenous Cis-Platinum and Cyclophosphamide IV in Patients with Optimal Stage III Ovarian Cancer	329
88/359	O	GOG 100 Monoclonal Antibody Against Free Beta HCG to Predict Developmetn of PGTD in Patients with Hydaditoform Mole	330
88/359	C	GOG 102A - Master Protocol for Intraperitoneal Drug Studies in Residual Ovarian Malignancies After Second-Look Surgery	331
88/360	O	GOG 87C A Phase II Trial of Hydroxurea, DTIC and VP16 in Patients With Advanced Uterine Sarcomas	332
89/350	C	GOG 76H A Phase II Trial of Echinomycin (NSC#E526417) in Patients with Advanced Squamous Cell Carcinoma of the Cervix	333
89/351	O	GOG 87D A Phase II Trial of VP-16 in Patients with Advanced or Recurrent Uterine Sarcoma	334
89/352	O	GOG 101 A Phase II Evaluation of Preoperative Chemoradiation for Patients with Advanced Vulvar Cancer	335

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

89/353	C	GOG 102C A Phase II Study of Intraperitoneal Administration of Cisplatin (NSC#119875) and Recombinant Alpha 2 Interferon in Residual Ovarian Carcinoma	336
89/354	O	GOG 107 A Randomized Study of Doxorubicin vs Doxorubicin Plus Cisplatin in Recurrent Endometrial Adenocarcinoma Previously Diagnosed as Primary Stage III or IV (Phase III)	337
89/355	O	GOG 102E Intraperitoneal Administration of Cisplatin (NSC#119875) and Etoposide (VP-16) (NSC#141540) in Patients with Residual Ovarian Carcinoma (Phase II)	338
89/356	O	GOG 102F Intraperitoneal Administration of Alpha Recombinant Interferon (aIFN) in Residual Ovarian Carcinoma (Phase II)	339
90/350	O	GOG 108 Ifosfamide and the Uroprotector Mesna, With or Without Cisplatin, in Patients With Advanced or Recurrent Mixed Mesodermal Tumors of the Uterus	340
90/351	O	GOG 109 A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy VS Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection	341
90/352	O	GOG 26EE: A Phase II Trial of Didemnin B in Patients with Advanced Pelvic Malignancies	342
90/353	O	GOG 26GG: A Phase II Trial of Fazarabine (NSC#281272) in Patients with Advanced/Recurrent Pelvic Malignancies	343
90/354	O	GOG 26HH: A Phase II Trial of 5-Fluorouracil and Leucovorin in Advanced Metastatic or Recurrent Pelvic Malignancies	344
90/355	O	GOG 102G: Intraperitoneal Administration of Cisplatin (NSC#119875) and Thiotepa in Residual Ovarian Carcinoma	345
90/356	O	GOG 111: A Randomized Phase III Study of Cisplatin and Cyclophosphamide Versus Cisplatin and Taxol in Patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma	346

DEPARTMENT OF PEDIATRICS

78/40X	O	-001 - Use of Laboratory Animals (Cats) to Teach Medical Skills	348
--------	---	---	-----

Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

82/403	O	POG 7799 - Rare Tumor Protocol for Childhood Solid Tumor Malignancies, Ancillary	349
82/414	O	POG 8158 - NWTS Long Term Follow-Up Study: A Non-Therapeutic Study	350
82/420	O	POG 8451 - Intergroup Rhabdomyosarcoma Study III	351
83/401	T	Prevalence of Endometriosis Externa in Adolescent Women Complaining of Severe Dysmenorrhea	352
86/403	C	Prophylactic Intravenous Immunoglobulin for Infections in HIGH Risk Neonates (PR).....	353
86/408	O	POG #8600 - Laboratory Classification in Acute Lymphoid Leukemia of Childhood (ALinC 14C) Phase III	355
86/410	O	POG 8602 ALinC #14: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALinC#14) - A Pediatric Oncology Group Phase III Study	356
87/401	O	POG 8625/8626 - Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA1 Hodgkin's Disease in Pediatric Patients, A Pediatric Oncology Group Phase III Study	357
87/403	C	POG 8638 - Randomized Phase II Study of Carboplatin (CBCDA) VS CHIP in Treatment of Children with Progressive Brain Tumors	358
87/404	O	POG 8653/54 - A Study of Childhood Soft Tissue Sarcomas (STS) Other Than Rhabdomyosarcoma and Its Variants, A Pediatric Oncology Group Phase III Study	359
87/405	C	POG 8695 - Front Loading Chemotherapy in Children with Increased Medulloblastoma (PR) ..	360
87/406	C	Effects of Oral Contraceptive Agents on Coagulation Parameters in the Adolescent Patient (PR)	362
87/408	T	Efficacy of Prophylactic Anti-Migraine Therapy in the Adolescent Therapy Patient - A Double Blinded Study	363
88/400	O	POG 8704 T-Cell #3 Protocol: A Pediatric Oncology Group Phase III Study	364
88/401	C	POG 8741/42 Stage D NBL#3 Treatment of Stage D Neuroblastoma in Children >365 Days at Diagnosis	365
88/402	O	POG 8759 Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma	366

Ongoing (O), Completed (C), Terminated (T), Published (F), or Submitted for Publication (SP), Presentations (PR).

			Page
88/403	C	POG 8763 Evaluation of Response and Toxicity of Ifosfamide and VP-16-213 in Children with Resistant Malignant Tumors	367
88/404	O	Ceftriaxone vs Amoxicillin/Clavulanate for Initial Empirical Therapy of Occult Bacteremia.	368
88/405A	O	Macromolecular Absorption in the Post-Asphixated Small Intestines of the Adult Rat	369
88/408A	O	Effect of Human/Animal Interaction on Stress Levels During Outpatient Pediatric Oncology Visits	371
88/409	T	The Correlation of Perinatal Events with Neonatal Morbidity: A Scoring System	372
89/400	O	POG 8710 Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia (SIMAL #5)	373
89/401A	O	An Observational Study on the Response of Children to the Presence of a Stuffed Animal VS a Live Animal During a Neuromuscular Exam (PR)	374
89/402	C	Newborn Informed Consent Study	375
89/403A	O	Effect of Inflammation in Chronic Pneumonia in Rats Due to Pseudomonas Aeruginosa ---Medication by Bacterial Exoproducts	376
89/404	O	POG 8725 Randomized Study of Intensive Chemotherapy (MOPP/ABVD) + or - Low Dose Total Radiation Therapy in the Treatment of Stages IIB, IIIA-2, IIIB, IV Hodgkin's Disease in Pediatric Patients	377
89/405	O	Clonidine Treatment of Constitutional Delay of Growth and Puberty--A Prospective Double Blind Study	378
89/406	C	POG 8495 A Phase I Study of Hyperfractionation in Brain Stem Glioma in Children	379
89/407	O	Baby Development Follow-up Network Project	380
89/408	O	Comparison of Cotinine Hair and Saliva Analysis in the Determination of Passive and Active Cigarette Smoking Exposure in Adolescents	381
90/400	T	A Treatment IND for Retrovir Brand Zidovudine (AZT) Therapy of Pediatric Patients with HIV Disease (TX 304-IND-33,760)	382
90/401	O	Experience with Multiple Doses of Survanta in Premature Infants	383
90/402A	O	Training for Pediatricians in Emergency Procedures	384
90/403A	O	Studies of the Hemodynamic Consequences of Partial Cardiopulmonary Bypass in the Lamb	385

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PR).

90/404	C	Revision of Bayley Scales of Infant Development	180
90/405	O	Followup of the NICU Graduate in Military Medical Facilities	181
90/406	O	POG 8788 Intergroup Rhabdomyosarcoma Study IV: A Pilot Study for Clinical Group IV Disease	182
90/407	O	POG 8821 AML#3: Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia	183
90/408	O	POG 8823/24 Recombinant Alpha Interferon in Childhood Chronic Myelogenous Leukemia	184
90/409	O	POG 8827 Treatment of Children with Perianth Disease in Relapse - Phase II	185
90/410	O	POG 8829 A Protocol for a Case-Control Study of Hodgkin's Disease in Childhood - A Nontherapeutic Study	186
90/411	O	POG 8832 Pre-XRT Cisplatin and Ara-C for GBM with Incompletely Resected Supratentorial Malignant Brain Tumors	187
90/412	O	POG 8850 Evaluation of Vincristine, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly Diagnosed Ewing Sarcoma or Primitive Neuroectodermal Tumor of Bone	188
90/413	O	POG 8889 Intergroup Rhabdomyosarcoma Study IV: Pilot Study for Clinical Group IV Disease	189
90/414	O	POG 8828 Late Effects of Treatment of Childhood Disease: A Pediatric Oncology Group Therapeutic Study	190
90/415	O	POG 8650 National Wilms' Tumor Study (NWTS-4), A Pediatric Hematology-Oncology Phase III Study	191

DEPARTMENT OF PATHOLOGY

89/450	C	Evaluation of the Available Plastic Containers and Tubes for Storage of Patient Specimens	192
--------	---	---	-----

DEPARTMENT OF RADIOLOGY

80/602	O	I.V. Administration of ¹³¹ I-labeled N-palmitoyl-norcholesterol (NP-59) for Adrenal Evaluation and Imaging	193
--------	---	---	-----

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PK).

88/600	T	a. The Usefulness of Magnetic Resonance Imaging and Transrectal Ultrasound in the Staging of Prostatic Cancer: Comparison to 1mm Whole Gland Mounts.	
		b. Artifacts and Variants of the Normal Prostate Seen by MRI and Transrectal Ultrasound: Comparison to 1mm Whole Gland Mounts	402
88/601	O	Body Fat Determination by Dual Photon Absorptiometry	404
88/602	O	The Comparative Renal Clearances of Disofenin and Mebrofenin	405
89/602	O	The Utility of the Bard "Biopty" Gun in the Breast: Correlation with Surgical Excisional Specimens	406

DEPARTMENT OF PRIMARY CARE & COMMUNITY MEDICINE

80/650A	O	The Ontogenesis of Hemoglobin in the American Opossum (Didelphis Virginia) (P)	408
87/650	T	Clonal Fidelity of Erythroid Lineage in Dyserythropoiesis: An Inquiry Into Ultrastructure	411

DEPARTMENT OF NURSING

86/700A	O	Introduction to Suturing Techniques Using Outbred Adult Rats	413
88/700	C	A Study of the Clinical Nurse Specialist in the AMEDD (PR) (P)	414
90/700	O	A Pilot Study: A Comparison of Subarachnoid Block Anesthesia with Tetracaine and Epidural Anesthesia with Lidocaine and the Effects on the Umbilical Artery Acid-Base Results and Five Minute Apgar Scores of Neonates Following Uncomplicated Cesarean Section	415
90/701	C	Assessment of Post Myocardial Infarction Patients Learning Needs During Hospitalization and Post Discharge	416
90/702	O	The Impact of Practice at Fitzsimons Army Medical Center Upon Registered Nurses Professional Role Conception	417

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PR).

PHYSICAL MEDICINE

90/750	O	Onset-to-Onset Difference Between the Median Motor Nerve and the Anterior Interosseous Nerve Using a Common Stimulation at the Antebubital Fossae	419
90/751	C	The Frequency That Physicians Recommend Aerobic Exercise in the Management of Patients with Rheumatoid Arthritis	420

MEDDAC

83/902A	O	Use of Goats for Training in Emergency Medical Procedures	422
88/900	O	IOLAB Investigational Plan for the Clinical Study of Intraocular Lenses	423
88/901	O	COBURN IOL at GLWACH, Ft. Leonard Wood, MO ...	424
89/900	O	Evaluation of a Phase I <u>Coxiella burnetii</u> Vaccine (IND 610) for Immunization Against Q Fever	425
89/901	O	Continued Evaluation of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83 Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142	426
89/902	O	Evaluation of New Lots of Tularemia Vaccine Protocol B: Comparative Assessment of <u>Francis tularensis</u> Vaccine, Live, NDBR 101, IND 157	427
89/903	O	Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 As a Booster in At-Risk Personnel, IND 914	428
89/904	O	Use of the Sixteen Personality Factor Questionnaire to Predict Susceptibility to Occupational Stress Among US Army Recruits	429
89/905	C	Comparative Evaluation of Jet Injected PPD Based on the Mantoux Response in Initial Entry Training Soldiers	430
90/900	O	Iron Deficiency Anemia in 11-14 Month Old Infants at 6,000 Feet, (1830m) Elevation. A Study to Evaluate the Response to a Therapeutic Trial of Iron	431
90/950A	O	Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care. Resuscitation of the Newborn Utilizing Young Cats	432

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PR).

EMERGENCY USE PROTOCOLS

EU-89-1	C	POG 8633/34 Treatment of Children Less Than Three Years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation	434
EU-89-2	O	POG 8743	435
-----	C	Compassionate Enrollment in POG 8696/97	436
One	C	Compassionate/One Time Use Protocol - Ribovirin (2-wk course)	437
Two	C	Tc99m Antimony - Trisulfide Colloid	438
Three	T	Itraconazole	439
Four	T	POG 8751	440
Five	C	Intravenous Ciprofloxacin	441
Six	C	Strontium Chloride Sr-89	442

UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY 90 culminated in the publication of 148 articles and 159 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1990, there were 347 research protocols on the DCI register. Of these, 263 projects were ongoing, 57 projects completed, 27 projects terminated, and for this FY there were 127 new registrations.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medicine. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18,

Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.

Description	Grade	MOS	Br	Auth	Req	Act	Name	Rank
C, Dept Clin Inv	05	60P9B	MC	1	1	1	HARRISON	LTC
C, Micro Svc	05	68A00	MSC	1	1	1	Andron	LTC
C, Biomet & Resh	04	68T00	MSC	0	1	1	Sherman	MAJ
C, Biochem Svc	04	68C9C	MSC	1	1	1	White	MAJ
C, Immunol Svc	04	68E00	MSC	1	1	1	Stewart	MAJ
C, Cell Phys Svc	03	68J00	MSC	1	1	1	Jackson	CPT
C, Animal Res Svc	04	64C9B	VC	1	1	1	Banks	MAJ
NCOIC-Med Lab	E6	92B30M		1	1	0	Remmick	SSG
Operating Rm Sp	E5	91D2R		1	1	1	Haynes	SGT
Bio Sci Asst	E6	01H3R		1	1	0	Brady	SSG
Bio Sci Asst	E7	92B4RM		1	1	1	Dalton	SFC
Bio Sci Asst	E5	01H3R		1	1	1	Sanders	SGT
Vet Sp	E6	91T3R		1	2	1	Barrett	SSG
Vet Sp	E5	91T2R		1	1	1	Wendt	SGT
Bio Sci Asst	E4	01H1R		1	1	1	Cruz-Saez	SPC
Bio Sci Asst	E4	01H1R		1	1	1	Williams	SPC
Bio Sci Asst	E4	01H1R		1	1	1	Sipple	SPC
Bio Sci Asst	E4	01H1R		1	1	1	Schaphorst	SPC
	E6	01H1R		1	1	0	Stinnett	SSG
Supv Res Chem	13	1320	GS	1	1	0	Gutierrez	
Microbiologist	11	0403	GS	3	3	3	Lima Paine Hoyt	

Description	Grade	MOS	Br	Auth	Req	Act	Name	Rank
Microbiologist	09	0403	GS	3	6	3	Morse Petring Muehlbauer	
Med Technologist	11	0644	GS	0	1	1	Rush	
Med Technologist	09	0644	GS	0	6	5	Ramirez (Term) Pinney (Term) Goodgion (Term) Sachanandani (Term)	
Med Technician	07	0645	GS	1	1	1	Nelson	
*Research Chem	11	1320	GS	4	3	3	Noble O'Brien	
Bio Lab Tech (Animal)	09	0404	GS	1	1	1	Mercill	
Animal Caretaker (Foreman)	04	5048	WS	1	1	1	Jones	
Research Prot Sp	09	0301	GS	1	1	1	Bilak	
Animal Caretaker	05	5408	WG	1	3	2	Chase (overhire) Hitchcock	
Secretary	06	0318	GS	1	1	1	Montoya	

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

	FY 88	FY89	FY 90
OMA Civilian Personnel	668,953.	1,260,000.	834,529.
Contracts/Supplies	259,514.	218,800.	453,777.
Ceel. Equipment	28,599.	4,350.	64,424.
Travel	6,552.	6,031.	9,978.
Military Personnel		1,260,000.	754,499.
OPA MEDCASE	282,809.	579,122.	740,811.
Civilian Consultants	FY 90 - \$828.00		
Publication Costs	FY 90 - \$9,081.00		

Personnel

	Authorized	Required	Assigned
Officers	6	7	7
Enlisted	12	12	12
Civilian	15	34	26
VA Civilian	2	2	4

GRANTS

USAMRDC

Prospective Double Blind Study of Zidovudine (AZT) in Early Stage HIV Infection. \$84,000

A Double Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Gram-Negative Sepsis/Gram Negative Septic Shock.

Veterans Administration (VA)

VA Funds (Sherman) \$29,800

USAMRDC Grants Total: 205,000

HUGH MAHON LECTURESHIP AWARD COMPETITION - 1990

This student research award was established in 1950 and honors the late Colonel Hugh W. Mahon, MC, USA, Retired, who was Chief, Department of Pathology, Fitzsimons Army Medical Center, for 12 years. The lectureship consists of the presentation of papers judged best from among those submitted by officers in training status at FAMC.

The Hugh Mahon Lectureship Award Competition is divided into the categories of retrospective or prospective clinical studies, basic laboratory investigations, and literature reviews/case reports. This year there were a total of 36 submissions; 6 manuscripts in the laboratory category, 13 in clinical studies, and 17 case reports/literature reviews. Last year's submission was the largest with 41, while in 1988 there were 23 papers submitted and in 1987, 18.

Judging was done by the members of the FAMC clinical teaching staff and a panel of distinguished university and community professors. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

A Grand Prize Winner was chosen from among the five finalists in all three categories based on the presentation and question-and-answer period during the Hugh Mahon Lectureship Conference. The finalists receive Army Achievement Medals, and the Grand Prize Winner is awarded the Army Commendation Award. The finalists for 1990 are as follows:

Clinical Studies

1st Place: Study of the Efficacy of Influenza Vaccine in Chronic Structural Lung Disease with Analysis of Corticosteroid Effects: Part 1. Richard E. Winn, LTC, USAF, MC, Pulmonary Disease.

Grand Prize Winner and 2nd Place: Kids and Guns: A Five Year Analysis of Firearm Deaths in Colorado Children. Sivanthini Hines, CPT, MC, Pediatrics

Laboratory Studies

1st Place: Comparison of Beta-Adrenergic Antagonists on Guinea Pig Tracheal Smooth Muscle: Effects of Lipid Solubility, Beta₁-Selectivity, Intrinsic Sympathomimetic Activity and Alpha-Adrenergic Antagonism. Michael A. O'Connell, CPT, MC, Allergy-Immunology.

2nd Place: A Comparison of Patellar Tendon Graft Fixation Techniques in Anterior Cruciate Ligament Reconstruction Using a Goat Model. R. Todd Hockenbury, CPT, MC, Orthopedic Surgery

Case Reports/Literature Reviews

One Prize Only: Covert Hypothyroidism Presenting as a Cardiovascular Event. Homer J. LeMar, MAJ, MC, Endocrine.

Animal Resources Service - FY 90

An air-operated box stapler and a hot glue applicator gun were procured to facilitate packaging of live animals for shipment. New cleaning utensils of metal and plastic construction were bought for the animal facility to replace wooden handled tools. Two infant anatomical models were purchased to assist in the training of Newborn Service staff members in the resuscitation of newborn and premature infants. Foamed alcohol hand degermers were installed throughout the animal facility to aid in the elimination of cross-contamination between animal rooms. A high pressure washer was purchased to aid in cleaning animal rooms. A new blanket purchase agreement was obtained for the purchase of conditioned goats and sheep.

Two computer-based training programs were purchased in the text-only version, one to assist in the training of investigators in the use of laboratory animals and the other to assist technicians in preparing for certification and to maintain proficiency. The accompanying graphics programs will be sought when hardware is available, i.e., a VGA board and monitor.

Work was begun in September installing suspended ceiling in the corridor and animal areas where it was omitted during original construction. Installation of stainless steel wall protectors on exposed walls in the large animal enclosures was also started at that time.

MAJ Trahan passed the Colorado State licensing examination given by the State Board of Veterinary Medicine, and was accredited for the State of Colorado by the USDA, APHIS, Veterinary Services. MAJ Trahan and Mr. Jones attended the national AALAS meeting, held in Little Rock, AR, during October, 1989.

Biochemistry Service - FY 90

The Biochemistry Service has a new look for 1990. We have a new medical technologist and a molecular geneticist. We are renovating lab space for their work now. We hope to bring this exciting area of DNA and RNA research on line soon.

We completed work on our blood lead protocol and presented results at the March 1990 meeting of the Society of Armed Forces Laboratory Scientists in Baltimore, Maryland. The current blood lead project involves screening pediatric populations close to smelters and mines. This is a collaborative effort between Colorado Department of Health and our lab. The Biochemistry Service is one of only two labs in Colorado that is OSHA certified to perform blood lead analysis.

We completed work developing an assay for cotinine (the major stable metabolite of nicotine) in hair. This assay supports a protocol that assesses passive smoking exposure.

The amino acid laboratory provides physiological amino acids for Army physicians in long term civilian training at University of Colorado Health Sciences Center, Perinatal Division.

We completed one collaborative research project with Denver University Endocrine Department. We also support many FAMC endocrine protocols with binding and other specialized assays.

Our Service has an active HPLC lab that specializes in the assay of red blood cell metabolites. We are expanding and improving our HPLC capabilities in this area which has an excellent record of publishing its research.

Cell Physiology Service - FY 90

Cell Physiology Service (CPS) provides clinical research support for FAMC in a number of scientific areas. These include: histochemistry, immunocytochemistry, electron microscopy, tissue culture, and animal modeling in tumor growth and treatment.

CPS received a new chief in January 1990. Although CPS's basic mission support remains the same, CPS collaborated on new projects with a somewhat different emphasis. CPS and Pulmonary Disease Service (PDS) are studying physiologic factors contributing to long-term acclimatization in newcomers to intermediate altitude as measured by physical performance (2 mile run time on AFPT). Biochemical and metabolic indicators relating to improved oxygen delivery were determined on a group of soldiers both at low and after assignment to intermediate altitude in order to evaluate the time course of acclimatization. Results suggest that even relatively mild hypoxic environments elicit physiological responses that indicate tissue hypoxia. This investigation is supported by the Command group and the Physical Fitness School, Ft. Benjamin Harrison, Indians. Preliminary findings will be presented at The American Thoracic Society meeting May 1991.

Polytetrafluoroethylene (Gortex) patches of different porosities were cultured in epithelial cells in vitro. Results demonstrated that cells successfully attached to and infiltrated the gortex especially with 30 and 60 micron pores. Subsequently, patches were utilized as soft tissue grafts in rabbits. Dr. Walton, an Ophthalmology resident, will present his findings at a conference this Spring. CPS cell culture lab also is actively involved in an orthopedic study which will determine whether human fibroblasts will grow to titanium rods with or without hydroxyapatite coating with prospect of improving biocompatibility of implanted prosthetic devices. Culturing is complete and the rods were sent to New Orleans for sectioning. Other research conducted in tissue culturing involve: improvement in keratinocyte growth and isolation for collaborative work with Dermatology Service; and successful culturing of osteoblasts for possible use in studying

different drug treatment modalities for bone or joint disorders. Evidence was provided through autoradiography and histology for cell viability in different surgical procedures utilized for skin-flap repair. The results are being incorporated into a publication.

CPS and FAMC's Dermatology Service are evaluating new strains of immunodeficient mice for use as a recipient of human skin grafts in order to study the etiology of subcutaneous lupus erythematosus (SCLE). Beige nude Xid (X - linked mutation) mice have rendered promising results demonstrating a greater potential for skin graft acceptance.

Clinical Biometrics and Research Design Service - FY 90

During this fiscal year two major research programs were initiated with funding from MRDC. They concern (1) evaluation and prediction of lower limb injuries during basic combat training at Ft. Sill and during normal work at FAMC and (2) determination of etiology of low back pain during combat exercises at Ft. Carson and normal work at FAMC. The Service continues to run entirely from grant funds. With the exception of the Chief, none of the five and half full time equivalent positions are paid from HSC funds. MRDC has funded an experimental surgery program set to begin in October which will provide an additional 1/ 1/2 slots to the Service and virtually all other orthopedic research programs are now fully or mostly funded by grants. Significant changes in staffing patterns at FAMC have resulted in the assignment of many new staff who are strongly oriented toward participation in long term, complex, frequently multicenter, very expensive research projects rather than sporadic participation by students in minor, inexpensive, local projects. This has resulted in an explosion in the number, complexity, and cost of research protocols.

Immunology Service - FY 90

The Immunology Service continues to maintain its premiere reputation in flow cytometry amongst the military medical centers. Work with immunophenotyping, DNA analysis of both fresh and preserved tissues, and antigen specificity studies will soon be expanded to include intracellular calcium analysis in the UV excitation wavelengths. A second argon laser will replace the unused krypton laser on the EPICS V to provide dedicated support to this endocrinology research. The HIV Natural History Protocol continues to constitute more than 60% of the Service's workload. The Allergy Therapy protocol continues with antigen analysis of the investigated pollens and many soon include binding studies. A presentation was made at the 1990 SAFMLS Annual Meeting in Baltimore on capabilities of the Vanguard radioisotope imaging scanner now in routine use in lymphocyte transformation studies. New instrumentation installed in the third and fourth quarters include a peptide sequencer, a peptide synthesizer, and a research grade video densitometer. The first two systems will provide core level capabilities on par with any research center in the country,

and will be used in antigen-analysis, antigen-antibody binding studies, and structural comparisons of bacterial and HLA antigens. The video densitometer will greatly enhance our capabilities in gel and advanced image analysis. Still due into the Service (but held up in contracting due to vendor failure) is an advanced systems upgrade to the Department's graphics handling system which will include optical character recognition hardware and software, a color image scanner, a color printer, and color video imaging software and firmware (Targa board).

Microbiology Service - FY 90

The Mycobacteriology Section demonstrated excellent performance on CAP proficiency surveys and maintains its CAP accreditation. Cycloserine, Amikacin, and Ciprofloxacin will be added to the standard 8 drug susceptibility panel. A seven drug panel including Amikacin, Trimethoprim/Sulfa-Methoxazole, Kanamycin, Doxycycline, Minocycline, Cefoxitin, and Ciprofloxacin was instituted to test the rapid growing mycobacteria. These additions will greatly improve the ability of physicians to treat infected patients.

Two new diagnostic tests for hepatitis C (non-A, non-B hepatitis) were evaluated and used to survey HIV patients who had indications of liver cell damage unexplained by other tests. The commercial ELISA test for Hepatitis C was used for screening and positives were confirmed by recombinant immuno-blot assay (RIBA).

New protocols involving Limulus testing of human ascites fluid and investigation of pollen samples for microbiological contamination were developed. Three abstracts were accepted for presentation at the HIV International Congress and manuscripts are in preparation describing results of the early treatment with Zidovudine of HIV infection. A new multi-center protocol involving IV immunoglobulin treatment for endotoxic shock was initiated. New studies are underway with laboratories in Boston and Maryland to survey sera obtained from Reservists training at Ft. McCoy, Wisconsin for antibodies to tick saliva products and to quantitate *Borrelia burgdorferi* antigenemia.

PUBLICATIONS

C = Protocol Related

DEPARTMENT OF MEDICINE

Allergy Service

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Henry AR, Ledoux RA, Weber RW, Vaughan TR: The Effect of Physiologic Propranolol Concentrations on Isolated Guinea Pig Tracheal Ring Sections: Studies with Histamine, Albuterol, and Atropine Sulfate. J Allergy Clin Immunol, 85:286, 1990. (C)

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Larsen LV, Weber RW, Ledoux RA: A New Monoclonal Antibody to an Allergenic Determinant of Salsola Kali (SK). J Allergy Clin Immunol, 85:203, 1990. (C)

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Spaulding HS: Pruritus Without Urticari in Acute Giardiasis. Ann Allergy, 65:161, 1990.

Stafford WW, Weber RW, Vaughan TR: The Role of Food in Migraine Headache. Asthma Allergy Pediatr, 3:142, 1990. (C)

Weber RW: Allergen Immunotherapy and Standardization and Stability of Allergen Extracts. J Allergy Clin Immunol, 84:1093, 1989. (C)

Cardiology Service - No Report

Dermatology Service - No Report

Endocrinology Service

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Fortenbery EJ, McDermott MT, Duncan WE: The Effect of Theophylline on Calcium Metabolism and Circulating Vitamin D Metabolites. *J Bone Min Res*, 5:321-324, 1990. (C)

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Hofeldt FD, Rector WG, Kidd GS, Hossack KF: Hepatic Modulation of the Pancreatic Islet Cell Hormones in Cirrhosis. (in press, 1990).

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Merenich JA, McDermott MT, Asp AA, Harrison SM, Kidd GS: Evidence of Endocrine Involvement Early in the Course of Human Immunodeficiency Virus Infection. J Clin Endocrinol Metab, 70:566-571, 1990. (C)

Merenich JA, Pfander NA, Georgitis WJ: Addition of Bedtime Ultralente Insulin to NIDDM Patients Suboptimally Controlled with Oral Agents. Diabetes (Suppl 1), 1990. (C)

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McNally PR, Collier EH, Lopiano MC, Brewer TG, Wong RKH: Congenital Esophageal Stenosis: A Rare Cause of Food Impaction in the Adult. Dig Dis Sci 35:263-266, 1990.

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Infectious Disease Service

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Nephrology Service - No Report

Neurology Service - Negative Report

Hematology/Oncology Service - No Report

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DEPARTMENT OF SURGERY

General Surgery Service

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Neurology Service - No Report

Orthopedic Service

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PRESENTATIONS

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DEPARTMENT OF MEDICINE

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Goodman DL: Pediatric Food Allergy: Presented: XVith Scientific Assembly of the Uniformed Services Academy of Family Practice, Richmond VA, March 1990. (C)

Goodman DL: Pediatric Allergy: Treat or Refer: Presented: XVith Scientific Assembly of the Uniformed Services Academy of Family Practice, Richmond VA, March 1990. (C)

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Endocrinology Service

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General Medicine Service

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Hematology/Oncology Service - No Report

Internal Medicine Service - No Report

Pulmonary Disease Service

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Kollef MH: Transtracheal Oxygen and the Perception of Dyspnea: Presented: American College of Physicians, San Francisco, CA, October 1989 (cancelled-earthquake).

Kollef MH: Intralipid Induced Pulmonary Toxicity: Reversal with Plasma Exchange: Presented: XVI World Congress on Diseases of the Chest and the 55th Annual Scientific Assembly, Boston, MA, October 1989.

Kollef MH: Effect on Pneumothorax Management by a Full-time Pulmonary/critical Care Specialist (PCCS): Presented: Annual meeting of the American Thoracic Society, Boston, MA, May 1990.

Kollef MH: Risk Factors for the Misdiagnosis of Pneumothorax in the Intensive Care Unit: Presented: Annual Meeting of the American Thoracic Society, Boston, MA, May 1990.

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Nephrology Service - No Report

Neurology Service - No Report

Rheumatology Service - No Report

DEPARTMENT OF SURGERY

General Surgery Service

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Freeman IHG, Clark JR: The Fitzsimons Experience with Thyroid Cancer: A Twenty Year Review: Presented: Gary P. Wratten Surgical Symposium, Washington, DC, April 1990. (C)

Goff JM Jr, Hollis HW Jr: Acquired Factor V Inhibitors in Aortic Surgery: Presented: Colorado Chapter, American College of Surgeons, Colorado Springs, CO, May 1990.

Goff JM Jr, Mallory PL II, Clark JR: Oxygen Delivery Problems in SICU Patients: Presented: Gary P. Wratten Surgical Symposium, Washington, DC, April 1990.

Mallory PL II: Management of Candida Infection in the Surgical Intensive Care Unit: Presented: Colorado Chapter, American College of Surgeons, Colorado Springs, CO, May 1990.

Schoelkopf L, Beckwith JB, Clark JR: Extrarenal Wilms' Tumor: Presented: Gary P. Wratten Surgical Symposium, Washington, DC, April 1990.

Ophthalmology Service

Buys YM, Buncic JR, Enzenauer RW, Mednick E: Congenital Aplasia of the Iris Sphincter and Dilator Muscles - A Case Report and Review of the Literature: Presented: Poster at the 16th Annual Meeting of the American Association for Pediatric Ophthalmology and Strabismus, Lake George, Bolton Landing, New York, July 1990.

Enzenauer RW, Calderwood S, Levin AV, Elder JE, Morin JD: Screening for Fungal Endophthalmitis in Febrile Children: Presented: 32nd Annual Departmental Research Day, Department of Ophthalmology, U of Toronto, Toronto, Ontario, CANADA, April 1990.

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Weston BC, Enzenauer R, Kraft SP: Stability of Post-Operative Alignment in Adjustable Suture Strabismus Surgery: Presented: Poster at the 16th Annual Meeting of the American Association for Pediatric Ophthalmology and Strabismus, Lake George, Bolton Landing, New York, July 1990.

Orthopedic Service

Bizousky DA: Medial Epicondylectomy for Ulnar Compression Neuropathy at the Elbow: Presented: Barnard, 1990.

Coe R: Limb-sparing Surgery for Distal Lower Extremity Soft Tissue Sarcomas: Presented: Barnard, 1990.

Coe RA: Palmoris Longus Tendon Transfer for Distal Radioulnar Joint Instability: Presented: SOMOS, San Antonio, TX, December 1989.

Cope EE: Thermography and Carpal Tunnel Syndrome: Presented: Barnard, 1990.

Deffer PA: MRI of the Ankle with Arthroscopic Correlation: Presented: Barnard, 1990.

Getter MD: Management of Resistant Talipes Equino Varus Deformities in Myelomeningocele Patients Using Astralagectomy: Presented: Barnard, 1990.

Gillogly SD: Orthopaedic Surgery in an Underdeveloped Country: The Honduras Experience: Presented: SOMOS, San Antonio, TX, December 1989.

Gillogly SD: Acute Shoulder Trauma: Presented: 16th Annual Primary Care Orthopedic Course, Keystone, CO, August 1990.

Gillogly SD: Management of Forearm Fractures: Presented: 16th Annual Primary Care Orthopedic Course, Keystone, CO, August 1990.

Gillogly SD: Acute Knee Trauma: Presented: 16th Annual Primary Care Orthopedic Course, Keystone, CO, August 1990.

Hockenbury RT: A Comparison of Patellar Tendon Graft Fixation Techniques in ACL Reconstruction Using a Goat Model: Presented: Barnard, 1990. (C)

Hrutkay JM: Treatment of Pelvic Fractures at a Community Based Trauma Hospital: Presented: Barnard, 1990.

Karstetter K, Sherman R: Relationships Between RSD Related Pain and Patterns of Near Surface Blood Flow: Stability of (1) Concurrent Changes Due to Treatment and Over Time and (2) Relative Locations of Pain and of Blood Flow Asymmetries: Presented: Annual Meeting American Pain Society, 1990. (C)

Karstetter K: Regional Anesthesia of the Foot: Presented: Colorado Certified Registered Nurse Anesthetist Association Annual Meeting, Denver, CO 1990.

Peters JD: Zielke Instrumentation for Idiopathic Scoliosis: The Fate of the Coronal and Sagittal Curves: Presented: SOMOS, San Antonio, December 1989.

Schaefer RA: Evaluation of Anterior Cruciate Ligament Reconstruction Using Gadolinium-DPTA Enhanced MRI: Presented: Barnard, 1990.

Schaefer RA, Gillogly SD, Rak KM, Getter MD: Assessment of Revascularization of Free Patellar Tendon Graft after ACL Reconstruction Using Gadolinium-DPTA Enhanced MRI: Presented: American Orthopaedic Assoc. Newport Beach, Ca, 1990; SOMOS, San Antonio, TX, December 1989.

Searle J, Arena J, Sherman R: A Portable Activity Monitor for Musculoskeletal Pain Disorders: Presented: Proceedings of the IEEE Engineering in Medicine Society's 11th Annual International Conference, 1989. C)

Sherman R, Arena J, Bruno G, Young T: A Comparison of Surface EMG and Thermographic Evaluations of Five Diagnostic Categories of Low Back Pain Subjects: Presented: Proceedings of the American Pain Society's 1989 Annual Meeting, Phoenix, AZ, October 1989. (C)

Sherman R: Mechanisms of Phantom Pain: New Findings: Presented: Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology, Washington, DC 1990. (C)

Sherman R: Ambulatory Recording Methodology: Presented: Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology, Washington, DC 1990. (C)

Speza PM: Morton's Neuroma: Non-surgical Treatment with Local Injection of B-12/Solumedrol/Lidocaine Combination: Presented: Barnard, 1990.

Otolaryngology Service - Speech Language Rehabilitation Section

Beck WB: Peak Clipping or Amplitude Compression? Limiting the Out Put of Hearing Aids: Presented: 1990 Military Audiology Short Course, Virginia Beach, VA, 27-29 March 1990.

Ferrer-Vincent ST: Audiology/Audiologist in the Care of Children with Otitis Media, Part of a University of Northern Colorado, Greeley, CO continuing education course, October 1989.

Hasbrouck JM, Randall B: An Intensive Treatment of Stuttering in a Public School Setting: Presented: 4th Annual Metro Speech/Language Symposium, Denver, CO March 1990.

Lowry MF: Post Operative Issues for the Laryngectomee - How to Prevent Them: Presented: American Cancer Society Midwinter Cancer Seminar: Tobacco Related Malignancies and Preventable Diseases, Vail, CO, January 1990.

Lowry MF: Laryngectomies Can Swim: Presented: Lost Chord Club of Colorado Springs, CO, March 1990.

Lowry MF: Sertoma Long-Range Plans: Presented: SERTOMA Regional Convention, Roswell, NM, May 1990.

Lowry MF: The Colorado Speech-Language-Hearing Association Perspective on Licensure: Presented: 7th Annual CSHA Conference on Professional Issues, Denver, CO, September 1990.

Lowry MF: Care and Treatment of the Performing Voice: Presented: Departments of Music and Communication Disorders, Colorado state University, Ft. Collins, CO, September 1990.

Snelling TM: The Missing Step in Language Stimulation: Presented: Weld County BOCES, LaSalle, CO, October 1989.

Snelling TM: Otitis Media and Language/Learning Disabilities: Presented: Department of Continuing Education, University of Northern Colorado, Greeley, CO, October 1989.

Snelling TM, Silveira B: Speech-Language Development and Disorders: Presented: Pediatric Conference, Humana/Aurora Hospital, Aurora, CO, February 1990.

Otolaryngology Head and Neck Surgery Service

Carnel Sb, Lepore ML, Moul MJ, Chandlger DW: Reconstruction of the Ossicular Chain Following Impulsive Acoustic Trauma: Presented: American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc., Annual Meeting, San Diego, CA, September 1990.

Eusterman VD, Fitzpatrick JE, Blakeslee DB, Woods TR: Metastatic Basal Cell Carcinoma: Presented: American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc., Annual Meeting, San Diego, CA, September 1990. (C)

Lepore ML, Carnel SB: Total Septal Transposition for Reconstruction of Severe Nasal Deformities: Presented: American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc., Annual Meeting, San Diego, CA, September 1990.

Lepore ML, Goldstein JL: Rehabilitative Aspects of the Haring Impaired Geriatric Patient: Presented: American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc., Annual Meeting, San Diego, CA, September 1990.

Yakes WF, Sargent DW, Lepore ML, Luethke J, Lanier DM, Eusterman VD: Embolizatin of Delayed Surgery of Head and Neck Tumors (Neuroradiology Exhibit): Presented: Radiological Society of North American, Chicago, IL, November/December 1989.

Yoshida GY: Anemone Tumor of the Head and Neck: Case Report and Literature Review: Presented: Pacific Coast Oto-Ophthalmological Society 74th Annual Meeting, Vancouver, British Columbia, June 1990.

Yoshida GY, Woods TR, Barrs DM: Mastoid Pneumatocele: Unusual Complication after Transmastoid Translabyrinthine Labyrinthectomy: Presented: American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc., Annual Meeting, San Diego, CA, September 1990.

Plastic Surgery Service - No Report

Thoracic Surgery - No Report

Urology Service - No Report

DEPARTMENT OF CLINICAL INVESTIGATION

Andron LA, Andrews J, et al: Zidovudine Treatment in Early HIV Infection: Laboratory Studies: Presented: 6th International Conference on AIDS, San Francisco, CA, June 1990. (C)

Banks RE: The Veterinarian and the IACUC: Presented: 1990 CDI Meeting, San Antonio, TX May 1990.

Banks RE: Biosafety Equipment and Research Equipment: Presented: Uniform Services University, Army Lab Animal Medicine Residency Program, February 1990.

Banks RE: Biology, Husbandry, Management, and Diseases of the Guinea Pig: Presented: Uniform Services University, Army Lab Animal Medicine Residency Program, April 1990.

Banks RE: Care and Management of Laboratory Animals: Presented: Walter Reed Army Institute of Research Military Medical Research Fellowship, July 1990.

Banks RE: Facility Design and Management: Presented: Walter Reed Army Institute of Research Military Medical Research Fellowship, July 1990.

Banks RE, Davis JA: Modification of the RITARD Procedure in the Rabbit: Presented: 1990 American Veterinary Medical Association, July 1990.

Bennion SD: The Expression of ICAM-1 in Inflammatory Skin Diseases: Presented: Western Regional Meeting SIC, Carmel, CA, May 1990.

Bennion SD: What's New in Immunodermatology: Presented: 15th Annual Uniformed Services Dermatology Seminar, Keystone, CO, May 1990.

Harrison SM, et al: Ability to Distinguish Between 800mg ZDV/Day and Placebo by Walter Reed/DOD Classification Scheme of Progression in a Double Blind Study of DoD 2-5 with <500 CD4/mcL: Presented: 5th International HIV Conference, San Francisco, Ca., 1990. (C)

Searle J, Arena J, Sherman R: A Portable Activity Monitor for Musculoskeletal Pain Disorders: Presented: Proceedings of the IEEE Engineering in Medicine Society's 11th Annual International Conference, 1989. (C)

Sherman R, Arena J, Bruno G, Young T: A Comparison of Surface EMG and Thermographic Evaluations of Five Diagnostic Categories of Low Back Pain Subjects: Presented: Proceedings of the American Pain Society's 1989 Annual Meeting, Phoenix, Arizona, October 1989. (C)

Sherman R: Mechanisms of Phantom Pain: New Findings: Presented: Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology. Washington, DC, 1990. (C)

Sherman R: Ambulatory Recording Methodology: Presented: Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology, Washington, DC, 1990. (C)

Sherman R, Karstetter K: Relationships Between RSD Related Pain and Patterns of Near Surface Blood Flow: Stability of (1) Concurrent Changes Due to Treatment and Over Time and (2) Relative Locations of Pain and of Blood Flow Asymmetries: Presented: Annual Meeting of the American Pain Society, 1990. (C)

DEPARTMENT OF OB-GYN

Jones RO: Catastrophic Uterine Rupture in Patients Undergoing A Trial of Labor: Presented: OB-GYN Conference, Garmish, Germany, February 1990.

Jones RO: Management of Post Dates: Presented: OB-GYN Conference, Garmish, Germany, February 1990.

Jones RO: Twin Pregnancies Complicated by Death of One Twin: Presented: OB-GYN Conference, Garmish, Germany, February 1990.

Jones RO: Twin Pregnancies Complicated by Death of One Twin: Presented: Denver General Hospital, Denver, CO, May 1990.

Jones RO: Catastrophic Uterine Rupture in Patients Undergoing A Trial of Labor: Presented: Canon City, CO, June 1990.

Jones RO: Post Dates: Presented: Canon City, CO, June 1990.

Lundblad EG: Menopause and ERT: Presented: UCHSC, Denver, CO, May 1990.

Lundblad EG: Approach to the Infertile Couple: Presented: UCHSC, Denver, CO, May 1990.

Lundblad EG: Menopause and ERT: Presented: U.S. Air Force Academy, Colorado Springs, CO, August 1990.

Lundblad EG: Approach to the Infertile Couple: Presented: UCHSC, Denver, CO, August 1990.

DEPARTMENT OF PEDIATRICS

General Pediatric Service - Negative Report

Neonatal Service

Kinsella JP, Gerstmann DR, Clark RH et al: Cardiopulmonary Effects of High Frequency Ventilation in the Premature Baboon with Hyaline Membrane Disease: Presented: Uniformed Services Pediatric Seminar, Williamsburg, VA, March 1990.

Kinsella JP, Gerstmann DR, Gong AK, deLemos RA: Hemodynamic Consequences of Surfactant Treatment and Mechanical Ventilation in a Primate Model of Hyaline Membrane Disease: Presented: 7th Conference on High Frequency Ventilation of Infants. Snowbird, UT, April 1990.

Kinsella JP, Gerstmann DR, Gong AK, deLemos RA: Exogenous Surfactant Therapy and Patent Ductus Arteriosus Shunting in the Premature Baboon: Presented: Conference on Military Perinatal Research, Aspen CO, July 1990.

No Report - - - DEPARTMENT OF PATHOLOGY AND ALS

PHYSICAL MEDICINE SERVICE

Bavaro, S: Occupational Therapy Assessment and Treatment of Affective Disorders and Neurotic Disorders: Presented: Colorado State University; Fort Logan, Colorado, May 1990.

DEPARTMENT OF NURSING

Degenhardt EF: Health Locus of Control and Health Maintaining Activities of the Type II Diabetic: Presented: Army Nurse Research Symposium, Quade Center, Fitzsimons Army Medical Center, March 1990.

Frelin AJ: Role of the clinical Nurse Specialist in the AMEDD: Presented: AMEDD Clinical Nurse Specialist/Nurse Practitioner Conference, Quade Center, FAMC, February 1990.

Frelin AJ: The Matter of Staffing, An Ethical Dilemma. FAMC Ethics and Legal Issue in Nursing: Presented: Quade Center, FAMC, April 1990.

Frelin AJ: The Role of the Clinical Nurse Specialist in the AMEDD: Presented: Phyliss J. Verhonick Research Seminar, Washington, DC, April 1990.

Paige PL: Intraventricular Hemorrhage, Hydrocephalus and Seizures: Presented: Neonatal Nursing Conference, Wilmore Center, Denver, CO, October 1989.

Paige PL: Death and Dying: Presented: FAMC National Group of Chaplains, October 1989.

Paige PL: Transportation and Resuscitation of the High Risk Newborn: Presented: Critical care Course, Denver, CO, January 1990.

Paige PL: Infant Stimulation: Presented: Non-practicing/Part-time Nurses Association, Denver, CO, March 1990.

Paige PL: Hypoglycemia and Hypocalcemia: Presented: Neonatal Nursing Conference, FAMC, April 1990.

Paige PL: Intraventricular Hemorrhage, Hydrocephalus, and Seizures: Presented: Neonatal Nursing Conference, FAMC, May 1990.

Paige PL: Discharge Planning for the Medically Fragile Neonate: Presented: Neonatal Intensive Care Course, Denver, CO, May 1990.

Paige PL: Pediatric Pulmonary Management and Pediatric Congenital Heart Defects: Presented: Critical Care Course, Denver, CO, September 1990.

Paige PL: Psychosocial Needs of Pediatric Patient and Family:
Presented: Critical Care Course, Denver, CO, September 1990.

Rupkalvis C: Korean Childbirth Practices: Presented: Sigma Theta
Tau, University of Southern Colorado, April 1990.

DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE

Negative Report

No Report - - - - DEPARTMENT OF PSYCHIATRY

DEPARTMENT OF RADIOLOGY

Blue PW: The Increasing Clinical Importance of Nuclear Nephrology:
Presented: Present Concepts in Diagnostic Radiology #20, Letterman
Army Medical Center, San Francisco, CA, May 1990.

Blue PW: Radionuclide Evaluation of Renal Structure and Function:
Presented: Nuclear Medicine Review Course, Society of Nuclear
Medicine Annual Meeting, Washington, DC, June 1990.

Lueth J, Parker S, Haas D, Carter T: Intraoperative Ultrasound
Guided Brain Biopsies Utilizing the Bard Biopsy Gun: Presented:
American Roentgen Ray Society, 1989.

Parker SH, Jobe WE, Stavros AT, Slater D, Yakes WF: Ultrasound
Guided Breast Biopsies with a Biopsy Gun: Presented: Program 34th
Annual Convention of the American Institute of Ultrasound in
Medicine, New Orleans, LA, March 1990.

Parker SH, Jobe WE, Lovin JD, Luethke JM, Stavros AT, Yakes WF:
Percutaneous Breast Biopsy Using a Biopsy Gun in Conjunction with
Stereotactic Mammography and Ultrasound: Presented: Program 15th
Meeting Society of Cardiovascular and Interventional Radiology,
Miami, FL, March 1990.

Parker SH, Jobe WE, Stavros AT, Slater D, Yakes WF: Ultrasound
Guided Breast Biopsies with a Biopsy Gun: Presented: 34th Annual
Convention of the American Institute of Ultrasound in Medicine, New
Orleans, LA, March 1990.

Yakes WF, Luethke JM, Parker SH, Stavros AT, Dreisbach JM, Seibert
Ce, Griffin DJ, Latchaw RE: Ethanol Ablation of Symptomatic
Vascular Malformations: Presented: Program for the 15th Annual
Meeting of the Society of Cardiovascular and Interventional
Radiology, Miami, FL, March 1990.

Yakes WF: Arterial Embolization of Vascular Malformations:
Presented: Program for the 2nd Annual Meeting of Recent Advances
in Diagnostic Imaging and Percutaneous Surgery. San Antonio, TX,
April 1990.

Yakes WF: Ethanol Embolo-Ablation of Symptomatic Vascular Malformations: Presented: Program of the 15th Annual Meeting and Post-Graduate Course of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), Brussels, Belgium, May 1990.

Yakes WF, Kumpe DA, Brown SB, Parker SH, Cook PS, Griffin DF: Percutaneous Transluminal Aortic Angioplasty: Techniques and Results: Presented: Program of the 15th Annual Meeting and Post-Graduate Course of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), Brussels, Belgium, May 1990.

Yakes WF: Clinical Applications of Interventional Radiology: Presented: 57th Annual Postgraduate Assembly of the Omaha Midwest Medical Society Annual Meeting, Omaha, NE, November 1989.

Yakes WF, Luethke JM, Parker SH, Stavros AT, Dreisbach JM, Seibert CE, Griffin DJ, Latchaw RE: Ethanol Embolotherapy of Vascular Malformations: Presented: 15 Annual Meeting of the Society of Cardiovascular and Interventional Radiology, Miami, FL, March 1990.

Yakes WF, Coldwell DM: Embolotherapy: Workshop Session: Presented: 15 Annual Meeting of the Society of Cardiovascular and Interventional Radiology, Miami, FL, March 1990.

Yakes WF: Arterial Embolization of Vascular Malformations: Presented: Recent Advances in Diagnostic Imaging and Percutaneous Surgery, 2nd Annual Meeting, San Antonio, TX, April 1990.

Yakes WF: Ethanol Embolotherapy of Symptomatic Vascular Malformations: Presented: Tidewater Radiological Society and Eastern Virginia Medical School Radiology Residency Program Grand Rounds Meeting, Norfolk, VA, April 1990.

Yakes WF: Percutaneous Transluminal Aortic Angioplasty: Further Experience: Presented: Tidewater Radiological Society and Eastern Virginia Medical School Radiology Residency Program Grand Rounds Meeting, Norfolk, VA, April 1990.

Yakes WF: Ethanol Embolo-Ablation of Symptomatic Vascular Malformations: Presented: Program of the 15th Annual Meeting and Post-Graduate Course of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), Brussels, Belgium, May 1990.

Yakes WF, Kumpe DA, Brown SG, Parker SH, Cook PS, Griffin DA: Percutaneous Transluminal Aortic Angioplasty: Techniques and Results: Presented: Program of the 15th Annual Meeting and Post-Graduate Course of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), Brussels, Belgium, May 1990.

Yakes WF: Live Case Demonstration and Lecture on Ethanol Emboloblation of Symptomatic Vascular Malformations: Presented: University of Paris VII; Department of Interventional Neuroradiology; Lariboisiere Hospital; Paris, France, May 1990.

Yakes WF: Live Case Demonstration and Lecture on Ethanol Emboloblation of Symptomatic Vascular Malformations: Presented: 8th International Workshop on Vascular Anomalies; Academic Medical Center; Amsterdam, The Netherlands, June 1990.

Yakes WF: Ethanol Endosurgical Ablation of Vascular Malformations Along the Neural Axis: Presented: 3rd Interventional Neuroradiology Morbidity and Mortality Symposium, Keystone, CO, August 1990.

Yakes WF: Ethanol Embolotherapy of Symptomatic Vascular Malformations: Presented: 52nd Midsummer Conference and Annual Meeting of the Rocky Mountain Radiological Society, Breckenridge, CO, August 1990.

SOCIAL WORK SERVICE

Olsen IG: Writing Effective OER's: Presented: Army Social Work Conference, San Antonio, TX, May 1990.

Pittman JO: Intervention Strategies in a Terrorist/Hostage Incident - A Role for Army Social Work Officers: Presented: Army Social Work Conference, San Antonio, TX, May 1990.

DEPARTMENT OF MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/120 (3) Status: Ongoing

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis:
Investigations into the Frequency, Type and Mechanisms
of Carbohydrate Tolerance

(5) Start Date: 1981 (6) Est Compl Date: 1991

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:

(11) Key Words: carbohydrate hyperthyroidism Fred D. Hofeldt, COL, (Ret)
Robert J. Sjoberg, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 11 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance test. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each

patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress: No patients have been enrolled in this study during the past academic year. The research study is still entirely valid and worthwhile in purpose. The principal investigator has not had adequate time to pursue this project as it is very complex. However, it is still hoped that a new Endocrine Fellow will pick up this project and complete it within the next year to a year and a half. A tremendous amount of effort has already been expended on this study, and it is requested that the protocol be continued in hopes of mobilizing associate investigators to pursue the project.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald S. Kidd, COL, MC

(11) Key Words:
osteoporosis
bone density
calcitonin deficiency
thyroid hormone

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Aug 90 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, lose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and than normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - calcitonin deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal

controls. (SPA) single photon absorptiometry-distal and midradius serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip- cross-sectionally.

(17) Progress: Thyroidectomized patients had lower bone density in the forearm in the first cross-sectional analysis but after 2 years did not lose bone at a greater rate than goiter or control patients. 6-8 year longitudinal data in the forearm and cross-sectional data in the spine and hips have been collected in most patients but the data have not yet been analyzed. (FY 90) Many of the initial subjects have had their followup single photon absorptiometry and their initial dual photon absorptiometry, but not all have been restudied as of yet. Subjects benefit from knowledge of their bone density value but have no other benefit.

Publications:

McDermott MT, Kidd GS, Blue P, Ghad V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res (1(suppl. 1):352, 1986 (Abstract).

Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 81/118 (3) Status: Ongoing

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald S. Kidd, LTC, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis
gonadotropins, pituitary

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress: No progress in the past year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 81/119 (3) Status: Completed

(4) Title: The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion

(5) Start Date: 1981

(6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, LTC, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Comp.
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: In order to gain a better insight into the mechanism of gonadal dysfunction in hypothyroidism, the objective of this protocol is to study the effect of a thyrotropin releasing hormone (TRH) infusion on basal and gonadotropin releasing hormone (GnRH) stimulated gonadotropins in normal subjects.

(16) Technical Approach: Sixteen normal males will be studied with either a normal saline infusion or a TRH infusion. During these infusions, GnRH will be given as a bolus with measurement of appropriate hormone to determine interaction between releasing hormones.

(17) Progress: Sixteen subjects have been studied and the data analysis is complete. The TRH infusion produced a statistically significant

augmentation of the FSH response (both peak and total integrated response) to GnRH, while the LH response was unaffected.

Publications: McDermott MT, Bornemann M, Sjoberg RJ, Walden T, Hofeldt F, Kidd GS: Effects of a continuous TRH infusion on GnRH stimulated gonadotropin secretion. J. Lab. Clin. Med. (In press, 1990)

Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 82/114A (3) Status: Terminated

(4) Title: Growth of Basal Cell Carcinoma Cells in Defined Medium and Study of their Growth and Immunological Characteristics

(5) Start Date: 1982 (6) Est Compl Date: 1990

(7) Principal Investigator: Charles F. Ferris, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:

(11) Key Words: basal cell, carcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor in studies conducted under an FDA-awarded IND. May be continued on separate sheet, and designated as "(14)e".

(15) Study Objective: Growth and study of basal cell carcinoma cells in culture.

(16) Technical Approach: The approach to culturing of basal cells has, and will be the use of the media formulated by Dr. Ham's lab at the University of Colorado in Boulder termed MCDB 153. We have been successful to date in culturing normal cell carcinomas. This has included an attempt utilizing fibronectin coated plates. We next will be attempting growth utilizing basal cell tumors that we have successfully grown in nude mice.

(17) Progress: The Dermatology Service is unable to continue support. No further progress occurred.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 83/107 (3) Status: Ongoing

(4) Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma

(5) Start Date: 1984

(6) Est Compl Date: 1991

(7) Principal Investigator:
M. James Schleve, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators:
Scott Bennion, LTC, MC
Richard Gentry, LTC, MC
Kathy David, MAJ, MC

(11) Key Words:
retinoids
basal cell carcinoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost: *
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: 98
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Dry skin, chapped lips, myalgias.

(15) Study Objective: To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in high risk population; to examine possible side effects with long term administration of isotretinoin.

(16) Technical Approach: The study is a double-blind study with participants randomly assigned to the medication. Patients will take the med for three years and will be followed for a total of four-five years. Compliance side-effects and basal cells are very closely monitored.

(17) Progress: Total 98 patients randomized. 84 remain on the study. Five patients are deceased: Four have transferred to other sites: Five other are off the study for misc reasons. All patients have completed the three years on the medication and have been notified as to whether or not they were on isotretinoin or the placebo. All patients have opted to stay on the program until closure which will be 30 Sept 1991.

Publications:

Fitzpatrick JE, Mellette, JR: Geriatric Dermatology. In Geriatric Medicine: The Care of the Elderly Patient. First edition. W.B. Saunders Company.

Reed OM, Mellette JR, Fitzpatrick JE: Familial Cervical Hypertrichosis with Underlying-Kypho-Scoliosis. Journal of the American Academy of Dermatology.

Presentations:

Flap Combinations for Large Facial Defects - American Academy of Dermatology Annual Meeting, San Antonio, Texas, December 1987.

Helpful Hints for Dermatological Surgery - Thirteenth Annual Tri-Services Dermatology Symposium, San Antonio, Texas.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 83/113A (3) Status: Ongoing

(4) Title: Growth of Human Keratinocytes

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:
Ronald L. Jackson, CPT, MS

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:
Scott D. Bennion, LTC, MC
Jose A. CruzSaez, SPC
Rodncy F. Williams, SPC

(11) Key Words:

keratin

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Growth and study of human kertinocytes in culture and subsequent studies using athymicmice as an in vivo culture system.

(16) Technical Approach: The technical approach has been to grow keratinocytes obtained from newborn foreskins using serum-free media. A more successful approach has been to culture the cells in complete MCDB 153 media. A new mechanism of freezing the cells has commenced. The final phase of the study will include identifying specific proteins expressed by these cells and the presence of protein hormone receptors on the cell surfaces.

(17) Progress: Improved growth of cultures, new principal investigator on this study.

Publications:

Grimwood RE, Clark RAF, Baskin JB, Nielson LD, Ferris CF: Fibronectin is Deposited by Keratiocytes in the Basement Membrane Zone during Tissue Organization. Accepted for publication in Journal of Investigative Dermatology.

Grimwood RE, Ferris CF, Baskin JB, Nielson LD, Clark RAF: Fibronectin is Deposited by Keratinocytes in the Basement Membrane Zone during Tissue Organization. J. Invest. Dermatol., Vol 86, #4, 479, 1986.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 83/122 (3) Status: Ongoing

(4) Title: The Role of Food Allergy in the Pathogenesis of Migraine Headaches

(5) Start Date: 1983 (6) Est Compl Date: 1990

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators: Teresa Copeland, CPT, MC David L. Goodman, LTC, MC

(11) Key Words: migraine food hypersensitivity mediators

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 12 _____
d. Total Number of Subjects Enrolled to Date: _____ 104 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To study the value of allergy food skin test in directing and defining a diet which will cause a decrease in the frequency of migraine headaches in affected patients. To determine if immunological mediators can be detected in positive responders.

(16) Technical Approach: Approximately 100 patients with dx of migraine headaches who suffered 3 or more IIA/month will keep a 1 month food diary/st diary. They will then be skin tested to 83 common foods and undergo an additional 1 mo diet eliminating suspected food, and skin test positive foods. Positive regimens will be studied with open chall. and double blind food challenge with immunologic mediators precursors.

(17) Progress: 104 patients completed the protocol. 37% report a 50% reduction in migraine frequency; 17 patients with positive double-blind food challenge. Five patients studied with histamine, PGD2 determinations during DBPCFC's. No problems encountered. Results of immunol. studies show initial increase in histamine and PGD2 and late rise of PGD2 alone during active challenge. Source of late PGD2 is unclear. Request one year extension to study additional patients with addition of serotonin assay. This will allow cell source of PGD2 to be determined (basophil vs platelet).

Presentations:

(1) Vaughan, TR, Stafford, WW, Miller, BT, Weber, RW, Tipton, WR, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: American College of Allergists, Phoenix, AZ, January 1986.

(2) Vaughan, TR, Stafford, WW, Miller, BT, Tipton, WR, Weber, RW, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: Aspen Allergy Conference, Aspen, CO, July 1986.

(3) Vaughan TR, Stafford WW, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Presented. Southwest Allergy Forum, El Paso, TX, March 1987.

(4) Vaughan TR, Stafford WS, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Accepted for presentation American College of Allergists.

(5) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double-Blind, Long-term Followup Study. Presented: VI International Food Allergy Symposium, Boston, MA., November 1987.

(6) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double Blind, Long Term Followup Study. Presented: Harold S. Nelson Allergy Symposium, Aurora, CO., January 1988.

(7) Vaughan TR: Food and Migraine Headache. Presented: Keystone Allergy Conference, Keystone, CO., February 1988.

Publications:

1. Stafford WM, Weber RW, Vaughan TR. The Role of Food in Migraine Headache. Am J Asthma Allergy, 3:143-152, 1990.

2. Vaughan TR. Food and Migraine Headache: A Review. Current Views in Allergy (in press) 1990.

(1) Date: 30 Sep 90 (2) Protocol #: 93/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: 1983 (6) Est Compl Date: 1991

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/ Endocrine (10) Associate Investigators:

(11) Key Words:
prostaglandin synthetic
hypothyroidism
water electrolyte balance, imbalance

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in

a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: Because of competing priorities, no subjects have yet been studied. A new fellow will be assigned to complete the study, protocol is still worthwhile and should be continued.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 84/100 (3) Status: Ongoing

(4) Title: The Effect of Abnormal Thyroid State on the Metabolism of Theophylline and Methylprednisolone

(5) Start Date: 1984 (6) Est Compl Date: 1990

(7) Principal Investigator: Michael T. McDermott, LTC, MC
Ray Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:
Stanley J. Szeffler, MD
Harold S. Nelson, MD

(11) Key Words:
theophylline
methylprednisolone
hyperthyroidism
hypothyroidism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine whether hyperthyroidism and hypothyroidism result in alterations of theophylline and methylprednisolone metabolism.

(16) Technical Approach: Hypo- and hyperthyroid subjects are studied when thyroid function is abnormal and again when it is normal by studying the disappearance rate of theophylline and methylprednisolone from serum after bolus injections.

(17) Progress: No further patient enrollment. A manuscript is being prepared.

Presentations: Lavins B, Vaughan R, Szeffler S, Weber R, Nelson H:
Effect of thyroid disease on metabolism of theophylline and
methylprednisolone. Meetings of the American College of Allergists,
Boston, Mass, October 1987.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 84/115 (3) Status: Completed

(4) Title: Heterotransplantation of Basal Cell Carcinomas to Nude Mice

(5) Start Date: 1984 (6) Est Compl Date: 1990

(7) Principal Investigator: Charles F. Ferris, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:

(11) Key Words:
carcinoma, basal cell
transplantation
mice, nude

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To develop an in-vivo model of human basal cell carcinoma in the athymic mouse.

(16) Technical Approach: Basal cell carcinoma tissue obtained from excess tissue obtained from Moh's surgery is transplanted to a subcutaneous pocket created by a linear incision on the abdomen of the nude mouse. The mouse will have been splenectomized and transplantation is followed by weekly intraperitoneal injections of antilymphocyte serum. Tumor weight is taken before implantation and measurements of tumor size taken at weekly intervals. Autoradiography and immunofluorescent studies are performed at the time of tumor harvest as well as routine histology and tumor weight.

(17) Progress: No progress this year. Dermatology Service is unable to continue support.

Presentations:

(1) Grimwood RE, Johnson CA, Kramer LC, MercillDB and Huff JC: Hetero-transplantaion of Human Basal Cell Epithelimoas in Nude Mice. Presented: SID Meeting, Washington, DC, May 1984.

(2) Grimwood, RE, Ferris CF, Nielsen LE, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude mice Produce and Deposit Fibronectin in the Extracellular Matrix. Presented: SID Meeting, Washington, DC, May 1985.

Publications:

(1) Grimwood RE, Harbel J, Clark RAF: Fibronectin in Basal cell Epitheliomas: Sources and Significance. Journal of Investigative Derm 82:145-149, 1984.

(2) Grimwood RE, Johnson CA, Ferris CF, MercillDB, Mellette JR, Huff, JC: Transplantatin of Human Basal Cell Carcinomas in Athymic Mice. Cancer

(3) Ferris, CF, Grimwood, RE, Kramer LC, Mercill DB and Huff JC: The Proliferating Cells of a Human Basal Cell Carcinoma are the Peripheal Pallisaded Cells. Abst. Clinical Research, Vol. 33, No. 2, 636A, April 1985.

(4) Grimwood RE, Ferris CF, Mercill DB and Huff JC: The Proliferating Cells of Human Basal Cell Carcinoma are Located on the Periphery of Tumor Nodules. J. Investigative Derm. Clin. Res., Vol. 33 No. 4, Page 825A.

(5) Grimwood RE, Ferris CF, Mercill DB, Huff JC: The Proliferating Cells of Human Cell Carcinoma are Locatede on the Periphery of Tumor Nodules. J. Invest. Dermatol., Vol 86, No. 2, Pg 191-194, February 1986.

(6) Grimwood RE, Ferris CF, Nielson LD, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude Mice Produce and Deposit Fibronectin in the Extracellular Matrix. J. Invest. Dermatol., 87:42-46, 1986.

(7) Grimwood RE, Siegle RJ, Ferris CF and Huff JC: The Biology of Basal Cell Carcinomas - A Revisit and Recent Developments. J. Dermatol. Surg. Oncol., 12:8, August 1986.

(8) Siegle R, Grimwood R: Athymic Mice - A Model for the Transplantation of Human Basal Cell Carcinoma. J. Dermatol. Surg. Oncol., 12:6, June 1986, pp. 646.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 84/119 (3) Status: Ongoing

(4) Title: Treatment of Graves' Ophthalmopathy with Cyclosporin

(5) Start Date: 1984

(6) Est Compl Date: 1992

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Leonard Wartofsky, COL, MC

(8) Facility: FAMC
WRAMC
MAMC
BAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Anthony Truxal, CPT, MC

(11) Key Words:
eye disease
cyclosporin
prednisone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Cyclosporin - Acne (1 pt.) Prednisone - Acne, swelling (1 pt.) Arthralgia on withdrawal (1 pt.)

(15) Study Objective: To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach: Patients with Graves' eye disease will receive a 3-week course of cyclosporin or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporin (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and B-2 microglobulin (urine).

(17) Progress: No new patients enlisted from FAMC in the past year. Two patients added from other medical centers. Results in patients evaluated thus far as a group are kept at Walter Reed and have not yet been analyzed.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 85/100 (3) Status: Ongoing

(4) Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III
SWOG #7804

(5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/102 (3) Status: Completed

(4) Title: Combined Modality Therapy for Breast Carcinoma, Phase III
SWOG #7827

(5) Start Date: 1979 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 1 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/122 (3) Status: Completed

(4) Title: Treatment of Advanced Bladder Cancer with Preoperative Irradiation and Radical Cystectomy vs. Radical Cystectomy Alone, Phase III
SWOG #8221

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/132 (3) Status: Completed

(4) Title: Evaluation of Adjuvant Therapy and Biological Parameters
in Node Negative Operable Female Breast Cancer,
Intergroup Study
SWOG #8294

(5) Start Date: 1982 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 9 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/133 (3) Status: Completed

(4) Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III SWOG #8300

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words: drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 85/136 (3) Status: Completed

(4) Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER
Negative Stage II Carcinoma of the Breast, Phase III
SWOG #8313

(5) Start Date: 1974 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/139 (3) Status: Ongoing

(4) Title: National Intergroup Protocol for Intermediate Thickness
Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Margins
(2 vs 4 cm) Around the Primary Melanoma and Evaluation
of Elective Regional Lymph Node Dissection
SWOG #8393

(5) Start Date: 1983 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 85/141 (3) Status: Completed
g

(4) Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II
SWOG #8411

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/142 (3) Status: Completed

(4) Title: Evaluation of Tamoxifen in Unresectable and Refractory
Meningiomas, Phase II
SWOG #8415

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 85/147 (3) Status: Completed

(4) Title: HLA and Gm Genes in Systemic Lupus Erythematosus
Antibody Expression

(5) Start Date: 1985

(6) Est Compl Date: 1988

(7) Principal Investigator:
Christopher LeSueur, MD
Sterling West, MD

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology

(10) Associate Investigators

(11) Key Words:
lupus erythematosus, systemic
HLA antigens

Moses Shanfield, Ph.D.

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____ 150

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if patients with systemic lupus erythematosus have increased prevalence of any HLA and Gm genes as it relates to their autoantibody expression compared to a control group.

(16) Technical Approach: After patient education and consent form is signed, the patient has eight tubes of heparinized blood drawn for HLA and Gm typing. The patient's clinical symptoms, signs and other laboratory parameters are collected according to protocol and correlated with the patient's HLA and Gm typing.

(17) Progress: A total of 150 patients have been HLA and Gm typed. Data collected from this protocol is presently being compiled for publication.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/157 (3) Status: Completed

(4) Title: Phase III Study to Determine the Effect of Combining
Chemotherapy with Surgery and Radiotherapy for Resectable
Squamous Cell Carcinoma of the Head and Neck
SWOG #8590

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
chemotherapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/158 (3) Status: Completed

(4) Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole Plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon, Phase III-Intergroup
SWOG #8591

(5) Start Date: 1985 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/163 (3) Status: Completed

(4) Title: The Effect of Theophylline and Nifedipine on Hormone Secretion

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, COL, MC

(11) Key Words:
theophylline
nifedipine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 10 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this protocol are to study the effect of theophylline and nifedipine on hormone secretion patterns in order to probe the intracellular mechanisms of hormone secretion and to better understand the effects of these medications on endocrine function tests.

(16) Technical Approach: Subjects will have a combined pituitary stimulation study (TRH, GnRH and ACTH) on 3 occasions: control period, during a theophylline infusion, after 2 days of taking nifedipine. Basal and peak hormone responses to the stimulating hormones will be compared among the 3 periods.

CONTINUATION SHEET, FY 90, ANNUAL PROGRESS REPORT Protocol #: 85/163

(17) Progress: 10 subjects have been studied. Theophylline enhanced the cortisol response to ACTH but no other hormone responses. Nifedipine had no significant effect on any hormone response.

Publications: McDermott MT, Walden T, Bornemann M, Sjoberg RJ, Hofeldt F, Kidd GS: The effects of theophylline and nifedipine on ACTH stimulated adrenal cortisol secretion. *clin Pharmacol Ther* 47:435-8, 1990.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/165A (3) Status: Ongoing

(4) Title: An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae

(5) Start Date: 1985 (6) Est Compl Date: 1990

(7) Principal Investigator: David Goodman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators

(11) Key Words: pollen hypersensitivity allergens R. Ledoux Bernard L. Crosby, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate patterns of cross allergenicity among pollens of the weed families, Chenopodiaceae and Amaranthaceae.

(16) Technical Approach: Evaluation of cross reactivity using human antigen and ELISA in inhibition, rabbit antisera and CIE, CRIE. Allergen characterization using PAGE, IEF, and Western Blot.

(17) Progress: Comparison of Adjuvant Preparations. We are presently completing the immunoassays (CIE, ELISA, SDS-PAGE, and immunoblots) necessary to define quantitative and qualitative antibody production (in the rabbit model) utilizing the four adjuvant systems: Freund's adjuvant, RIBI adjuvant system, Aluminum hydroxide. Assessments of Antigenicity will be completed during the first 6 months of the calendar year 1990. These are presently under way and include SDS-PAGE and IEF separatin of allergenic extract proteins, and subsequent characterization of antigenicity by crossed-immunoelectrophoretic assays. Assessments of allergenicity and cross-reactivity will similarly be completed during FY 90. Presently, we are comparing cross-

specific rabbit antipollen antibody (IgG) production, and specific human antipollen antibody (IgE, IgG) production. Additionally, we are developing an enzyme-linked crossed-immunoelectrophoretic assay that may offer additional evidence of allergenic similarities amongst these weed pollen family members. This protocol using polyvalent antisera from the rabbit model will represent an important foundation step for the work of MAJ Larsen from this Service utilizing monoclonal antibodies. The delineation of the specific allergenic epitopes of these pollen families is realistically achievable.

Presentations:

Crosby BL, Ledoux RA, Vaughan TR, Weber RW, and Goodman DL: Chenopod-Amaranth Crossreactivity: Evaluation of Cross-Reactivity Between Redroot Pigweed, Russian Thistle, Palmers Amaranth, and Lenscale by ELISA Inhibition and Enzyme-Linked Immunoblots: Presented: Harold S. Nelson Allergy Symposium, FAMC, February 1990 and American Academy of Allergy and Immunology, Baltimore, MD, March 1990.

Goodman DL, Crosby BL, Weber RW, Vaughan TR: Chenopod-Amaranth Cross-Reactivity: Comparison of Four Adjuvant Systems in the Production of Rabbit Anti-Russian Thistle IgG: Presented: Harold S. Nelson Allergy Symposium, FAMC, February 1990.

Goodman DL, Ledoux RA, Weber RW: Comparison of Adjuvant Systems in the Production of Pollen Antisera in Rabbits. Presented: American Academy of Allergy & Immunology Annual Meeting, Washington, DC, February 1987.

Muggleberg, ML, Ledoux RA, Weber RW: Cross-Allergenicity of Western Prairie Grasses Evaluation by ELISA Inhibition. Presented: American Academy of Allergy & Immunology, Anaheim, CA., March 1988.

Publications: Two publications expected to be completed this FY.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/166 (3) Status: Completed

(4) Title: Colon Inflammation in Reiter's Syndrome: Response to Sulfasalazine. Results in a Controlled Study

(5) Start Date: 1985 (6) Est Compl Date: 1989

(7) Principal Investigator: David Nordstrom, MD
Sterling West, MD
Peter Andersen, MD (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology (10) Associate Investigators

(11) Key Words:
Reiter's disease
reactive arthritis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: _____ / 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To see if patients with idiopathic Reiter's syndrome have colon inflammation and to see (in double-blinded fashion) if this responds to Sulfasalazine.

(16) Technical Approach: Colonoscopy with biopsy is performed on Reiter's patients and controls (patients with inflammatory arthritis that is not Reiter's).

(17) Progress: Completed, manuscript in preparation. Patients and controls continue to be added to the protocol. Although numbers are still small, patients with Reiter's seem to have a favorable response to Sulfasalazine, and their microscopic inflammation improves as well. A small number of new patients (10) have been added this FY and patients treated with Sulfasalazine continue to be followed closely for 6-8 months.

Publication: Nordstrom DM, West SG, Freeman S, Reddy V: HLA-B27 Positive Enterogenic Reactive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Arthritis Rheum. 30:524, 1987.

Presentation: HLA-B27 Positive Enterogenic Reactive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Presented: Nat. A.A. Rheu. Ass., Washington, DC, July 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/167 (3) Status: Ongoing

(4) Title: The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test

(5) Start Date: 1985 (6) Est Compl Date: 1991

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators

(11) Key Words: thyroid diseases
thyroid function tests
thyroid gland
William J. Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC
Tony L. Walden, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 12 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effect of age on the perchlorate discharge test in individuals with thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without thyroid disease by history, physical examination and lab evaluation will be studied. A perchlorate test will be performed in Nuclear Medicine.

(17) Progress: No progress has been made due to inadequate time of principal investigator; however, the study is thought to still be valid and worthwhile. A new Endocrine Fellow will pick up this protocol and complete it.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 85/174 (3) Status: Completed

(4) Title: Evaluation of Combination Chemotherapy Using High Dose
ARA-C in Adult Acute Leukemia and Chronic Granulocytic
Leukemia in Blastic Crisis, Phase III
SWOG 8326/27

(5) Start Date: 1983 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 86/10X-001 (3) Status: Terminated

(4) Title: Feasibility Study to Determine if Estrogen and Progesterone Affect in-vitro Growth of Cultured Malignant Melanoma (MM) Cell Lines

(5) Start Date: 1986

(6) Est Compl Date: 1990

(7) Principal Investigator:
Charles F. Ferris, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators

Donald B. Mercill, DAC

(11) Key Words:
malignant melanoma
receptors
estrogen
progesterone

Thomas P. O'Barr, DAC

Charles F. Ferris, CPT, MS

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether malignant melanoma cell lines previously obtained and stored (frozen) have estrogen and progesterone receptors. If receptors can be identified, then a full scale protocol can be undertaken to determine if estrogen and progesterone have an effect on cell growth.

(16) Technical Approach: Malignant melanoma cells lines currently stored in the Cell Physiology Service will be grown to confluence. Specific binding will be characterized utilizing a dextran-coated charcoal technique.

(17) Progress: The feasibility study did not support the original hypothesis.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 86/103 (3) Status: Completed

(4) Title: Evaluation of Low Dose Ara-C versus Supportive Therapy
Alone in the Treatment of Myelodysplastic Syndromes
(ECOG EST 4483)
SWOG #8592

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/107A (3) Status: Ongoing

(4) Title: In-Vitro Drug Sensitivity Utilizing the Guinea Pig Airway Smooth Muscle Model

(5) Start Date: 1986

(6) Est Compl Date: 1991

(7) Principal Investigator:
T. Ray Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:
drug sensitivity

Anthony R. Henry, LTC, MC
Michael A. O'Connell

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 47-60 Guinea Pigs
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: We have previously demonstrated in the guinea pig tracheal model the development of subsensitivity to beta-adrenergic agonists. It would now be useful to have an animal model in which we can safely study the pharmacodynamic interactions involved in beta-adrenergic blocker induced bronchoconstriction. Specifically, it will be important to determine the direct effects of beta-adrenergic blockers on tracheal smooth muscle prior to histamine-induced tracheal constriction. Then, it will be important to determine the effects of beta-adrenergic agonists and anticholinergics on beta-adrenergic blocker induced tracheal constriction.

(16) Technical Approach: In-vitro blockade of beta-adrenergic receptors of the guinea pig trachea will be achieved after the guinea pig tracheas have been excised, divided into segments, and placed into tissue chambers under physiologic conditions. Subsequently, the effects of beta-adrenergic blockers will be studied before and after the induction of tracheal smooth muscle contraction by histamine. Finally, the effects of beta-adrenergic agonists and anticholinergics on the beta-adrenergic blocker induced tracheal smooth muscle constriction will be studied.

(17) Progress: (a) Propranolol (10-4M) causes no significant tracheal smooth muscle contraction. (b) Pretreatment with propranolol potentiates histamine-induced tracheal smooth muscle contraction. (c) Pretreatment with propranolol attenuates albuterol reversal of histamine-induced smooth muscle contraction. (d) We have established an in-vitro model with which we can safely study the pharmacodynamic interactions involved in beta-blocker potentiated bronchoconstriction. (e) Atropine methylnitrate causes no significant reversal of the histamine-induced tracheal smooth muscle contraction during the observation period (5-10 minutes). (f) Atropine sulfate causes reversal of the histamine-induced tracheal smooth muscle contraction. (g) Propranolol (10-6M) causes no significant tracheal smooth muscle contraction. (h) Pretreatment with propranolol (10-6M) appears to potentiate histamine-induced tracheal smooth muscle contraction. (i) Both g & h are important because of 10-6M propranolol reflects reported tissue concentrations of propranolol in the lung.

Presentations: American College of Allergist National Meeting, 1986; Hugh Mahon Lectureship Award Competition (1st place award in lab category and grand prize award) FAMC, 1989. Aspen Allergy Conference Regional Meeting, 1989. American College of Allergy & Immunology National Meeting, 1989. American Academy of Allergy & Immunology 1990. Harold S. Nelson Symposium, FAMC 1990. Aspen Allergy Conference, Aspen, CO 1990. 1st Place Lab Category HMLAC 1990.

Publications: Ann. All. 56:117-119, 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/109 (3) Status: Ongoing

(4) Title: The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism

(5) Start Date: 1986 (6) Est Compl Date: 1991

(7) Principal Investigator: John Merenich, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael E. Perry, COL, MC
Michael T. McDermott, MAJ, MC
Fred Negron, CPT, MC
Peter Blue, LTC, MC

(11) Key Words:
calcium
vitamin D rifampin
vitamin D deficiency

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The purpose of this study is to see if INH therapy alters vitamin D and/or calcium metabolism in a significant manner. This may then lead to further evaluation to determine if patients would benefit from vit D or calcium supplementation while receiving INH therapy.

(16) Technical Approach: Ten to 20 patients will be begun on INH therapy for their recent PPD conversion. Determinations of Vit D (25-OH, 1,25-OH), serum calcium, PTH, 24-hour urine calcium and SMA-18 are drawn at baseline, 2 weeks, 6 and 9 months. Bone densitometry is obtained before and after therapy.

(17) Progress: Seven patients have been entered in the study as of this date. No progress made concerning patients. The following events and progress has been made: 1) Protocol approved in November at Eisenhower AMC (Dr. Asp); 2) A plan has been set up with LTC Criswell, Preventive Medicine, for recruiting patients.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HTLV-1 Infection and Disease in a
United States Military Community

(5) Start Date: 1986 (6) Est Compl Date: 1992

(7) Principal Investigator: Gates, Robert H. LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators
Leo A. Andron, LTC, MS

(11) Key Words:
HIV virus

Roland N. Hannon, PA-C, CW3(RET)
Jefferey Casserly, PA-C, CW3(RET)
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan 90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 100
d. Total Number of Subjects Enrolled to Date: 550
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough understanding of
the pattern of disease progression and clinical course in individuals
with documented HIV infection within the general military population
including active duty, dependents, and retirees. This will provide
critical information for clinical and administrative management of
patients.

(16) Technical Approach: Collect data on all patients who are required
to be staged by DA directives and any who request staging.

(17) Progress: No changes except as noted for amendments in the
protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/118 (3) Status: Completed

(4) Title: Maintenance vs. No Maintenance BCG Immunotherapy of
Superficial Bladder Cancer
SWOG #8507

(5) Start Date: 1985 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
chemotherapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/119 (3) Status: Completed

(4) Title: Randomized Comparison of Cisplatin + 5-Fluorouracil vs.
CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced
Squamous Cell Carcinoma of the Head and Neck, Phase III
SWOG #8514

(5) Start Date: 1986

(6) Est Compl Date: 1990

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Closed to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/120 (3) Status: Ongoing

(4) Title: A Phase II Comparison of CHOP versus m-BACOD versus ProMACE-CytaBOM versus MACOP-B in Patients with Intermediate or High Grade Non-Hodgkin's Lymphoma
SWOG #8516

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 2 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/123 (3) Status: Completed

(4) Title: Phase II Evaluation of Methyl-Glyoxal Bis-Guanylhydrazone
(MGBG) in Patients with Advanced Bladder Cancer
SWOG #8519

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/124 (3) Status: Completed

(4) Title: Treatment of Limited Small Cell Lung Cancer with Concurrent
Chemotherapy, Radiotherapy and Intensification with High
Dose Cyclophosphamide
SWOG #8573

(5) Start Date: 1985 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Closed to accrual.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 86/126 (3) Status: Completed

(4) Title: A Prospective Randomized Trial to Determine the Benefit
of Surgical Resection of Residual Disease Following
Response of Small Cell Lung Cancer to Combination
Chemotherapy
LCSG #832

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept, Svc: MED/Hema/Oncol (10) Associate Investigator:

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum FDA Cases:
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or equivalent agency
studying under an FDA-awarded IND. May be reported on the Unit Summary
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the LCSG #832

(16) Technical Approach: See Protocol

(17) Progress: Terminated

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/128 (3) Status: Terminated

(4) Title: A Clinical Trial in Patients with Stage II and III
Completely Resected Non-Small Cancer of the Lung
Comparing Chemotherapy vs. No Therapy Following
Surgery
LCSG #853

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Terminated

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HOCR 40-21) (Continued)

(1) Date: 30 Sep 90 (2) Protocol #: 86/132A (3) Status: completed

(4) Title: The Effect of Theophylline on Calcium and Vitamin D Metabolism in Male Sprague-Dawley Rats

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: Edwin J. Fortenberry, CPT, MC
Michael T. McDermott, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators
Gerald S. Kidd, COL, MC

(11) Key Words:
theophylline
vitamin D
calcium

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 49 male rats
d. Total Number of Subjects Enrolled to Date: 49 male rats
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of the study are to determine the effect of chronic theophylline administration on calcium and vitamin D metabolism and bone mineral content in rats.

(16) Technical Approach: Theophylline (300mg) or saline (med) are administered by continuous infusion with an Alzet osmotic pump for a period of 4 weeks. After 2 1/2 weeks, measurements are made of 24 hour calcium intake, urine calcium, and fecal calcium excretion and overall calcium balance is calculated. After 4 weeks, the rats are sacrificed and serum calcium PTH, 25 (OH) vitamin D and 1,25 (OH)₂ vitamin D are measured. The rats are ashed for determination of total body calcium.

(17) Progress: All animals have been studied. Chronic theophylline increased urinary calcium excretion and decreased 25 (OH) vitamin D levels.

Presentations:

(1) McDermott MT, Fortenbery EJ, Duncan WE. Theophylline alters vitamin D and calcium metabolism in rats. 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) McDermott MT, Fortenbery EJ, Duncan WE: Theophylline alters vitamin D and calcium metabolism in rats. J Bone Min Res 3(Suppl. 1): 5115 (188A)

(2) Fortenbery EJ, McDermott MT, Duncan WE: The effect of theophylline on calcium metabolism and circulating vitamin D metabolites. J Bone Min Res 5:321-4, 1990.

(1) Date: 30 Sep 90 (2) Protocol #: 87/102 (3) Status: Terminated

(4) Title: Anti-Histone Antibody Production in Procainamide Associated Drug-Induced Lupus Erythematosus: Association of Serologic Patterns and Lymphocyte Subsets

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:
James D. Singleton, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology

(10) Associate Investigators
Peter A. Andersen, LTC, MC
West, Sterling, LTC, MC

(11) Key Words:
procainamide
drug-induced lupus
histones

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 19 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: There are two study objectives: a) to survey the population of patients receiving procainamide to determine baseline data and b) to evaluate a subgroup of patients chosen randomly from patient populations determined by amount of drug administered, serologic status, and the presence of symptomatology.

(16) Technical Approach: Autoantibodies are one of the hallmarks of SLE yet mechanisms of their production and their pathogenetic import remain unclear. Drug-induced lupus makes feasible the investigation of potential early immunologic abnormalities which would lead to autoantibody production. Demographic, clinical and serologic data will be obtained on patients taking procainamide. Selected patients will, additionally, have T-cell and B-cell lymphocyte studies and be followed serially to

discover correlates, if any, in studied parameters.

(17) Progress: Although only 19 patients have been enrolled in the study and baseline data obtained, approximately 110 individuals receiving procainamide have been identified. Very few patients could be contacted; an inordinate number of those enrolled were lost to followup due to death or unwillingness to continue in the study.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/103 (3) Status: Ongoing

(4) Title: Identification of Those at Risk for Osteoporotic Fractures
by a Non-Invasive Measurement

(5) Start Date: 1987 (6) Est Compl Date: June 1990

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald Kidd, COL, MC

(11) Key Words:
osteoporosis
hip fractures

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 70
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To evaluate possible risk factors for osteoporosis
by comparing hip fracture patients and matched controls for bone
density, calcium intake, smoking, medications, mental status, visual
acuity, vitamin D levels and exercise history.

(16) Technical Approach: Hip fracture patients, within 5 days of
fracture, and normal matched controls will have measurement of bone
density at 3 sites in the unaffected hip and in the spine by dual photon
absorptiometry and in the non-dominant midradius by single photon
absorptiometry. All subjects will have a history and physical
examination to include dietary and exercise history. Twenty subjects
from each group will have visual acuity and 25-hydroxy vitamin D levels
evaluated.

(17) Progress: Patients with hip fractures had significantly reduced bone density in the hip and lumbar spine and significantly lower calcium intakes. No further progress. The manuscript has been submitted for publication.

Presentations:

(1) McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. Presented: 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) Perloff JJ, McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. J Bone Min Res 3(Suppl. 1):587(73A), 1988, (Abstract).

(2) Perloff JJ, McDermott MT, Perloff KG, Blue PW, Enzenhauer R, Seik E, Chantelois A, Dolbow A, Kidd GS: Risk factors for osteoporotic hip fractures (Submitted for publication).

(1) Date: 30 Sep 90 (2) Protocol #: 87/104 (3) Status: Ongoing

(4) Title: A Randomized Investiation of High-Dose Versus Standard
Dose Cytosine Abarinoside with Daunorubicin in Patients
with Acute Non-Lymphocytic Leukemia, Phase III
SWOG 8600

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/105 (3) Status: Completed

(4) Title: Pre-operative Cimetidine Therapy in Patients Undergoing Parathyroid Exploration: Efficacy and Mechanisms of Action

(5) Start Date: 1987 (6) Est Compl Date: 1989

(7) Principal Investigator: John A. Merenich CPT, MC
Jeffrey R. Clark, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators
Michael T. McDermott, MC
William J. Georgitis, MAJ, MC
Arnold A. Asp, MAJ, MC
Gerald S. Kidd, COL, MC

(11) Key Words:
hyperparathyroidism
postoperative hypocalcemia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 20 _____
d. Total Number of Subjects Enrolled to Date: _____ 20 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".----Last year one patient developed moderate elevations of liver function tests. She was completely asymptomatic, but her parathyroid surgery was postponed (until her tests returned to normal) and she was dropped from the study. She has subsequently undergone surgery without complications and LFT's remain normal. This year, none of the new patients experienced any complications.

(15) Study Objective: To determine whether or not pre-operative cimetidine therapy can reduce the incidence of post-operative hypocalcemia in patients undergoing parathyroid explorative surgery.

(16) Technical Approach: Patients are given placebo or cimetidine for 10 days prior to their surgery in a double-blind fashion. Calcium and its regulatory hormones are monitored before and after surgery to see if cimetidine favorably alters calcium homeostasis.

(17) Progress: Completed. All but one subject undergoing parathyroid exploration agreed to participate.

Publications: Abstract submitted to 1990 Endocrine Meeting.

Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/111 (3) Status: Ongoing

(4) Title: A Prospective Double Blind Study of Zidovudine in Early HIV Infection

(5) Start Date: 31 Oct 87 (6) Est Compl Date: 1991, Oct

(7) Principal Investigator: Shannon Harrison, LTC, MC (8) Facility: FAMC Denver Health & Hospitals

(9) Dept/Svc: DCI (10) Associate Investigators

(11) Key Words: ZDV asymptomatic HIV R.N. Hannon, PA-C Leo Andron, LTC, MS Robert H. Gates, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report. (Fenced HSC/HIV monies & P6 MED R&D Grant renewed for FY 90 & 91

(14) a. Date, Latest IRC Review: Feb 90 b. Review Results: Ongoing ___
c. Number of Subjects Enrolled During Reporting Period: none
d. Total Number of Subjects Enrolled to Date: 66 & 1500 DH&H
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". (1 RBC aplasia; 4 granulocytopenia; 6 thrombocytopenia; 1 severe nausea and vomiting; none off study).

(15) Study Objective: To look for efficacy and toxicity in terms of difference in natural history of DoD class 2 through early 5, HIV infected individuals given zidovudine at 200mg every 6 hours, 1/2 started 87, 88, 1/2 started 15 Aug 90.

(16) Technical Approach: 16 study endpoints/78 withdrawals: misentries, 1 for toxicity.

(17) Progress: Protocol was closed 1 February 1989. 110 patients still on study.

Publications and Presentations: (a) 3 abstracts; International HIV Meeting, San Francisco, CA, Jun 90; (b) 2 presentations; WRAIR Retrovirology Seminar, Sep 88, Sep 89; (c) 1 presentation; US Army HIV symposium, Dallas, TX 28 Jan 90 - 2 Feb 90.

(1) Date: 30 Sep 90 (2) Protocol #: 87/112 (3) Status: Ongoing

(4) Title: (PTOG-85-01) Prospective Trial for Localized Cancer of The
Esophagus: Comparing Radiation as a Single Modality to the
Combination of Radiation Therapy and Chemotherapy, Phase
III Intergroup
SWOG-8598

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/113 (3) Status: Completed

(4) Title: A Phase II Randomized Trial of Combination Therapy for Multiple Myeloma: Comparison of (1) VMCP/VBAP to VAD or VMCP/VBAPP for Induction, (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha -2b Interferon + Dexamethasone for Incomplete or Nonresponders

SWOG 8624

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 1 _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/114 (3) Status: Ongoing

(4) Title: Patient Evaluation of Physicians' Humanistic Qualities

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gen. Med Svc. (10) Associate Investigators
Cathy L. Ow, CPT, MC

(11) Key Words:
humanistic qualities
medical residents

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 5/90 b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) to determine what behaviors are considered by patients to be important markers of humanistic qualities in their physicians; b) to develop and test a questionnaire for a patient to rate the humanistic qualities of their own physician, and (c) to determine whether feedback, based on their own patients' ratings, can result in a change in physicians' humanistic behaviors.

(16) Technical Approach: The study consists of three phases: (a) open-ended interviews with patients to elicit important physicians' humanistic behaviors; (b) development and testing of a questionnaire from the responses generated in Phase a, and (c) we will give back feedback to physicians, based on their own patients' evaluation of their humanistic behaviors, using the questionnaire developed, and measure whether there is any change on a repeat questionnaire, post-feedback.

(17) Progress: Data analysis completed for 1st version of questionnaire. Questionnaire is being revised for 2nd version to be tested on larger number of interns and residents.

Publications:

Weaver MJ, Ow CL, Walker DJ and Degenhardt EF: Evaluation of Residents Humanistic Qualities by Patients and Attending Physicians (Abstract Submitted)

Presentations:

Ow C, Weaver M, Walker D, Degenhardt E: Patient Evaluation of Physicians Humanistic Qualities. (Accepted for presentation at Army Regional LAP meeting, October 1989).

Weaver MJ, Ow CL, Walker DJ, Degenhardt EF: Evaluation of resident's humanistic qualities by patients and attending physicians. Presented at 5th Biennial Symposium for Teaching Internal Medicine, Boston, MA Nov. 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/115 (3) Status: Terminated

(4) Title: Double Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Richard Winn, LTC, USAF, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul Dis Svc. (10) Associate Investigators
Shannon M. Harrison, LTC, MC
Robert H. Gates, MAJ, MC

(11) Key Words:
gram negative shock
gram negative sepsis
monoclonal antibody
HA-1A monoclonal antibody

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Objective: To determine the efficacy of HA-1A monoclonal antibody in reducing the mortality and/or direct morbidity of gram-negative sepsis as compared to a placebo treated control group. To determine the impact that HA-1A has on patient benefit. To determine the impact that HA-1A has on laboratory parameters/clinical signs associated with sepsis. To determine the safety and potential for immunogenicity of HA-1A monoclonal antibody administration in patients presenting with clinical syndrome of gram-negative sepsis.

(16) Technical Approach: Patients with the clinical diagnosis of septic shock or sepsis suspected of being secondary to gram-negative organisms will be treated with one dose of either placebo or HA-1A monoclonal antibody. A comparison of morbidity and mortality between the placebo and HA-1A group will be made to determine efficacy and safety of the drug.

(17) Progress: Enrollment of patients at FAMC is complete. Additional study on specimens and samples will be performed. Terminate study.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/116 (3) Status: Ongoing

(4) Title: Effect of Iodine Containing Water Purification Tablets
on Thyroid Function in Man

(5) Start Date: Aug 87 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators
John R. Barrett, LTC, MC
William J. Georgitis, LTC, MC
Robert J. Sjoberg, MAJ, MC
John A. Merenich, CPT, MC
Kenneth Simcic, CPT, MC

(11) Key Words:
iodine
water purification tablets
thyroid function tests

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study are to investigate
the effects of iodine containing water purification tablets on thyroid
function and job performance in soldiers in a field environment.

(16) Technical Approach: See Protocol

(17) Progress: No progress has been since last FY. The manuscript has
been submitted for publication and the reviewers have asked that we
measure serum iodine levels. We have been working with Biochemistry
Service, DCI, since then to try to develop an assay for serum iodine but
have so far been unsuccessful. Alternately we may eventually send them
to a commercial lab. We are still trying to get serum iodide
measurements.

Presentations: Georgitis WJ, McDermott MT. Iodide water purification
tablets alter thyroid function in man. Presented: 71st Meeting of the
Endocrine Society, Seattle, WA. Endocrinology 124(Suppl):480 (1830A),
1989.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 67/117 (3) Status: Terminated

(4) Title: Analysis of von Willebrand Factor Multimers Before
and After Cardiopulmonary Bypass

(5) Start Date: 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: B. Vishnu V. Reddy, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Pathology (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the effect of the cardiopulmonary bypass machine on the multimeric structure of von Willebrand's factor and to provide clinical research experience for FAMC residents and staff.

(16) Technical Approach: See Protocol

(17) Progress: Since the PCS of the original principal investigator no new subjects have been enrolled. Efforts to establish a laboratory method to analyze the multimeric structure of von Willebrand's factor have failed.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/101 (3) Status: Terminated

(4) Title: Centralized Non-Small Cell Lung Cancer Specimen
Repository and DNA/RNA Bank
LCSG 871

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hemo/Oncol Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 22
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the LCSG group protocol.

(16) Technical Approach: See protocol.

(17) Progress: Terminated

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/102 (3) Status: Completed

(4) Title: Effect of Chronic Coumadin Therapy on Cortical and Trabecular Bone Density in Man

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc. (10) Associate Investigators
Gerald S. Kidd, COL, MC
Peter Blue, LTC, MC

(11) Key Words:
bone density
coumadin
osteocalcin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to investigate the bone density of cortical and trabecular bone in patients on chronic coumadin therapy and in age-matched controls.

(16) Technical Approach: See protocol.

(17) Progress: Coumadin patients do not have lower bone density than matched controls.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/103 (3) Status: Completed

(4) Title: Clinical Efficacy of Phenindamine as Determined
by Skin Test Suppression

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators
Edward W. Green COL, MC
Paul R. Sklarew, CPT, MC

(11) Key Words:
antihistamine
phenindamine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 12 _____
d. Total Number of Subjects Enrolled to Date: _____ 12 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None

(15) Study Objective: To examine the null hypotheses that there is no
difference in skin test suppression and side effects produced by phenin-
damine 25mg qid, chlorpheniramine 8mg tid, and placebo in 2 week trials
in normal subjects.

(16) Technical Approach: Twenty subjects will take part in a placebo
controlled crossover study of the skin test suppression produced by
phenindamine, chlorpheniramine, and placebo. Results will be used to
evaluate the efficacy, as determined by skin test suppression, of
phenindamine compared to chlorpheniramine and placebo.

(17) Progress: Investigators are now available. However, as
phenindamine is being marketed as a non-sedating antihistamine, we feel
the more appropriate comparison would be with terfenadine (seldane).
An amendment to this protocol is being prepared. FY 90 - 12 completed
study, results statistically significant in that phenindamine was less
potent and produced more drowsiness than terfenadine.

Publications and Presentations: Nelson HS: Allergy-Immunology
Symposium, Feb 90; Am. College of Allergy-Immunology, San Francisco, CA
Nov 90.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/104 (3) Status: Ongoing

(4) Title: A Descriptive Study of Pastoral Care Interventions Designed to Assist HIV+/AIDS Patients in Achieving Their Maximum Quality of Life

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: F. William Miles, LTC, USAR (Chaplain) (8) Facility: FAMC

(9) Dept/Svc: Minis. & Past. Care (10) Associate Investigators
Shannon M. Harrison, LTC, MC
Robert L. Campbell (CH), COL
Jerry Webb, COL (CH)
Robert H. Gates, LTC, MC

(11) Key Words:
psycho-social-spiritual
cognitive, moral and
faith development

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: Tst 47/Intr 7
d. Total Number of Subjects Enrolled to Date: Tst 397/Intr 96
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: (a) To observe and document the continuity of pastoral care with a traumatically stressed patient population (FAMC and beyond). (b) To conduct a longitudinal descriptive study that shows process from the point of view of patient, family member, supervisor and pastoral care giver. (c) To encourage personal processing of issues that impact on a sense of well being, decision making, psycho-social-spiritual growth through the use of an intentional and prescribed series of pastoral interventions. To provide the patient personal gain from telling his/her own "story." (d) To look at life histories, values, moral/faith development, personality types as they inform the pastoral care giver for ministry.

(16) Technical Approach: We have developed a pastoral data base of information relative to providing pastoral care to HIV+/AIDS patients. This was accomplished through regular personality inventories and interviews every six months during the HIV staging process, as well as follow-up questionnaires and support visits/calls to determine continuity of pastoral care and individuals functioning at unit/home.

(17) Progress: The protocol ended the data gathering phase in May 1990. We cut off new data gathering, except for followup testing and interviews, and prisoners and women, by 30 May 90. coordination with HSC, FORSCOM, and Ft. Carson to obtain a control group, a random sample of soldiers by age, MOS, and rank, with whom to compare our patient group was not successful. An inadequate (not randomized, etc.) control group is used which consists mostly of soldiers and dependents from the FAMC area (or who came through the I.D.S. for other reasons), as well as spouses of patients. During the last two years, the following testing was completed in the HIV Pastoral Research Project (since began testing o/a 1 Oct 87). Totals for the current year, 16 Dec 89-30 Jun 90, are included to the right in [bold] parentheses.

- a. Patients tested/interviewed - 397 [47] (Black=136, White=156, Others=36)
- b. Second testings - 115 [18] (Prisoners=30)
- c. Third testings - 45 [9] (Women=63, HIV+=25) (Total=86)
- d. Fourth testings - 12 [6]
- e. Fifth testings - 6 [6]
- d. Values inventories -302 [26] (includes 43 HIV-)
- e. Second values Inv.- 6 [2]
- e. D.I.T. - 290 [16] (includes 47 HIV-)
- f. D.I.T. #2 - 79 [22] (given at 1 year)
- g. MBTI - 335 [27]
- h. TJTA - 493 [66] (253+, 63-)
- i. MPD - 212 [27] (includes 33 HIV-)
- j. MPD #2 - 18 [5]
- k. Fowler Interviews - 96 [0]
- l. 2nd Interviews - 51 [7]

Publications:

- (1) For the General Convention of the Episcopal Church, Detroit, Michigan, July 1988, Short article describing the research projects being conducted in Infectious Disease Service/DMPC at FAMC.
- (2) Haburchak DR, Harrison SM, Hannon RN, Miles FW: Resolving Patient Feelings of Guilt - A Need for Physician Chaplain Liaison. AIDS Patient Care, Oct 1989, p.42-3.
- (3) Letter to the Editor of the Colorado Episcopalian, dated June 1989.
- (4) Miles F.Wm: Churches Must Be Hospitable as AIDS Virus Spreads. Colorado Episcopalian, p. 10, October 1989.
- (5) Miles F.Wm: What Happens When a Soldier is HIV+? Submitted to Command Magazine, in press, 1990.

Presentations:

- (1) Psycho-social-spiritual Aspects of HIV+Patients: Presented: Ft. Leavenworth, Kansas, September 1987.

(2) AIDS for professionals, The Next Step. 2 presentations: "Guilt, Shame, and Grief" and "A Wellness/wholeness Approach for the HIV+ Patient." New York City, 15 April 1988.

(3) Episcopal Diocese of Colorado Workshop: AIDS, The Church's Response. w/Mr. Hannon and Dr. Harrison. Presented: Denver, Colorado, 6-7 February 1988.

(4) HIV/AIDS Briefing - Psycho-social-spiritual Aspects. Physical Therapy Students. Presented: University of Colorado Medical Center, Denver, CO, April 1988.

(5) HIV/AIDS Briefing/A Psycho-Social-Spiritual Model of Wellness in the HIV+ Patient. Presented: MEDDAC, Ft. Hood, Texas, May 1988.

(6) Workshop on Ministry to the HIV+Soldier/AIDS Ministry. Presented four times; FORSCOM/TRADOC Chaplains' Conference, st. Luis, MO, December 1988

(7) HIV/AIDS Update-A Psycho-Social-Spiritual Model of Wellness in the HIV+ Patient. Presented: Chaplain Training Conference, Health Services Command, San Antonio, TX, May 1988.

(8) HIV/AIDS Briefing for Physical Therapists w/a Wellness model of Treatment. Presented: Physical Therapy Students, UCMC, February 1990.

(9) Wellness & Spiritual Aspects of Ministry to HIV+PWA for Medical Professionals. Presented: Patient Care Conference; Nursing Conference on AIDS, FAMC March 1990.

(10) The Challenge to the Church in the Age of AIDS. Presented: Wild Rose UCC, Evergreen, CO April 1990.

(11) Free Indeed: Christians Workshop: AIDS and Addictions Reaching the Addicted. Presented: Second Annual National Freed Indeed Conference, Denver, CO, August 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/106 (3) Status: Completed

(4) Title: Use of Nifedipine Gastrointestinal Therapeutic System in the Treatment of Hypertension

(5) Start Date: Sep 1988 (6) Est Compl Date: 1989

(7) Principal Investigator: J. Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology Svc. (10) Associate Investigators V. Bray

(11) Key Words:
nifedipine
hypertension

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the efficacy of the gastrointestinal therapeutic system utilizing nifedipine in the control of hypertension.

(16) Technical Approach: Study with baseline, titration, and efficacy phases study. Blood studies and baseline and after 12 week efficacy period.

(17) Progress: Twenty-one patients enrolled, 9 completed entire study. Eight patients did not meet required BP measurements during baseline. One patient withdrew for personal reasons. Three withdrawn for protocol violations.

Publications and Presentations: Abstract presented at Am. Heart. Assn. Meeting with all collaborative centers.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88,109 (3) Status: Ongoing

(4) Title: Methotrexate in the Treatment of Steroid Dependent
Asthmatics

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators

(11) Key Words: asthma, steroid dependent
methotrexate David L. Goodman, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effectiveness of weekly methotrexate in reducing the steroid requirements of steroid dependent asthmatics. The purpose is to demonstrate a statically significant reduction in the steroid dose over the placebo control, without involvement of the other parameters.

(16) Technical Approach: Double blind crossover design with methotrexate and placebo following pulmonary function tests, symptom scores with attempt to taper corticosteroids.

(17) Progress: Twelve patients have completed the study, and eight have benefited judged by increase in PFTs and decrease in total steroid use.

Presentations:

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Harold S. Nelson Symposium, FAMC, Feb 89.

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Aspen Allergy Conference, Aspen, CO July 1989.

American College of Allergy & Immunology Annual Scientific Meeting, Orlando, FL, Nov, 89.

Publications: None

(1) Dyer PD, Vaughan TR, Weber RW: Methotrexate in the Treatment of Steroid Requiring Asthma. J All Clin Immunol (in press) 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/110A (3) Status: Ongoing

(4) Title: Biological Investigation of Cutaneous Lupus Employing
Athymic Mice as Skin Heterotransplant Recipients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Scott Bennion, LTC, MC

(9) Dept/Svc: MED/Dermatology Svc. (10) Associate Investigators
Larry Urry, MAJ, MC

(11) Key Words: Don Mercill, DAC
Silvija Coulter, UCHSC
James Fitzpatrick, LTC, C
William Weston, MD, UCHSC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in vivo model demonstrating
cutaneous lupus as manifested in humans and to use such model to sequen-
tially study the biological causes of the diseases.

(16) Technical Approach: See Protocol.

(17) Progress: Recently we did an experiment to determine the ability
of the Hsd:Athymic Nude-nu AF mice which are currently in our mouse
colony to accept human skin grafts. That experiment is not yet
completed but the necessity of finding a better immunocompromised mouse
for human skin grafting is apparent from the current results.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/111 (3) Status: Completed

(4) Title: The Use of Fibrin Monomer and D-Dimer in the Evaluation of Patients with Chest Pain

(5) Start Date: April 1988 (6) Est Compl Date: 1991

(7) Principal Investigator: (8) Facility: FAMC
Mark E. Dorosy, CPT, MC
Robert W. Hull, CPT, MC

(9) Dept/Svc: MED/Internal Med Svc (10) Associate Investigators
Leo W. Jordan, MAJ, MC

(11) Key Words: Steven d. Atchley, MAJ, MCC
fibrin monomer
D-dimer
unstable coronary artery disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 30
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the diagnostic usefulness of fibrin monomer and D-dimer in patients presenting with chest pain requiring evaluation for unstable coronary disease. To determine the prognostic value of these levels in patients with unstable angina and acute myocardial infarction.

(16) Technical Approach: Patients admitted to the CCU for evaluation of chest pain are divided into two groups - those with unstable coronary d3 (MI, unstable angina), and those determined to have noncardiac chest pain based on initial history and physical, EKG, serial CK determinations and additional workup (TMST, cardiac cath, etc.). Blood is drawn at the time of admission for determination of fibrin monomer and D-dimer levels.

(7) Progress: The sensitivity and specificity of the initial D-dimer study were found to be 90% each for detecting unstable coronary disease. An unexpected finding of markedly elevated D-dimer levels were found in the patients with unstable angina. We are looking at plasminogen activator inhibitors levels in these patients in an attempt to explain this observation. Patient enrollment complete, awaiting results of PAJ-1 levels.

CONTINUATION SHEET, ANNUAL PROGRESS REPORT FY 90 Protocol No. 88/111

Publications and Presentations: Information is to be presented in abstract form at the 1988 Army ACP meetings, Cardiology section by Dr. Hull.

1989 Colorado Regional ACP meeting presentation.

October 1989 Army ACP Meeting, San Francisco. Abstract accepted and published. Meeting cancelled due to earthquake.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/112 (3) Status: Completed

(4) Title: Long Term 5-Fluorouracil Infusion for Recurrent Head and Neck Cancer

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hem/Oncol Svc (10) Associate Investigators
Frank Ward, MAJ, MC
Denise Lanier, LTC, MC
Patrick W. Cobb, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The study is designed to assess the effectiveness of a continuous infusion of 5-FU on patients with recurrent head and neck cancer. Tumor response, toxicity and survival will be monitored.

(16) Technical Approach: See Protocol.

(7) Progress: No patients entered at FAMC. Patient accrual completed. FAMC inactive in SWOG when protocol was active.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/113 (3) Status: Ongoing

(4) Title: Methotrexate versus D-penicillamine in Rheumatoid Arthritis: A Randomized Comparative Study

(5) Start Date: 1988 (6) Est Compl Date: 1991

(7) Principal Investigator: James D. Singleton, M.D., M.C. (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology Svc (10) Associate Investigators: Sterling G. West, LTC, MC

(11) Key Words:
methotrexate
D-penicillamine
rheumatoid arthritis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare clinical efficacy, toxicity and radiographic progression of joint disease in patients receiving methotrexate or D-penicillamine.

(16) Technical Approach: Patients with rheumatoid arthritis will be randomly assigned to receive either methotrexate or D-penicillamine. Clinical assessment will be performed every 3 months and radiographic assessment every year.

(7) Progress: A total of 28 pts have now been enrolled in study. Very few patients have dropped out of the study; several have been continued on the protocol on the "other" medication. MTX patients have responded more quickly overall; D-PCM patients are responding but more slowly.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/115 (3) Status: Ongoing

(4) Title: The Impact of an Ambulatory Care Rotation on Interns
Psychosocial Attitudes

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael J. Weaver, COL, MC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.

(16) Technical Approach: Each intern who does a one month ambulatory care rotation in the internal medicine clinic is given a cognitive knowledge test and a psychosocial attitudes questionnaire at the beginning of the rotation, and again at the end of the rotation.

(17) Progress: We have completed testing 8 interns during the training 1989-90. We will continue testing the next 8 interns who are scheduled to have the ambulatory care rotation through June 1991.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/116A (3) Status: Ongoing

(4) Title: Mouse Anti-Chenopod/Amaranth Pollen Monoclonal Antibody Production

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators

(11) Key Words: Lawrence V. Larsen, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop mouse monoclonal antibodies to chenopod-amaranth pollen antigens. The purpose is to use these antibodies to study the crossreactivity of chenopod-amaranth pollen antigens. The importance of the latter is the eventual improvement of allergen extracts for diagnostic and therapeutic utilizations.

(16) Technical Approach: Stage I: Characterization of allergen extracts by PAGE and Western Blot. Stage II: Monoclonal antibody production and characterization by injecting mice with allergen extract, screen for antibody with ELISA, and develop hybridomas.

(17) Progress: Have obtained monoclonal antibody against three antigenic determinants to the weed russian thistle; have shown by Western Blot that two determinants occur in several molecular weight protein species; have shown that limited crossreactivity exists for the monoclonal antibodies between russian thistle and kochia; have polyclonal sera for redroot pigweed, kochia. Protocol on hold until return of Dr. Larsen.

Publications: None

Presentations:

(1) Larsen LV, Copeland T, Vaughan TR: Allergen Extraction Methods: Effect of Temperature and Time: Presented: Harold S. Nelson Symposium, FAMC, February 1990.

(2) Larsen LV, Copeland T, Vaughan TR: Characteristic of Chenopod-Amaranth Extract Enzyme Activity: Presented: Harold S. Nelson Symposium, FAMC, February 1990.

(1) Date: 30 Sep 90 (2) Protocol #: 88/117 (3) Status: Ongoing

(4) Title: A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvants to Opiate Analgesics in the Management of Pain in Cancer Patients

(5) Start Date: 1988 (6) Est Compl Date: 1991

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hemo/Oncol Svc (10) Associate Investigators
Rose A. Gates, MAJ, ANC

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May 90 b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NONE

(15) Study Objective: a. To compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases; b. Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate; c. Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics in the treatment of pain associated with malignant disease.

(16) Technical Approach: See protocol.

(7) Progress: Three subjects at Fitzsimons. One of our patients receiving an antidepressant noted a difference in pain control when the study medication was withdrawn. Problems encountered was obtaining patients who meet the criteria and getting patients who are willing to complete the pain diary.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/118 (3) Status: Completed

(4) Title: CAP Study 12-21-87 - Use of Nifedipine (Gastrointestinal Therapeutic System) in the Treatment of Angina Pectoris

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: Richard C. Davis, Jr., COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Cardiology Svc (10) Associate Investigators
John M. VanDeren, III, CPT, MC

(11) Key Words:
nifedipine GITS
angina pectoris
silent ischemia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 5/90 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective. To establish the efficacy of Nifedipine GITS as monotherapy or combined therapy with beta blockers in angina pectoris. Secondly, to try to clarify some of the issues regarding mechanism of action of a new delivery system, Nifedipine GITS compared to other antianginal therapies.

(16) Technical Approach: Qualified patients will be placed on Nifedipine GITS placebo in a single blind fashion after all other antianginal therapy except beta blockers are discontinued. They will then undergo Holter monitoring. Those with objective evidence of ischemia will be placed on Nifedipine GITS and dose titrated over 7-12 weeks to maximum efficacy with Holter monitoring performed at the completion of the efficacy phase. A single blind placebo control period will then be repeated with Holter monitoring at the completion.

(7) Progress: To date, eight patients have been enrolled in the study, five patients have been dropped after the first placebo control period due to lack of ST changes on Holter monitoring. One patient has been dropped from the study due to significant resting ST segment depression. Two patients have completed the study. These two individuals responded well to the study drug with marked improvement in frequency of angina. They are currently on chronic long term drug therapy and doing well. Holter monitoring did not reveal significant change in the frequency of silent ischemia in those two individuals. No problems encountered. No new patients entered during the last year. In November 1989 Nifedipine GITS was approved by the FAMC formulary committee after FDA approval. The two patients on chronic therapy are now on the commercially available form of the drug.

Publications and Presentations: Abstract accepted for Army ACP Meeting, Cardiology Section, San Francisco, CA October 1989. Abstract title: "The Use of Nifedipine GITS in the Treatment of Angina Pectoris" ACP meeting was cancelled.

(1) Date: 30 Sep 90 (2) Protocol #: 88/120 (3) Status: Ongoing

(4) Title: Ventilatory Effects of Transtracheal Oxygenation

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael Perry, COL, MC
Peter Blue, COL, MC

(9) Dept/Svc: MED/Pulmonary Dis. (10) Associate Investigators:
Douglas Dothager, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 1 _____
d. Total Number of Subjects Enrolled to Date: _____ 10 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the ventilatory effects of transtracheal oxygen therapy.

(16) Technical Approach: A group of 10 COPD patients will have their resp. parameters measured while receiving supplemental oxygen through a nasal cannula and then again while receiving transtracheal oxygen at a flow rate equivalent to that of the nasal cannula. The 2nd part of the study will examine the effects of transtracheal oxygen on radioactive xenon wash.

(17) Progress: Computer program modified as per ammendment. One new patient enrolled since modification.

Publications and Presentations: HMLAC, Oct 88; Army ACP meeting; An. Thoracic Soc. May 89; Abstract: Review of Am. Respiratory, Apr 89.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/121 (3) Status: Ongoing

(4) Title: Bone Densitometry in Thyroid Extract Treated Patients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
William J. Georgitis, LTC, MC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug 89 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 27 controls
d. Total Number of Subjects Enrolled to Date: 47
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether thyroid extract has greater adverse effects on bone density and calcium metabolism than synthetic l-thyroxine. The second is to assess the reversibility of any documented effect.

(16) Technical Approach: The effects of thyroid extract treatment on bone densitometry will be investigated. Subjects taking thyroid extract treatment matched with a thyroxine controlled group will have assessments of thyroid replacement therapy status, mineral metabolism and bone density. Thyroid extract subjects found to be subclinically hyperthyroid may enter a longitudinal assessment of bone density after crossing over to euthyroid thyroxine replacement.

(17) Progress: From eighty-five refill prescriptions for thyroid extract, seventy-one patients were sent letters. Twenty-eight potential subjects were counseled about the study and twenty have been studied.

TRH tests and 24hr urine collections have been completed on the controls who are all awaiting bone densitometry measurements through the Nuclear Medicine Service.

Publications and Presentations:

1. Georgitis WJ, Abrams LF, Dolbow A, Bunker DM: Bone densitometry in patients taking thyroid extract. Presented: American Society for Bone and Mineral Research/International Conference on Calcium-regulating Hormones. 1st Joint Meeting. Abstract 219:S172, Montreal, Quebec, September 1989.
2. Abrams L, Georgitis W, Dolbow A, Bunker D, Kidd G: Is anyone taking thyroid extract consistently euthyroid? The Endocrine Society, 72nd Meeting, Atlanta, GA, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/122 (3) Status: Terminated

(4) Title: LCSG 881 - A Randomized Phase II Study of Preoperative Therapy for Patients with Technically Unresectable Non Small Cell Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the LCSG group protocol.

(16) Technical Approach: See Protocol

(17) Progress: Terminate.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/124 (3) Status: Ongoing

(4) Title: Corticosteroids in the Treatment of Stable Chronic Obstructive Pulmonary Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators: David L. Goodman, LTC, MC

(11) Key Words:
COPD
obstructive lung disease
corticosteroids

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 7 - 4 complete
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine if subjects with severe obstruction lung disease would benefit from extended therapy with corticosteroids.

(16) Technical Approach: Approximately 10 subjects who have COPD that is not responsive to maximal beta-agonist therapy will be enrolled (elevated FEC, <10%) they will then be randomized to receive either 32mg methylprednisolone per day or placebo for 4 weeks followed by a washout period of 4 weeks and finally crossover to receive the alternate drug. Spirometry and body plethysmography will be performed prior to beginning the study and at 2 week intervals throughout the study period.

(18) Progress: Four subjects enrolled; 2 in the final 4-week period. Patient recruitment is somewhat difficult in that most "irreversible" COPD subjects have demonstrated a >10% response to Q2 therapy. Q2 therapy still remains a problem.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/100 (3) Status: Ongoing

(4) Title: The Application of Orem's Self-Care Model in Type II Diabetes: An Outcome Study of Diabetic Self-Care Classes and Self-Care Contracting Comparing Self-Care Knowledge, Health Care Beliefs, Weight Loss and Metabolic Control

(5) Start Date: Aug 88 (6) Est Compl Date: Aug 90

(7) Principal Investigator: Ann Marie Bianchi, MAJ, An (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators: Nancy Pfander, MAJ, AN

(11) Key Words:
noninsulin dependent diabetes
Orem's self-care model
locus of control
contract vs noncontract

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 27
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine whether Type II (NIDDM) clients who attend diabetic self-care classes and also contract for specific self-care activities will significantly gain in self-care knowledge and activities as measure by knowledge questionnaire, Locus of control tool, wt. control, and metabolic control (FBS, HgbA1c, chol, TG), relative to those who do not contract for self-care behaviors.

(16) Technical Approach: Subjects were randomly selected from type II diabetic clients referred for diabetic education. They were given a pretest questionnaire. The locus of control tool was also given to elicit information about subjects' health beliefs. Metabolic data (FBS, HgbA1c, chol, TG) was also obtained. The clients were then randomly assigned to the contract or noncontract group. The above data will be collected again at 3 mo., 6 mo., and at 12 months.

(17) Progress: 20 clients have completed the study. One more will complete it by 31 Aug 90. Then all that remains is the analysis of the data.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/102 (3) Status: Ongoing

(4) Title: Factors Determining Peak Bone Mass and Subsequent Bone Loss

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC
Peter W. Blue, COL, MC
Harry N. Tyler, Jr., DAC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:

(11) Key Words:
bone density
peak bone mass

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine factors associated with the development of peak bone mass and subsequent bone loss.

(16) Technical Approach: Bone density of the radius (single photon absorptiometry) and of the hip and spine (dual photon absorptiometry) will be done in a large group of male and female volunteers, who will also, on another protocol, be having total body fat and lean mass measured by dual photo absorptiometry. Questionnaire concerning present and past calcium intake, exercise and other habits will also be administered.

(17) Progress: No progress this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/103 (3) Status: Ongoing

(4) Title: Transient Hypoxia During Sedated Endoscopic Proc.

(5) Start Date: Dec 88 (6) Est Compl Date: Jun 89

(7) Principal Investigator: Steven P. Lawrence, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent

(10) Associate Investigators:
Stephen Freeman, LTC, MC
Scott Hallgren, MAJ, MC
Jeffrey Dunkelberg, MAJ, MC
John Van Deren, CPT, MC

(11) Key Words:
endoscopy
hypoxia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of transient hypoxia during sedated endoscopy and correlate this with changes in blood pressure, cardiac rhythm, overall clinical status of the patient and type and/or stage of endoscopy.

(16) Technical Approach: Room air arterial oxygen saturation, blood pressure and heart rate will be recorded prior to, during and after intravenous sedation and endoscopy.

(17) Progress: No work has been done on this protocol in the past year. The protocol, however, should remain active as the intent of the principal investigator is still to continue and complete the protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/104 (3) Status: Ongoing

(4) Title: Efficacy of Corticosteroids in the Acute Treatment of
Asthma: Is Duration of Symptoms Important?

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators:
David L. Goodman, LTC, MC

(11) Key Words:
asthma
corticosteroids
emergency management

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the beneficial effect of corticosteroids seen in the treatment of status asthmatics is dependent on the duration of asthmatic symptoms.

(16) Technical Approach: 120 subjects presenting to the E.R. or allergy clinic with acute episode of asthma will be studied. Subjects will receive either 125mg methylpredisolone or placebo within 30 minutes of arriving for tx. They will be divided into 2 sps - these with IRS of <24 hours duration and those with sxs for more than 24°. Spirometry and admission rate will be analyzed.

(17) Progress: Pharmacy and ER staff have been consulted and have agreed to participate in the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/105 (3) Status: Ongoing

(4) Title: Role of Blood Pressure Control in Progression of Diabetic Nephropathy and Other Microangiopathies

(5) Start Date: Dec 88 (6) Est Compl Date: Dec 93

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald Kidd, COL, MC
Joseph White, MAJ, MS

(11) Key Words:
nephropathy
diabetes

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a) Define a level of blood pressure control in a prospective, randomized, non-blinded fashion needed to prevent or delay the progression of diabetic nephropathy and other microvascular complications of diabetes; b) determine if there is a specific advantage to either a CEI or a Ca++ channel blocker as a mode of treatment for hypertension in regard to the onset or progression of diabetic nephropathy.

(16) Technical Approach: See protocol.

(17) Progress: None. Currently awaiting FDA approval of investigational new drug, Nitrendipine. Additional coordination with other participating institutions is required before initiating this study. Awaiting funding from NIH and/or University of Colorado Health Sciences Center.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/106 (3) Status: Ongoing

(4) Title: Immunologic Criteria for the Cessation of Immunotherapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: James S. Brown, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators:
Richard W. Weber, COL, MC
Robert Stewart, MAJ, MS

(11) Key Words:
immunotherapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 5 _____
d. Total Number of Subjects Enrolled to Date: _____ 26 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the presence of a marker for long term efficacy of immunotherapy.

(16) Technical Approach: A. Identifiable change in sub-populations of lymphocytes with immunotherapy; B. Identification of anti-idiotypic antibodies to allergens; C. Demonstration of effect of immunotherapy on late-phase skin tests.

(17) Progress: Delays have occurred with the development of various assays. The three areas of investigation appear to be nearly ready. We have shown an interesting non-specific adhesion of allergen to b-cells. Adhesive problem is being worked on, and we are also awaiting reagents. No new patients enrolled since last APR. The idiotypic assay appears to be working and the significance of its demonstration is under assessment. The significance of adhesion of allergen to lymphocytes is also under consideration. Stimulation of lymphocyte populations to proliferate has been achieved. Whether this is associated with adhesion or not is being studied.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/107 (3) Status: Terminated

Title: A Multicentric Observer-Blind, Randomized Study
of the Safety, Efficacy and Tolerance of Cefpirome
(HR-810) Versus Ceftazidime in the Treatment of
Pneumonia

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Richard E. Winn, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul.Dis. (10) Associate Investigators:
Shannon Harrison, LTC, MC
(11) Key Words: pneumonia William E. Caras, MAJ, MC
Cefpirome Ceftazidime Ray C. Johnson, MAJ, MC
Marin H. Kollef, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: As per title.

(16) Technical Approach: Refer to Hoechst-Roussel Pharmaceuticals,
Inc., investigational drug study protocol 203.

(17) Progress: Cefpirome worked well, no adverse reaction. One
patient died while on drug, but was heart related rather than drug
related.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/108 (3) Status: Ongoing

(4) Title: Efficacy of Pentoxifylline in Treating Diabetic Impotence

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: (8) Facility: FAMC

John A. Merenich, MAJ, MC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:

diabetes
impotence
pentoxifylline

Clyde Roy, MAJ, MC
Nancy Pfander, MAJ, MC
William Georgitis, LTC, MC
Gerald S. Kidd, COL, MC
Ernie Lin, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if pentoxifylline is more effective than placebo in improving sexual function in non-insulin dependent diabetic men.

(16) Technical Approach: A single center, double-blind, placebo controlled study to examine the efficacy of pentoxifylline in improving sexual function in impotent NIDDM men. Diabetic men with impotence who meet the protocol entrance criteria will be randomly assigned placebo or pentoxifylline for 12 weeks. After completion of the treatment course subjects will be reevaluated, and groups will be compared to determine beneficial effects.

(17) Progress: No progress has been made on this study. Necessary equipment is still on order. Equipment reordered.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/109 (3) Status: Ongoing

(4) Title: The Effect of Percutaneous Endoscopic Gastrostomy
Tube Placement on Gastric Emptying

(5) Start Date: Jan 89 (6) Est Compl Date: 1990

(7) Principal Investigator: James E. Cremins, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med. (10) Associate Investigators:
Jeffery Dunkelberg, MAJ, MC
Stephen Freeman, LTC, MC
Scott E. Hallgren, MAJ, MC
Peter Blue, LTC, MC

(11) Key Words:
gastric emptying
gastrostomy tube

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To define the effect of PEG placement on gastric emptying.

(16) Technical Approach: Baseline gastric emptying studies will define subjects' status prior to PEG placement. Repeat gastric emptying studies at definite intervals post procedure will allow detection of any changes in gastric emptying. This will impact possibly on defining a standard approach to feeding these patients.

(17) Progress: To date only two patients have been enrolled who meet the inclusion criteria. However, both subjects expressed significant improvement in life by study participation, and one subject has actually gained weight while on protocol. Insertion of the PEG has allowed the two subjects who completed this protocol adequate means of maintaining nutritional status.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 89/110 (3) Status: Ongoing

(4) Title: Cyclic Oxygen Therapy at Rest and During Exercise

(5) Start Date: Jan 89 (6) Est Compl Date: Jun 89

(7) Principal Investigator: Ray C. Johnson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul. Dis. (10) Associate Investigators:
Michael E. Perry, COL, MC
Peter Blue, COL, MC

(11) Key Words:
cyclic oxygen therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 10 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if cyclic oxygenation can be used as an oxygen conservation measure. To determine physiologic correlates of efficacy.

(16) Technical Approach: A "baseline" continuous flow rate will be determined for each subject. The timing sequence and cycling flow will identify the corrected cycle flow for each subject at rest. The studies will be repeated while the subjects exercise to ascertain exercise baseline flows as a benchmark for comparison, to determine optimum timing sequences independent of resting conditions and to determine the effect of higher cycling flows.

(17) Progress: Preliminary findings indicate some people have good response to this therapy (two out of ten). The other subjects did not experience benefit. No subjects experienced adverse reactions.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/111 (3) Status: Ongoing

(4) Title: Multicenter Clinical Evaluation of Penicillin
Skin Testing Materials

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: James S. Brown, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:

(11) Key Words: penicillin
minor determinants Robert Ledoux, DAC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 70 _____
d. Total Number of Subjects Enrolled to Date: _____ 148 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the optimal test reagent in assessment for anaphylactic grade sensitivity to minor determinants of penicillin.

(16) Technial Approach: Prick and intradermal skin testing.

(17) Progress: 148 patients have been studied to date A number of individuals with a history of penicillin sensitivity have been tested and found to be positive to several of the test reagents. None of the negative controls have had positive tests. Benefits include demonstration of possible drug sensitivity. Need 50-60 persons who are history negative as controls and will be able to complete the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/112 (3) Status: Terminated

(4) Title: The Use of Megestrol Acetate to Treat Cachexia in Patients with Chronic Obstructive Pulmonary Disease and the Possible Improvement of Pulmonary Function

(5) Start Date: Apr 89 (6) Est Compl Date: 1991

(7) Principal Investigator: James I. Meyer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary (10) Associate Investigators: Marin Kollef, CPT, MC
Michael E. Perry, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To see if patients with COPD improve pulmonary function with wt gain 2° to using megestrol.

(16) Technical Approach: Clinial Trial.

(17) Progress: A total of four patients have been enrolled. Data collection is complete. Patients report improved appetite and well being. Study terminated due to insufficient patient referral.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/113 (3) Status: Terminated

(4) Title: LCSG NC 3 Natural History Registry for Patients with
Stage II Non-Small Cell Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hem/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the LCSG group protocol.

(16) Technical Approach: See Protocol.

(17) Progress: Closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/114 (3) Status: Ongoing

(4) Title: Response of Arthritis and Microscopic Colitis to Sulfasalazine in Rheumatoid Arthritis Patients

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Raymond J. Enzenauer, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology (10) Associate Investigators: Sterling G. West, MD
James Singleton, MD
Stephen Freeman, MD
Kenneth Sherman, MD, Ph.D.

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: May 90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 9 patients entered
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the effect of sulfasalazine on both microscopic colitis and arthritis in RA.

(16) Technical Approach: See Protocol.

(17) Progress: Approximately 8 total control colonoscopies with biopsy have been completed per the protocol addendum; one patient was entered onto the sulfasalazine protocol, however she discontinued her medication after less than one month due to gastrointestinal intolerance. Principal Investigator is due to PCS, Dr. West will assign a new PI.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/115 (3) Status: Ongoing

(4) Title: The Effect of Congestive Heart Failure (CHF) on the Erythrocyte Sedimentation Rate (ESR)

(5) Start Date: Aug 89 (6) Est Compl Date: Aug 91

(7) Principal Investigator: Mitcheli Kruger, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Cardiology Svc (10) Associate Investigators: Raymond Enzenauer, MAJ, MC

(11) Key Words:
congestive heart failure
erythrocyte sedimentation rate

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the effect of acute uncomplicated CHF on the ESR and attempt to analyze specific variables affecting the ESR in the setting of CHF.

(16) Technical Approach: Fifty patients evaluated will be admitted for routine elective cardiac catheterization while fifty patients evaluated will be admitted for treatment of congestive heart failure. This study will analyze certain blood chemistries that are not routinely drawn for examination in patients with CHF or for routine cardiac catheterization.

(17) Progress: Control subjects have been entered into the study. Patient's with CHF have been difficult to obtain. Many were excluded because of acute MI, some with CHF could not have appropriate labs drawn.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 89/116 (3) Status: Terminated

(4) Title: Atrial Natriuretic Peptide (ANP) Levels in Patients
With VVI Pacing With and Without Ventriculoatrial (VA)
Conduction Versus Dual Chamber Pacing

(5) Start Date: Aug 89 (6) Est Compl Date: Oct 89

(7) Principal Investigator: John Madonna, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Internal Medicine (10) Associate Investigators:
John Van Deren, MAJ, MC

(11) Key Words:
atrial natriuretic peptide
pacemaker syndrome

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To obtain data which could possibly add
information about the pathophysiology of Pacemaker Syndrome.

(16) Technical Approach: To take patients who have a dual chamber
pacemaker and measure serum ANP levels while they are in dual chamber
pacing mode, and compare these serum ANP levels with levels obtained
while these patients are in the VVI pacing mode. We will also document
VA conduction while in the VVI mode and relate this phenomenon to serum
ANP levels.

(17) Progress: Protocol was administratively terminated.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/117 (3) Status: Ongoing

(4) Title: Evaluation of Thermography in the Delineation of Late Phase Skin Tests

(5) Start Date: Sep 89 (6) Est Compl Date: Mar 90

(7) Principal Investigator: James Brown, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy Svc (10) Associate Investigators:
Edward Green, COL, MC
Richard Sherman, MAJ, MS
Richard Weber, COL, MC

(11) Key Words:
skin tests
thermography

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 7 Aug 90 b. Review Results: approved
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The accurate measurement of the area of involvement in the late phase reaction would enhance this parameter as a tool in studying the immunologic reaction of sensitizing substances.

(16) Technical Approach: Skin test materials will be applied to six allergic and six non-allergic volunteers. The sites will be photographed using the thermographic camera from the time of testing until the maximal immediate reaction has been reached (usually 15-20 minutes), and then photographed hourly for six hours. All studies will be recorded on a VCR. Visual estimations of reaction size will be made by circumscribing the area of involvement with a ballpoint pen and transferring the image to paper using transparent tape.

(17) Progress: Subjects are currently being enrolled in this recently approved study. Six subjects complete, need 2-4 more.

Publications: Brown J, et al: Evaluation of Thermography in Acclimation of Late Phase Skin Tests. J All Clin Immun, 85:209, 1990.

Presentations: Brown J: Evaluation of Thermography in Acclimation of Late Phase Skin Tests: Presented: 46th Annual Meeting of American Academy of Allergy and Immunology, Baltimore, MD, March 1990.

(1) Date: 30 Sep 90 (2) Protocol #: 89/118 (3) Status: Terminated

(4) Title: Bronchoalveolar Lavage in Intubated Patients with the Adult Respiratory Syndrome for the Evaluation of Fat Emulsion Induced Changes in Alveolar Characteristics

(5) Start Date: Aug 89 (6) Est Compl Date: Jun 90

(7) Principal Investigator: Martin Kollef, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MICU (10) Associate Investigators: Vishnu Reddy, LTC, MC James Meyers, CPT, MC

(11) Key Words: intravenous fat emulsion therapy pulmonary abnormalities

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine the ability of bronchoalveolar lavage (BAL) to detect changes in the chemical and histologic properties of the BAL fluid after the administration of intravenous fat emulsion therapy.

(16) Technical Approach: The triglyceride levels in the lavage fluid will be analyzed and compared to one another for ten patients before and after administration of the intralipid. The Oil Red O stains of the lavage fluid will be compared to one another and analyzed for staining within cells and for free floating fat in the fluid itself. Cell counts will be made in the lavage fluid in a standard manner.

(17) Progress: Three patients enrolled without any evidence of fat on BAC samples so the protocol was terminated. My method is not sensitive enough to find fat in BAL fluid at present time.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/119 (3) Status: Ongoing

(4) Title: Development of a Cardiopulmonary Resuscitation (CPR) Information Sheet and Assessment of Patient and Staff Response

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Rose Gates, MAJ, An (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators: Michael Weaver, COL, MC Robert Gates, MAJ, MC

(11) Key Words: cardiopulmonary resuscitation do-not-resuscitate order

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 219
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a) To assess the acceptability of an information sheet on CPT to both patients and professional staff; b) To determine the attitude of patients and professional staff regarding discussion of CPR and CPR options.

(16) Technical Approach: A CPR information sheet and questionnaire will be distributed as per objective. Discussions will be held at the time of collection of the questionnaires.

(17) Progress: Twenty-seven patient surveys have been completed; would like to collect approximately 25 more. Benefits subjects experience - information about CPR options. Plan to amend this protocol for survey of patients with revised information sheet and more detailed patient questionnaire.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/120A (3) Status: Completed

(4) Title: Mediastinal Tamponade Due to Closed Thoracostomy
in a Goat

(5) Start Date: Sep 1989 (6) Est Compl Date: Jan 90

(7) Principal Investigator: Marin H. Kolley, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Dis. Svc. (10) Associate Investigators:

(11) Key Words: Douglas Dothager, CPT, MC
tamponade
thoracostomy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To document objectively in an animal model whether a closed thoracostomy tube can cause impairment in cardiac output and thus hypotension by tamponading the inferior vena cava or right ventricle.

(16) Technical Approach: The design of the study is a prospective animal model which will evaluate the above stated hypothesis.

(17) Progress: Completed.

Publications and Presentations: Publication pending approval in Chest.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/100 (3) Status: Ongoing

(4) Title: Platelet Thromboxane and Aggregation and Whole Blood Prostacyclin Synthesis in Human Thyroid Disease

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Lynn F. Abrams, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators:
Gerald S. Kidd, COL, MC
John A. Merenich, MAJ, MC
Michael T. McDermott, LTC, MC
Chris White, MAJ, MS

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the roles of thromboxane and prostacyclin in mediating the phenomenon associated with thyroid dysfunction.

(16) Technical Approach: See protocol.

(17) Progress: Fifteen patients as of this date, no data yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/101 (3) Status: Completed

(4) Title: Study of the Efficacy of Influenza Vaccine in Chronic Lung Disease - Serologic Response and Disease Prevention

(5) Start Date: 1989 (6) Est Compl Date: 1990

(7) Principal Investigator: Richard Winn, LTC, USAF, MC (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators: Gordon Meiklejohn, MD
SSG Kenneth Williams

(11) Key Words: influenza
vaccine
serologic response

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To address influenza, vaccine serologic response and protective efficacy among patients with chronic structural lung disease in a prospective fashion.

(16) Technical Approach: Serum will be drawn from each patient prior to vaccine administration, 4-6 weeks following vaccination and at the conclusion of influenza season.

(17) Progress: Serologic and viral isolation studies are being performed by Dr. Meiklejohn at CU Medical Center.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 90/102 (3) Status: Ongoing

(4) Title: Effect of Prolonged Administration of Iodine Containing Water Purification Tablets in Man

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators: William J. Georgitis, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prolonged iodine administration (3 mos) causes persistent hypothyroidism or if compensation occurs and if goiters occur.

(16) Technical Approach: Iodine containing water purification tablets (4 tabs/day, 8mg iodine/tab) will be given to 15 subjects for 3 months. Baseline studies will include thyroid hormone and TSH levels, a TRH test, a radioactive iodine uptake and thyroid ultrasound thereafter, thyroid hormone levels, tSH and TRH test will be repeated at 7, 28 and 90 days. The radioactive iodine uptake will be separated at 7 and 90 days and the thyroid ultrasound will be repeated at 90 days.

(17) Progress: None thus far. We have been unable, so far, to standardize the thyroid ultrasound measurement.

Publications and Presentations: none

(1) Date: 30 Sep 90 (2) Protocol #: 90/103 (3) Status: Ongoing

(4) Title: The Limulus Amoebocyte Lysate Assay for the Diagnosis of Spontaneous Bacterial Peritonitis in Ascitic Fluid

(5) Start Date: 1990 (6) Est Compl Date: June 1991

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastro. (10) Associate Investigators: Stephen Freeman, LTC, MC

(11) Key Words:
limulus
SBP

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine efficacy of the limulus amoebocyte lysate assay in the early diagnosis of Gram negative spontaneous bacterial peritonitis.

(16) Technical Approach: The limulus assay is run on peritoneal fluid obtained from patients with ascites, and then compared to standard cell count/culture definitions of SBP.

(17) Progress: No cases of gram negative SBP have been seen since the onset of this study at this hospital. The cases examined to date were all negative by the limulus assay, as would be expected. However, several cases resulted in a negative inhibition control, indicating reaction inhibition does occur.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/104 (3) Status: Completed

(4) Title: Group C/Treatment Protocol: Levamisole (NSC 177023)
Plus 5-Fluorouracil as an Adjuvant to Surgery for
Resectable Adenocarcinoma of the Colon
(N C I P r o t o c o l 8 9 - 0 0 1 7)

(5) Start Date: 1990 (6) Est Compl Date: 1990

(7) Principal Investigator: Patrick Judson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Hem/Onc Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To make Levamisole available to treat patients
until FDA approval is obtained.

(16) Technical Approach: Per NCI protocol.

(17) Progress: Approximately 5 patients were treated. Drug recently
approved by the FDA. Protocol no longer needed.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/105 (3) Status: Ongoing

(4) Title: Incidence and Prevalence of Hematuria in Patients on Long-Term Anticoagulation

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James A. Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology Svc (10) Associate Investigators: Talley F. Culclasure, CPT

(11) Key Words:
hematuria
anticoagulation

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 180 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess incidence and prevalence of hematuria in anticoagulated population.

(16) Technical Approach: UA performed monthly on patients in coumadin clinic.

(17) Progress: Approximately 1200 pt/months followup.

Publications and Presentations: Abstract submitted to Army Regional ACP meeting.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/106 (3) Status: Completed

(4) Title: Self-Treatment of Anaphylaxis in an Outpatient Population

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Paul R. Sklarew, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy Svc (10) Associate Investigators: David L. Goodman, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 65
d. Total Number of Subjects Enrolled to Date: 65
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To study the factors which influence a physician's decision to prescribe epinephrine and a patient's decision to self inject the epinephrine.

(16) Technical Approach: I have received completed questionnaires from 65 patients who received epinephrine kits at FAMC.

(17) Progress: The study has been completed and is being prepared for presentation.

Publications and Presentations: Presentation at the 1990 American College of Allergy & Immunology Meeting; abstract publication in the Annals of Allergy, 1991, and the publication sometime in 1991 or 1992.

(1) Date: 30 Sep 90 (2) Protocol #: 90/107 (3) Status: Ongoing

(4) Title: A Double-Blind, Placebo-Controlled Randomized Trial of the Clinical and Hemodynamic Effects of Vasopressin in Patients with Cirrhosis and Acute Variceal Hemorrhage -- A Multi-center Study

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael Fisher, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Gastro. (10) Associate Investigators: Stephen Freeman, LTC, MC

(11) Key Words:
vasopressin
variceal hemorrhage

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Clinical: to evaluate the effect of vasopressin on the volume of variceal bleeding, early rebleeding, and death from bleeding compared to placebo. Hemodynamic: (1) to determine the relationship between the infusion rate of vasopressin, hepatic extraction of vasopressin, peripheral plasma concentration of vasopressin, and its clinical efficacy; (2) to determine whether hemodynamic tachyphylaxis occurs during prolonged infusion of vasopressin; (3) to determine whether abrupt discontinuation of vasopressin causes a rebound increase in portal pressure.

(16) Technical Approach: Multicenter, double-blind, placebo-controlled, randomized trial using a medical intensive care unit patient population.

(17) Progress: Patient accrual continues. Data analysis will be performed when the code is broken.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/108 (3) Status: Ongoing

(4) Title: Comparison of Impedance Plethymography, Venogram and Doppler Ultrasound in Diagnosing Deep Venous Thrombosis

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: David Kristo, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Int. Med. (10) Associate Investigators: Marin Kollef, MAJ, MC James Luethke, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare IPG and doppler vs and with venogram at this facility.

(16) Technical Approach: A blinded comparison fo the three studies.

(17) Progress: 15 patients enrolled to date.

Publications: Abstract sent to American Thoracic Society October 1990.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/109 (3) Status: Ongoing

(4) Title: Altitude Effects on Oxygen Kinetics During Exercise
in Acclimatized Fit Troops

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael E. Perry, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Svc (10) Associate Investigators:
James Meyers, CPT, MC

(11) Key Words:
altitude
exercise
oxygen kinetics

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 29
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate effects of altitude on exercise performance and oxygen kinetics in altitude-acclimatized troops.

(16) Technical Approach: Troops stationed at altitude for a least 1 year will undergo formal exercise testing both at altitude and at sea level.

(17) Progress: 29 subjects have completed studies at 5800 ft elevation (Ft. Carson) and -300 ft elevation (Death Valley, CA). Data indicates profound effects on ventilation parameters and also on oxygen kinetics. Data is still being analyzed for anaerobic threshold determinations as well as additional parameters of oxygen kinetics.

Publications and Presentations: Submitted, pending acceptance.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/110 (3) Status: Ongoing

(4) Title: Effects of Altered Calcium on Blood Pressure

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: James A. Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology Svc (10) Associate Investigators: Philip S. Travis, MAJ, MC

(11) Key Words:
renal failure
dialysis
hypercalcienia
hypertension

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Establish the effect of high calcium dialysate with calcium supplementation vs low calcium dialysate without calcium supplementation on blood pressure.

(16) Technical Approach: Randomized prospective crossover study utilizing a low or high calcium dialysate bath in the correction of hypertension in patients with renal failure.

(17) Progress: Patient enrollment continues. Insufficient data for analysis at this time.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/111A (3) Status: Ongoing

(4) Title: Prevention of Pseudomonas Colonization by Saccharomyces
boulardii or Lactobacillus Acidophilus in Antibiotic
Treated Mice

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Mark J. Jarek, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Svc (10) Associate Investigators:
Marin Kollef, MAJ, MC
(11) Key Words: Raymond Johnson, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To prove a benefit of prophylactic
administration of either Saccharomyces boulardii or Lactobacillus
acidophilus in the prevention of enteric Pseudomonas colonization in
mice treated with antibiotics.

(16) Technical Approach: See protocol.

(17) Progress: This study has never been started due to difficulties
in obtaining support for maintenance of the study animals. No plans to
continue it in the near future exist.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/112 (3) Status: Ongoing

(4) Title: Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM)

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: John A. Merenich, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: Michael T. McDermott, LTC, MC
(11) Key Words: Donna Bunker, DAC
Peter J. McNally, MAJ, MC
Vishnu V. Reddy, LTC, MC
Darci D. Ashley, DAC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 320
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a systemic means for all NIDDM patients at FAMC to be screened and to make physicians aware of the need for this intervention.

(16) Technical Approach: See protocol.

(17) Progress: 320 patients screened to date, no complications. POC is Dr. McNally and Dr. McDermott.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 90/113 (3) Status: Ongoing

(4) Title: Effect of Cold Remedies on Metabolic Control of Noninsulin Dependent Diabetes Mellitus

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Homer Lemar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: W.J. Georgitis, LTC, MC
Darci U. Ashley

(11) Key Words:
diabetes mellitus
sucrose
alcohol
antitussive

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine if sugar and alcohol free cough formulas have clinically significantly fewer adverse metabolic effects inpatients with diabetes mellitus compared to standard (sugar and alcohol containing) cough formulas.

(16) Technical Approach: Prospective crossover study in which all subjects will take both preparations in series and effects on blood sugar and lipids will be compared. Two groups of patients will be studied (well controlled and poorly controlled) in this manner.

(17) Progress: A small number of subjects have been enrolled but have not begun the actual study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/114 (3) Status: Ongoing

(4) Title: Assessment of Patient Utilities for Health Outcomes:
Influence on Aspirin Prophylaxis to Prevent Myocardial
Infarction

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Cathy Ow, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gen. Int. Med. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 52 _____
d. Total Number of Subjects Enrolled to Date: _____ 52 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine what patients' utilities are for
various health outcome states: (1) MI; (2) mild CVA; (3) moderate -
severe CVA. Determine whether patient utilities influence decision to
take ASA to prevent MI.

(16) Technical Approach: Decision analysis tree constructed using
probabilities from published trials of ASA as prophylaxis against MI.
Determine patient utilities by standard reference gamble interview.

(17) Progress: 52 subjects interviewed.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/115 (3) Status: Ongoing

(4) Title: Relationship of Blood Flow in Hemodialysis Access to
Recirculation with Variable Blood Pump Flow

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology (10) Associate Investigators:
CPT Bergstrom

(11) Key Words:
recirculation
access
dialysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: Relationship between blood pump flow rate and
recirculation.

(16) Technical Approach: Measure recirculation at variable blood pump
speeds.

(17) Progress: Twelve patients enrolled, no data yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/116 (3) Status: Ongoing

(4) Title: Smoking Cessation Enhancement by Estimated Lung Age and Measured Expiratory Carbon Monoxide Levels

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Vance Bray, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Int. Med. (10) Associate Investigators: Michael Weaver, COL, MC Ernest Degenhardt, CPT, AN

(11) Key Words: smoking cessation lung age

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun__ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluate the effect of patient education based upon calculated lung age and measured carbon monoxide exhalation on smoking cessation.

(16) Technical Approach: Initial spirometry, carbon monoxide measurement and questionnaires will be repeated at 6, 12 and 18 months in groups participating in the current smoking cessation classes and groups of smokers not participating the classes to evaluate the long-term success rate of patient education.

(17) Progress: Subjects are currently being enrolled, but no data is available for analysis at this time.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/117 (3) Status: Ongoing

(4) Title: The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
John Merenich, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine

(10) Associate Investigators:

(11) Key Words:

Homer J. Lemar, MAJ, MC
Gerald S. Kidd, COL, MC
Michael McDermott, COL, MC
William Georgitis, COL, MC
Mark Larson, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if suppressive doses of levothyroxine (documented by an 'ultrasensitive' TSH assay) reduces the size (by ultrasound) of newly discovered, biopsy "non-malignant" thyroid nodules; if response to suppression therapy differs between patients with truly uninodular lesions VS those in whom ultrasound examination uncovers the presence of multiple nodules; if any FNA cytologic changes occur after a course of suppression therapy and the utility of serum thyroglobulin as a biochemical marker of changes in nodular size or cytology.

(16) Technical Approach: See protocol.

(17) Progress: No data yet, placebo to arrive by 1 September 90 and then the project can be started.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/118 (3) Status: Ongoing

(4) Title: Effect of Gymnema Sylvestre on Blood Glucose and Serum Insulin Levels

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Lynn Abrams, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____5_____
d. Total Number of Subjects Enrolled to Date:_____5_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate the acute effects of gurmar on blood glucose and insulin levels acutely and during a 7-day treatment period.

(16) Technical Approach: A baseline 5-hour oral glucose tolerance test with measurement of glucose, insulin and c-peptide will be performed. Three days later the acute effect of the ingestion of 2 tablets of gurmar on glucose, insulin and c-peptide will be studied over 5 hours. Following this a 7-day period of daily ingestion of gurmar will be followed by a repeat 5-hour oral glucose tolerance test.

(17) Progress: Although formal statistical evaluation of the results for the first 5 subjects has not been performed, none experience symptomatic hypoglycemia or blood sugars below 50 mg/dl. Dr. William Georgitis prepared this report for FY 90.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 90/119 (3) Status: Ongoing

(4) Title: Epidemiological and Retrospective Analysis of Patients Consuming L-Tryptophan Containing Products

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Harry Spaulding, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:

(11) Key Words:
L-tryptophan
eosinophilia-myalgia syndrome

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To understand the side effects of L-tryptophan ingestion and its association with eosinophilia-myalgia syndrome.

(16) Technical Approach: A review of records, a questionnaire, and selected laboratory studies will be performed. Positive results will be relayed to the subject and a generic information letter will be sent to each subject explaining the results of the overall study.

(17) Progress: No progress to date.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/120 (3) Status: Ongoing

(4) Title: Dose Hepatitis-B Vaccine Promote Eosinophilia, Increase Serum IgE Levels or Sensitize Recipients?

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Harry Spaulding, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators: David Goodman, LTC, MC

(11) Key Words:
hepatitis-B vaccine
eosinophilia
IgE

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the standard hepatitis vaccine, in this case, Hepatvax-B, lot 074R, promotes any sensitivity, eosinophilia, or changes in total IgE to human recipients.

(16) Technical Approach: Only patients who are receiving this first series of vaccinations and, therefore, antibody negative will be entered into the study. Prick skin testing will be performed to hepatitis vaccine, 1:10 and full strength. After 15 minutes histamine control will be added. If prick testing is negative, they will be tested intradermally to 1:100 dilution of the vaccine. Blood will be drawn for baseline determinations. Subjects will be re-evaluated after their first booster and then 6 months after the third booster was administered.

(17) Progress: Subjects are currently being enrolled. No data is yet available.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/121 (3) Status: Ongoing

(4) Title: Temporal Course of Altitude Acclimatization

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Michael Perry, COL, MC (8) Facility: Fort Sill, OK
Fort Carson, CO

(9) Dept/Svc: MED/Pul. Dis. Svc. (10) Associate Investigators: Willian Annan, COL, IN
Harry Dolton, Jr., LTC, FA
Gerald Kidd, COL, MC
John O'Connor, LTC, IN

(11) Key Words: altitude effects
acclimatization

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun__ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the time requirement for completion of altitude-acclimatization

(16) Technical Approach: Subjects' anaerobic threshold will be determined using a 2-mile run and a two-part bicycle ergometer test at Ft. Sill. Arterial blood sample will be obtained. Using the same troops, the identical protocol will be carried out at Ft. Carson at 72 hrs, 1 mo, 6 mo, 9 mo 12 mo, and 18 mo after arrival for duty with the 4th ID.

(17) Progress: Approximately 20 subjects at Ft. Sill have undergone testing according to protocol guidelines. The same subjects are now undergoing testing at Ft. Carson.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/122 (3) Status: Ongoing

(4) Title: Evaluation of Viral Hepatitis in Patients Infected with the Human Immunodeficiency Virus (HIV)

(5) Start Date: 1990 (6) Est Compl Date: 1990

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastro. (10) Associate Investigators: Stephen Freeman, MAJ, MC
Shannon Harrison, LTC, MC
Leo Andron, LTC, MS

(11) Key Words: HIV
hepatitis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the prevalence of serologic markers of viral hepatitis including hepatitis B, hepatitis C, and hepatitis D in a military population and to determine the effect of AZT therapy on the markers of HB infection.

(16) Technical Approach: Bank sera of 220 HIV subjects will be used. Sera banked prior to AZT therapy will be studied using qualitative hepatitis B DNA probe assay. Data will be correlated to helper: suppressor status and serum markers of hepatic injury. Hepatitis C assay by ELISA will be performed on serial serum samples and at 6 month to 1 yr intervals to determine the incidence of hepatitis C in this population. Hepatitis D antibody testing will be performed in all HBsAg positive samples as well as any that may be HBV DNA positive but antigen negative on testing.

(17) Progress: Laboratory assays are being performed.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/123 (3) Status: Ongoing

(4) Title: Urinary Indices in Acute Renal Failure

(5) Start Date: 1990 (6) Est Compl Date: 1993

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent. (10) Associate Investigators:

(11) Key Words:
renal failure
serum creatinine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the use of several tests in diagnosing acute renal failure.

(16) Technical Approach: Prospective survey of serum creatinine in hospitalized patients for acute renal failure. Review of urinary diagnostic indices to include U/P creatinine, osmolality, FENA and FECL, FELI, NMR spectroscopy and transmission electron microscopy of urine as well as chart review.

(17) Progress: Patient enrollment is ongoing.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/124 (3) Status: Ongoing

(4) Title: The Effectiveness of Octreotide (Sandostatin*) to Prevent Pancreatitis Caused by Endoscopic Pancreato-Biliary Procedures: A Double-Blind, Randomized Study

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Michael Fisher, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent. (10) Associate Investigators: Stephen Freeman, COL, MC
Scott Hallgren, MAJ, MC
Peter McNally, MAJ, MC

(11) Key Words: pancreatitis
octreotide

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if administration of octreotide will decrease the risk of pancreatitis associated with endoscopic pancreato-biliary procedures and facilitate ampullary cannulation by decreasing S.O. and small bowel motility.

(16) Technical Approach: Patients undergoing endoscopic pancreato-biliary procedures will be randomized to either a treatment or placebo group, given 5-6 hrs pre- and then immediately post procedure. After each procedure the investigators will perform an abdominal exam and interview directed toward the presence or absence of pain. Cholangiopancreatography will be done by standard method.

(17) Progress: Patients are currently being enrolled in the study.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/125 (3) Status: Ongoing

(4) Title: SWOG 8697 Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P)TH or CMFH---Intergroup

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine most effective cancer treatment method.

(17) Progress: Open to patient accrual. No patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/126 (3) Status: Ongoing

(4) Title: SWOG 8710 Trial of Cystectomy Alone Versus Neoadjuvant
M-VAC + Cystectomy in Patients with Locally Advanced
Bladder Cancer, Phase III

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine most effective treatment method.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/127 (3) Status: Ongoing

(4) Title: SWOG 8737 A Phase III Study, AZQ 24 Hour Infusion Versus BCNU for Adult High Grade Gliomas (Intergroup 0093)

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine most effective treatment method.

(17) Progress: One patient enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/128 (3) Status: Ongoing

(4) Title: SWOG 8750 Pilot Study to Examine Cytogenic Abnormalities
in Patients with Acute Leukemia, Ancillary

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine most effective treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/129 (3) Status: Ongoing

(4) Title: SWOG 8814 A Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine most effective treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/130 (3) Status: Ongoing

(4) Title: SWOG 8899 A Prospective, Randomized Trial of Low-Dose Leucovorin + 5-FU, High-Dose Leucovorin + 5-FU, Levamisole +5-FU, or Low-Dose Leucovorin +5-FU + Levamisole Following Curative Resection in Selected Patients with Dukes' B or C Colon Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 90/131 (3) Status: Ongoing

(4) Title: VA Cooperative Study No. 316: Efficacy of Passive Immunization in the Prevention of Infection Due to Klebsiella Penumoniae and Pseudomonas Aeruginosa

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: William Byrne, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf.Dis.Svc (10) Associate Investigators: Marin Kollef, MAJ, MC
Phillip Mallory, MAJ, MC
Thomas Cosgriff, COL, MC
Robert Gates, LTC, MC
Shannon Harrison, LTC, MC

(11) Key Words: IVIG
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prophylactic administration of hyperimmune IVIG will prevent the acquisition of infection with those Klebsiella and P. aeruginosa serotypes included in the vaccine and that it will delay the onset and/or decrease the severity of infection in those patients who do become infected with these strains.

(16) Technical Approach: See protocol.

(17) Progress: OTSG approval pending.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/132 (3) Status: Ongoing

(4) Title: Prevention and Treatment of Steroid Induced Osteoporosis

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:
John Merenich, MAJ, MC
William Georgitis, LTC, MC
James Singleton, MAJ, MC
Sterling West, LTC, MC
James Brown, COL, MC

(11) Key Words:
osteoporosis
steroids

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Prevention and treatment of steroid induced osteoporosis.

(16) Technical Approach: Randomized controlled prospective single blind evaluation of the efficacy of a coherence therapy regimen in the prevention and treatment of steroid induced osteoporosis.

(17) Progress: Patients are currently being enrolled.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/133 (3) Status: Ongoing

(4) Title: The Effect of Terfenadine on Urination

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Paul Sklarew, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:

(11) Key Words: antihistamine urodynamics
Harry Spaulding, COL, MC
Brant Thrasher, CPT, MC
Craig Donatucci, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul ___ b. Review Results: ___
c. Number of Subjects Enrolled During Reporting Period: ___
d. Total Number of Subjects Enrolled to Date: ___
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if terfenadine alters the urinary pattern in normal, healthy men or in men with prostatic hypertrophy.

(16) Technical Approach: Randomized crossover study with at least a one-week washout. Subjects will be skin tested prior to the initiation of the drug, after 72 hours, and after one week of treatment. Following skin testing, the urinary flow rate will be measured with a Lifetech flowmeter. Total urine volume voided, micturation time, peak or maximum flow rate and corrected maximum flow rate will be measured.

(17) Progress: Phase I study in normal subjects completed. Seldane did not have any appreciable effects on urinary function.

Publications and Presentations: Abstracted submitted.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/134 (3) Status: Ongoing

(4) Title: Fibrinolytic and Thrombotic Activity in Unstable Coronary Disease

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Mark Dorogy, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Cardiology (10) Associate Investigators: Christopher Kozlowski, CPT, MC
Thomas Cosgriff, COL, MC
Bohdan Kudryk, PhD

(11) Key Words: fibrinopeptide analysis
coronary disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the relative contributions of thrombosis and fibrinolysis in the development of acute myocardial infarction and unstable angina.

(16) Technical Approach: Specific markers of thrombosis and fibrinolysis will be studied. These markers are fibrinopeptide A, and two other fibrinopeptides known as B-beta-1-42 and B-beta-15-42.

(17) Progress: Blood specimens are being accrued.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/135 (3) Status: Ongoing

(4) Title: Comparison of Liver Biopsy Versus Noninvasive Testing Using Hepatic Ultrasound, Radionuclide Scanning, Erythrocyte Folate Levels and Methotrexate Levels for the Determination of Methotrexate-Induced Hepatotoxicity

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Michael Fisher, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastro (10) Associate Investigators: Jeffrey Dunkelberg, MAJ, MC Stephen Freeman, COL, MC

(11) Key Words: methotrexate hepatotoxicity

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To correlate the findings at the time of liver biopsy with blood tests as well as images of the liver obtained by ultrasound and nuclear imaging of the effect of methotrexate on the liver.

(16) Technical Approach: See protocol.

(17) Progress: Subjects are being enrolled in the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/136 (3) Status: Ongoing

(4) Title: SWOG 8921 A Phase II Trial of Cyclophosphamide/IL-2,
DTIC/IL-2 and DTIC/Cisplatin/Tamoxifen in Stage IV
Melanoma

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul ___ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/137 (3) Status: Ongoing

(4) Title: SWOG 8312 Megestrol Acetate and Aminoglutethimide/
Hydrocortisone in Sequence or in Combination as
Second-Line Endocrine Therapy of Estrogen Receptor
Positive Metastatic Breast Cancer, Phase III

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/138 (3) Status: Ongoing

(4) Title: SWOG 8520 Cis-Diamminedichloroplatinum (II), Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/139 (3) Status: Ongoing

(4) Title: SWOG 8621 Chemo-Hormonal Therapy of Postmenopausal
Receptor-Positive Breast Cancer, Phase III

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/140 (3) Status: Ongoing

(4) Title: SWOG 8692 Therapy in Premenopausal Women with Advanced ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs the LH-RH Analog, Zoladex. Phase III Intergroup

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/141 (3) Status: Ongoing

(4) Title: SWOG 8711 A Study of Reproductive Function in Patients with Testicular Cancer

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/142 (3) Status: Ongoing

(4) Title: SWOG 8736 Treatment of Localized Non-Hodgkin's Lymphoma:
Comparison of Chemotherapy (CHOP) to Chemotherapy Plus
Radiation Therapy

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/143 (3) Status: Ongoing

(4) Title: SWOG 8793 Randomized Phase III Evaluation of Hormonal Therapy Vs Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: ___ Jul ___ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/144 (3) Status: Ongoing

(4) Title: SWOG 8794 Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/145 (3) Status: Ongoing

(4) Title: SWOG 8806 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Advanced Bladder Cancer

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/146 (3) Status: Ongoing

(4) Title: SWOG 8809 A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/147 (3) Status: Ongoing

(4) Title: SWOG 8819 Central Lymphoma Repository Tissue Procurement Protocol

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/148 (3) Status: Ongoing

(4) Title: SWOG 8836 A Study of Chest Irradiation Plus Concurrent Daily Low-Dose Cisplatin Followed by High Dose Consolidation for Locally Advanced Non-Small Cell Lung Cancer

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/149 (3) Status: Ongoing

(4) Title: SWOG 8896 Intergroup Phase III Protocol for Surgical Adjuvant Therapy of Rectal Carcinoma: A Controlled Evaluation of (A), Protracted Infusion of 5-Fluorouracil as a Radiation Enhancer and (B), 5-Fluorouracil Plus Methyl-CCNU Chemotherapy

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/150 (3) Status: Ongoing

(4) Title: SWOG 8905 Phase II/III Study of Fluorouracil (5-FU) and Its Modulation in Advanced Colorectal Cancer

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/151 (3) Status: Ongoing

(4) Title: Extrinsic Positive End-Expiratory Pressure (PEEP) Effects on Functional Residual Capacity in Normal Subjects and in Ventilated Patients Experiencing Air Trapping (AUTO-PEEP)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Douglas Dothager, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul.Dis.Svc. (10) Associate Investigators: Marin Kollef, MAJ, MC
Phillip Mallory, MAJ, MC
Robert Browning, BS, DAC

(11) Key Words: lung volume
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine lung volume changes when air-pressure is added through a ventilator in patients with lung disease on ventilators.

(16) Technical Approach: Ventilated subjects will be placed in an "iron lung" which will be used to measure lung volumes and changes in lung volumes. Computer hookup to subject will allow measurement of lung volume changes. Air pressure will be added to the ventilator a little at a time and any change in lung volumes will be measured. Blood pressure and heart rate will also be monitored.

(17) Progress: Patient enrollment continues, and data is being accrued.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/152 (3) Status: Ongoing

(4) Title: Residual Renal Function in Dialysis Patients

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology (10) Associate Investigators:
Barbara Hasbargen, RN,BSN
Peter Blue, COL, MC

(11) Key Words:
dialysis
renal function

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug ___ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principal objective of the study is to elucidate the relationship between modality of dialysis and residual renal function.

(16) Technical Approach: Fifteen patients who are on hemodialysis and 15 patients who are on CAPD and approximately 6 patients that will change from one modality to the other will be studied using blood samples and renal scans.

(17) Progress: Patients are currently being enrolled on this study which was approved in Aug '90.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/153 (3) Status: Ongoing

(4) Title: Relationship of Calcium and Glucose Metabolism on Blood Pressure

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology (10) Associate Investigators: Joseph White, MAJ, MC

(11) Key Words:
hypertension
calcium
glucose

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To allow for a more rational approach to antihypertensive therapy.

(16) Technical Approach: Evaluate the subgroups of essential hypertensives with respect to calcium/PTH axis, vs glucose/insulin axis, vs Na/renin axis. Specifically to evaluate the relationships of Ca/PTH and the potential role of diminished insulin release and hyperglycemia in essential hypertensives.

(17) Progress: Patients are currently being enrolled in this study which was approved in Aug '90.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/154 (3) Status: Ongoing

(4) Title: SWOG 8326 Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/155 (3) Status: Ongoing

(4) Title: SWOG 8810 Six Courses of 5-Fluorouracil and Cis-Platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck, Phase II Pilot Study

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/156 (3) Status: Ongoing

(4) Title: SWOG 8812 Treatment of Limited Small Cell Lung Cancer with
Concurrent Chemotherapy, Radiotherapy, with or without
GM-CSF and Subsequent Randomization to Maintenance
Interferon or No Maintenance

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
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e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/157 (3) Status: Ongoing

(4) Title: SWOG 8828 A Phase II Trial of Carboplatin (CBDCA) in Relapsed or Refractory Acute Myeloid Leukemia

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/158 (3) Status: Ongoing

(4) Title: SWOG 8851 A Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Co=t:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/159 (3) Status: Ongoing

(4) Title: SWOG 8892 A Study of Radiotherapy with or without
Concurrent Cisplatin in Patients with Nasopharyngeal
Cancer, Phase III

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/160 (3) Status: Ongoing

(4) Title: SWOG 8897 Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients and a Natural History Follow-up Study in Low-Risk, Node Negative Patients

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/161 (3) Status: Ongoing

(4) Title: SWOG 8910 Evaluation of Low Dose Continuous 5-Fluorouracil (5-FU) and Weekly Cisplatinum (CDDP) in Advanced Adenocarcinoma of the Stomach, Phase II Pilot

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/162 (3) Status: Ongoing

(4) Title: SWOG 8915 A Phase II Study of 6-Thioguanine Administered as 120 Hour Continuous Infusion for Refractory or Recurrent Small Cell Carcinoma

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/163 (3) Status: Ongoing

(4) Title: SWOG 8916 Evaluation of Merbarone in Pancreatic Adenocarcinoma, Phase II

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/164 (3) Status: Ongoing

(4) Title: SWOG 8952 Treatment of Advanced Hodgkin's Disease - A
Randomized Phase III Study Comparing ABVD vs MOPP/ABV
Hybrid

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/165 (3) Status: Ongoing

(4) Title: SWOG 8997 A Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/166A (3) Status: Ongoing

(4) Title: Evaluation of Allergenic Cross-Reactivity Amongst
Cockroach Species

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: David Goodman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators:
T. Ray Vaughan, MAJ, MC
Anthony Henry, LTC, MC
Jeffrey Glassheim, MAJ, MC
Robert Ledoux, BS, DAC

(11) Key Words:
cross-reactivity
antigenicity
allergenicity

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep ___ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of clinical hypersensitivity to cockroach, common insects, and mites in an atopic disease population; to determine if there is significant cross reactivity among the five common cockroach pests in North America; to determine cross-reactivity among cockroach, other common indoor insect pests and mite antigens.

(16) Technical Approach: Animal models will be used to develop antisera specific for cockroach and other insect species under investigation in this protocol. Prior to skin testing blood will be drawn for immunochemical analysis. Subjects will then be skin tested.

(17) Progress: Newly approved study. No progress.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/167A (3) Status: Ongoing

(4) Title: Animal Model of Physiologic PEEP (Positive End-Expiratory Pressure)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Marin Kollef, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pul.Dis.Svc. (10) Associate Investigators:
Michael McCormack, CPT, MC
(11) Key Words: Positive end-expiratory pressure Michael Perry, COL, MC
Kevin Bright, CPT, MC
Michael Lepore, COL, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine that physiologic PEEP does exist and that its removal will cause a decrease in lung volume, worsening gass exchange, and decrease in end-expiratory pressures of the trachea.

(16) Technical Approach: A prospective animal model will be used to evaluate the above stated hypothesis.

(17) Progress: None. New study approved in Sep'90.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/168A (3) Status: Ongoing

(4) Title: A Histologic and Immunopathologic Study of the Skin and Internal Organs of MRL+/+Mice

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Kathleen David, MAJ, MC (8) Facility: FAMC VA Hospital, Denver

(9) Dept/Svc: MED/Dermatology (10) Associate Investigators: Cheryl Teuton, CPT
(11) Key Words: lupus erythematosus Lele Lee, MD
Thomas Santoro, MD
Pat Skavlen, DVM

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: We predict that the MRL+/+ mice will have pathologic findings similar to those reported in MRL/lpr mice, but will develop these findings in a more delayed manner. Further, we predict that the lpr gene is not a prerequisite for autoimmune disease in the MRL mouse.

(16) Technical Approach: This autopsy study will involve 10 animals in each age group studied, 4,16,32,40,48 and 60 weeks or approximately 60-100 animals. Blood will be obtained, and various internal organs removed for pathologic studies. We will compare our findings with those reported for MRL/lpr mice and with findings reported in humans with lupus.

(17) Progress: New study recently approved. No progress.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/169 (3) Status: Ongoing

(4) Title: The Effect of Steroid Therapy on Recovery After
Tonsillectomy

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Glen Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryn. (10) Associate Investigators:

(11) Key Words:
steroids
tonsillectomy
anti-inflammatory

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the effectiveness of steroids to reduce the incidence and severity of postoperative symptoms and complications in patient undergoing tonsillectomy.

(16) Technical Approach: Twenty adult subjects will be randomized to receive either steroid or placebo intravenously at the time of surgery. A total of three doses will be given every 6 hrs. Patients will be asked to answer questions pertaining to their postoperative course at 24 hrs, 2 weeks and 2 months.

(17) Progress: No progress as stipulations for IRC approval are still pending.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/170 (3) Status: Ongoing

(4) Title: SWOG 8744 A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Refractory Multiple Myeloma

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/171 (3) Status: Ongoing

(4) Title: SWOG 8789 A Randomized Study of Etoposide plus Cisplatin and Etoposide Plus Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/172 (3) Status: Ongoing

(4) Title: SWOG 8792 A Phase III Study of Alfa-n1 (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/173 (3) Status: Ongoing

(4) Title: SWOG 8842 Dihydroxyazacytidine in Malignant Mesothelioma, Phase II

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/174 (3) Status: Ongoing

(4) Title: SWOG 8900 A Phase II Pilot of VAD and VAD/Verapamil for Refractory Multiple Myeloma

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/175 (3) Status: Ongoing

(4) Title: SWOG 8931 Phase III Comparison of Cyclophosphamide, Doxorubicin and 5-Fluorouracil (CAF) and a 16-Week Multi-drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/176 (3) Status: Ongoing

(4) Title: SWOG 8994 Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 90/177 (3) Status: Ongoing

(4) Title: National Co-operative rHu Erythropoietin Study in Patients with Chronic Renal Failure: A Phase IV Multi-center Study

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology (10) Associate Investigators:

(11) Key Words:
renal failure
erythropoietin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: __Sep__ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Expand the safety profile of erythropoietin in anemic patients with chronic failure. To understand the medical and social impact of erythropoietin therapy on the United States chronic renal failure population, including patients currently receiving erythropoietin and patients receiving therapy for the first time.

(16) Technical Approach: Active study of patients currently receiving or starting on erythropoietin.

(17) Progress: No progress. Recently approved study.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-25 JS Amend 1)

(1) Date: 30 Sep 90 (2) Protocol #: 90/178 (3) Status: Ongoing

(4) Title: The Efficacy and Safety of Orally Administered SQ 32,756 in the Treatment of Acute, Localized Non-Trigeminal Zoster in Immunocompetent Patients

(5) Start Date: 1990 (6) Est Compl Date: 1993

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology (10) Associate Investigators: James Fitzpatrick, LTC, MC
Katherine David, MAJ, MC
M. Jim Schleve, LTC, MC

(11) Key Words: herpes zoster

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess the relative efficacy and safety of SQ 32,756 when given orally in doses of 10 mg once daily (qd) or 40 mg qd vs. placebo qd in the treatment of acute, localized, non-trigeminal zoster in immunocompetent adults.

(16) Technical Approach: Multi-institutional, randomized, double blinded, placebo-controlled study of an investigational new drug.

(17) Progress: No progress. Recently approved by IRC. HCS-CIA approval pending.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/179 (3) Status: Ongoing

(4) Title: A Randomized Prospective Study of Clindamycin or Pyrimethamine Therapy for Prevention of Toxoplasmic Encephalitis in HIV-Infected Individuals with Serologic Evidence of Latent Toxoplasma gondii Infection (CPCRA 001).

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Robert Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf.Dis.Svc. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate clindamycin and pyrimethamine as prophylactic agents against toxoplasmic encephalitis in individuals who are coinfectd with HIV and latent t. gondii.

(16) Technical Approach: Multicenter, prospective, 4-arm, placebo-controlled (clindamycin, placebo for clindamycin, pyrimethamine, placebo for pyrimethamine) randomized, modified double-blind study.

(17) Progress: No progress. Recently approved by the IRC. Pending approval from HCS-CIA.

Publications and Presentations: None

DEPARTMENT OF SURGERY

(1) Date: 30 Sep 90 (2) Protocol #: 78/20X-001 (3) Status: Ongoing

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbit and Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: James C. Johns, Jr.
MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedic (10) Associate Investigators

(11) Key Words:
microvascular education
and training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for orthopedic staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: Continued training/education for resident/interns and students. Continued maintenance of staff skills. Microvascular techniques used for vein grafts, arterial and venous anastomoses, nerve repairs, and grafts. In progress, principal investigator on temporary duty elsewhere.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 78/20X-002 (3) Status: Ongoing

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and the Rat

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas E. Carter, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Neurosurgery (10) Associate Investigators

(11) Key Words:
microvascular education
and training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: New principal investigator, study to restart in 1990.

Publications and Presentations: None

(1) Date 30 Sep 90 (2) Protocol #: 78/20X-003 (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: (6) Est+ Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Berry E. Morton, LTC, MC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Training protocol.

(16) Technical Approach: See protocol.

(17) Progress: Five personnel have been trained this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: David Pernelli, MAJ, MC (8) Facility: FAMC
General Leonard Wood Army
Community Hospital

(9) Dept/Svc: Ophthalmology (10) Associate Investigators:

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Mar b. Review Results _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient. (See original protocol).

(16) Technical Approach: Extracapsular cataract extraction with posterior chamber IOL.

(17) Progress: In a 6-month period, 42 lenses have been implanted in aphakic subjects. Subjects have improved eyesight with no adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Floyd M. Cornell, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators
MAJ Robert Enzenauer
MAJ Ricardo J. Ramirez
CPT Thomas A. Gardner

(11) Key Words
cataract
aphakia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 450
d. Total Number of Subjects Enrolled to Date: 400/year
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NONE

3M, ALCON, IOLAB (PRECISION-COSMET), COBURN, CILCO, IOPEX, COPELAND, PHARMACIA INTERMEDICS, SURGIDEV, AMERICAN MEDICAL OPTICS

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: Results have been excellent with over 1,000 subjects enrolled. No adverse reactions due to implants perse, continue to enjoy good results. Silicon lenses are expensive but off core and adjunct studies.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 78/201.A (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date: Continuous

(7) Principal Investigator: Monte Dirks, MAJ, MC (8) Facility: FAMC
Munson ACH
Ft. Leavenworth, KS
66027

(9) Dept/Svc: Ophthalmology (10) Associate Investigators:

(11) Key Words:
cataract extraction
intra ocular lens implanting

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 80
d. Total Number of Subjects Enrolled to Date: 160
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Participation in IOL implantation to meet FDA requirements for safety and efficacy and to improve eyesight in patients having cataracts.

(16) Technical Approach: See Protocol

(17) Progress: Subjects are experiencing improved eyesight with decreased incidence of posterior capsular fibrosis with B-1-convex lenses. Approximately 160 lens have been implanted to date without complications.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol WU#: 78/201.C (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Paul Kuck, MAJ, MC

(8) Facility: FAMC
Irwin Army Community Hospital
Ft. Riley, Kansas 66442

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and compare those results with those who undergo cataract surgery without an implant. To determine the occurrence and time of postoperative ocular complications and adverse reactions for intraocular lens implant; to identify subgroups within the implant group that are risk of a particular complication.

(16) Technical Approach: After completing his residency, didactic courses, laboratory practice and assistance with an experienced surgeon, a surgeon who can perform a successful cataract surgery is then allowed to perform intraocular lens surgery. Postoperative examination includes: refraction, pachymetry, keratometry and a complete anterior and posterior segment examination. Contraindications to surgery with intraocular implants include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, any history of anterior or posterior uveitis. History of glaucoma would preclude the use of an anterior chamber implant.

CONTINUATION SHEET, FY 90, ANNUAL PROGRESS REPORT Proto. No. 78/201C

(17) Progress: At this time no pre-market lenses are being used. Anticipate possible use of these types of lenses in the future.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 78/201.D (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Jeffrey L. Bezier, MAJ, MC
(8) Facility: FAMC
Reynolds Army Hospital
Ophthalmology, Box 21
4700 Hartell Blvd.
Ft. Sill, OK 73503-6300
AV 639-0295/0296

(9) Dept/Svc: Ophthalmology (10) Associate Investigators:

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 3/90 b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 45-50 _____
d. Total Number of Subjects Enrolled to Date: 160 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None [CILCO]

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: visual acuity testing and keratometry. Contraindications to surgery include: proliferative diabetic retinopathy, rubeosis irides. Implanting CILCO lens now, but also authorized to implant Precision Cosmet, 3M, Alcon, and IOLAB.

(17) Progress: Cataract surgery with the intraocular lens implantation has been satisfactory with no unusual post operative complications to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 78/201.E (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Charles E. Aronson, COL, MC (8) Facility: FAMC
Evans Army Community Hospital
ATTN: EENT Clinic
Ft. Carson, CO 80913-5207
AV 691-7450

(9) Dept/Svc: Ophthalmology (10) Associate Investigators:
Horace Gardner, M.D.

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 3/90 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 200
d. Total Number of Subjects Enrolled to Date: 200
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None [COBURN]

(15) Study Objective: Participation in IOL implantation.

(16) Technical Approach: See protocol.

(17) Progress: Lens center well, none needed repositioned or removed. No evidence of prolonged inflammation other than normal healing process. No unusual complications.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 84/20X-001 (3) Status: Ongoing

(4) Title: Microvascular Arterial and Venous Anastomosis in Laboratory Rats

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Michael J. Raife
COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Urology (10) Associate Investigators
Thomas A. Jones, MAJ, MC
Craig Donatucci, MAJ, MC
Ronald Sutherland, CPT, MC
James B. Thrasker, CPT, MC
Karl Kreder, MAJ, MC
Timothy A. Moses, CPT, MC

(11) Key Words: microsurgery
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop and maintain microvascular skills.

(16) Technical Approach: Microsurgical exercises of increasing complexity will be performed under anesthesia.

(17) Progress: The protocol has been valuable in teaching microsurgical techniques.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol WU#: 86/200A (3) Status: Ongoing

(4) Title: Treatment of Urinary Tract Trauma in the Porcine Animal Model

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael J. Raife, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc (10) Associate Investigators
James B. Thrasher, CPT, MC
Thomas A. Jones, MAJ, MC
Ronald Sutherland, CPT, MC
Karl Kreder, MAJ, MC
Craig Donatucci, MAJ, MC
Timothy A. Moses, CPT, MC

(11) Key Words:
renal trauma
renovascular surgery
bladder augmentation and substitution

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To provide an opportunity for urologists in training to develop expertise in the surgical techniques which are useful in the management of urinary tract trauma, to include renovascular surgery, renal autotransplantation, and use of various types of bowel segments for augmentation or substitution.

(16) Technical Approach: Animals are subjected, under anesthesia, to simulated urinary tract trauma. Various surgical procedures are performed to allow resident training in management of these situations.

(17) Progress: This is an important teaching protocol for urology.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 86/209A (3) Status: Terminated

(4) Title: Effects of Nonsteroidal Anti-inflammatory Agents on Tendon Healing

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
R. Todd Hockenbury, CPT, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
tendon healing
non-steroidal
anti-inflammatory
agent

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if NSAID's effect heal rate of strength in rat tendon model.

(16) Technical Approach: Suture tendon laceration followed by haling with and without NSAID's.

(17) Progress: More detailed literature review indicates that similar studies have already been done.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/202 (3) Status: Ongoing

(4) Title: Improving Cancer Management Through the Tumor Conference

(5) Start Date: (6) Est Compl Date: 1989-1990

(7) Principal Investigator: Jeffrey R. Clark, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc. (10) Associate Investigators
Daniel T. Tell, MAJ, MC

(11) Key Words: Harris W Hollis, Jr., LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 351
d. Total Number of Subjects Enrolled to Date: 851
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: FAMC Tumor Board will be one of 22 in the state where in a randomized controlled fashion, multifaceted educational intervention (maintaining a randomly selected control group) will be introduced. The hypothesis is: Given emphasis on stimulating case presentations in a concert of patient management decision making, tumor boards can function as key elements in patient care and medical education.

(16) Technical Approach: The first 6 months will be baseline evaluation of tumor boards as they now exist. Then an interventional education package is randomly introduced to half the boards over one year and impact is seen. the other half receive no intervention. A crossover of intervention will occur after one year for one year's time. Then, six months of final analysis and recommendation made to NCI.

(17) Progress: Data is being collected through 31 Aug 90, then this data which was collected over the last two years will be analyzed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/203 (3) Status: Ongoing

(4) Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Disorders Marked by Altered Patterns of Peripheral Blood Flow

(5) Start Date: (6) Est Compl Date: 6/92

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
thermography
pain

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 54
d. Total Number of Subjects Enrolled to Date: 145
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area for patients with orthopedic related pain disorders.

(16) Technical Approach: We will make thermographic recordings of groups of ten subjects having one of the following conditions each time they come to Orthopedic Clinic from the initial diagnostic appointment through post-resolution follow-up: Frostbite, Charcot Joints, Carpal Tunnel Syndrome, Fibrositis, Sympathetic Dystrophy and Peripheral Neuropathy, Pre-amputation preparation, and Prediction of Bed Sore Formation. The clinical evaluations will not be related to the thermographic evaluations until the subject has completed participation in the study.

(17) Progress: This study is going smoothly but there are too few subjects in each group to determine the effectiveness of thermography for any of the groups begun to date. We have determined that videothermography is not a good way to track carpal tunnel syndrome, but is good for tracking reflex dystrophy.

Publications: None

Presentations: Thermography and Carpal Tunnel Syndrome. Presented to the Barnard Series at the University of Colorado Health Science Center, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/204 (3) Status: Ongoing

(4) Title: Mechanism Based Treatments of Phantom Limb Pain

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics

(10) Associate Investigators

(11) Key Words:

phantom limb pain
treatments

Timothy Young, MD, Augusta,
VAMC
Robert Rodinelli, MD,
Denver, VAMC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 15

d. Total Number of Subjects Enrolled to Date: 67

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate the effectiveness of treatments for burning phantom limb pain.

(16) Technical Approach: We will treat four groups of ten amputees each with the same six interventions. The amputees will be grouped by the description of their phantom pain. We will work with those describing their phantom pain as (1) only burning, (2) only cramping, (3) mixed cramping and burning, and (4) shooting / stabbing / shocking. Before treatment begins, there will be a three week baseline in which each amputee will be interviewed and stump muscle tension and heat outflow patterns will be recorded. Each amputee will receive each treatment for one month unless side effects force withdrawal. Treatment months will alternate with three week "washout" periods to permit phantom pain to return to baseline. The treatments will be: (1) topical application of nitroglycerine for mainly venous-side vasodilatative effects, (2) trental to reduce blood viscosity so more blood can reach tissues in the stump having compromised vascular beds, (3) Nifedipine as a Calcium channel blocker for its known peripheral vasodilatative effects, (4) Cyclobenzaprine for its ability to reduce spasms of local origin without interfering with muscle function, (5) muscle tension recognition and relaxation training for its proven ability to reduce microspasms and

tension related to intensification of phantom pain, and (6) body surface temperature recognition and control training for its ability to help people control vasodilation of peripheral vessels while under stress. Subjects will be recorded the same way they were during the baseline at each session to permit objective verification of physiological changes. They will come to the clinic every other week during treatments. At the end of the last treatment, there will be another three week baseline. Following the final baseline, the treatment which proved most effective, if any, will be continued for one year. Subjects will be recorded at monthly intervals. If no treatments are effective, subjects will still be followed for one year but will be recorded at six and twelve months.

(17) Progress: Virtually all patients were cured or helped substantially to the point where no more medication is required.

Publications:

Sherman R, Ernst J, Barja R, Bruno G: Phantom pain: A lesson in the necessity for carrying out careful clinical research in chronic pain problems. Rehabilitation Research and Development, 25(2): vii-x, 1988. (Editorial)

Sherman R, Barja R: Treatment of post-amputation and phantom limb pain. In (K. Foley and R. Payne, eds.) Current therapy of pain. B.C. Decker, Publisher, Ontario, 1988. (Chapter)

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 13(1):55, 1988. (Abstract)

Sherman R, Arena JG, Bruno GM, Smith JD: Precursor relationships between stress, physical activity, meteorological factors, and phantom limb pain: Results of six months of pain logs. Proceedings of the Joint meeting of the Canadian and American Pain Societies, Toronto Canada, November, 1988 (Abstract).

Sherman R: Phantom limb and stump pain. chapter in (R. Portenoy, ed) Neurologic Clinics of North America. W.B. Saunders Co., Publisher, 1989, (Chapter).

Sherman R, Sherman C, Grana A: Occurrence of acture muscle contractions in the residual limbs of amputees preceding acute episodes of phantom limb pain. Biofeedback and Self-Regulations, 1989 (Abstract).

Arena J, Sherman R, Bruno G: The relationship between humidity level, temperature, and phantom limb pain: Preliminary Analysis. Proceedings of the annual meeting of the Association for Applied Psychophysiology, 1989 (Abstract).

Presentations:

Sherman R: Mechanisms of phantom pain: new findings: Presented:
Proceedings of the 21 Annual meeting of the Association for Applied
Psychophysiology, Washington, D.C., 1990.

(1) Date: 30 Sep 90 (2) Protocol #: 87/205 (3) Status: Ongoing

(4) Title: Etiology of Low Back Pain Due to Muscle Tension

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators

David Hahn, LTC, MC

(11) Key Words:
low back pain
environmental recording
surface EMG

Timothy Young, MD, Augusta, VAMC

Robert Rodinelli, Ph.D., Denver,
VAMC

Bertram Rothschild, Ph.D.,
Denver, VAMC

John Arena, Ph.D., Augusta, VAMC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the relationship between (a) the intensity and duration of work, (b) patterns of muscle tension, and (c) onset of low back pain. To determine whether patterns of muscle tension occurring during normal daily activities are different among people with (a) chronic low back pain, (b) intermittent pain, and (c) no pain. To determine relationships between patterns of muscle tension observed among relatively young active duty soldiers with intermittent low back pain and relatively older veterans with intermittent and chronic low back pain of muscle tension origin. To determine whether simple preventive measures can decrease intensity and frequency of episodes of pain by changing response patterns of low back muscle tension.

(16) Technical Approach: We will do two week long, continuous muscle tension, activity, and pain recordings of relatively young active duty soldiers with duties ranging from strenuous to sedentary who are either

pain free, report intermittent low back pain due to muscle tension, or report almost continuous low back pain due to muscle tension. We will do similar recordings of relatively older veterans having similar activity patterns and similar back pain problems. If we are able to identify abnormal patterns, we will provide people who clearly show these patterns with behaviorally oriented muscle control treatments or mild muscle relaxants in order to determine the effect of these interventions on muscle contractions patterns and pain.

(17) Progress: No problems have been encountered. When they are pain free, subjects who frequently report low back pain have low back muscle patterns similar to subjects who virtually never report low back pain. When experiencing low back pain, these subjects have very different patterns than pain free subjects. EMG increases prior to onset of low back pain. Funding from MRDC and staff has been hired, significant delays due to hiring freeze.

Publications:

Sherman R, Sherman C: Relationships between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Biofeedback and Self-Regulation, 1989.

Sherman R, Sherman C: Relationship between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Biofeedback & Self-Regulation (14(2):168, 1989.

Sherman R, Arena J, Searle J: Development of an ambulatory recorder for evaluation of muscle tension related to low back pain and fatigue in soldier's normal environments. Accepted, Military Medicine, 1990.

Presentations:

Sherman R, Arena JG, Searle J, Sherman CJ: Relationships between low back pain, stress, and continuous recordings of paraspinal surface EMG and movement in patients' normal environments. Presented: Joint meeting of the Canadian and American Pain Societies, Toronto, Canada, November, 1988.

Sherman R, Sherman C: Relationships between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Presented: Annual meeting of the Association for Applied Psychophysiology, San Diego, 1989.

Searle J, Arena J, Sherman R: A portable activity monitor for musculoskeletal pain disorders. Proceedings of the IEEE Engineering in Medicine Society's 11th Annual International Conference, 1989.

Sherman R: Ambulatory recording methodology. Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology, Washington, DC, 1990.

(1) Date: 30 Sep 90 (2) Protocol #: 87/206 (3) Status: Ongoing

(4) Title: Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain

(5) Start Date: 1987

(6) Est Compl Date: 6/91

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS
John G. Arena, Ph.D.

(8) Facility: FAMC
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
David Hahn, LTC, MC
Timothy Young, MD, Augusta, VAMC

(11) Key Words:
low back pain
thermography
surface EMG
MMPI

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 38
d. Total Number of Subjects Enrolled to Date: 130
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To test the effectiveness of paraspinal surface EMG, the MMPI, videothermography, physical examination, and standard diagnostic procedures for ascertaining objective data concerning the patient's actual low back pain intensity and underlying physical problems.

(16) Technical Approach: We completed process of performing paraspinal surface EMG and videothermographic recordings of at least 360 subjects with low back pain of six diagnostic categories and who hurt most while in one of six different positions (6 x 6 cell design with ten subjects in a group). Each subject is being recorded four times: Twice while their pain intensity is the same and twice while it varies up or down from the two similar recordings. Thus, each subject is recorded at between two and three pain intensities. This provides data on change with time while pain is constant. All of these subjects are given a modified version of the MMPI designed to differentiate between psychological factors and changes in responses due to presence or absence of low back pain. Each subject is also given a complete orthopedic physical examination and any standard diagnostic procedures not already well documented is done.

(17) Progress: Thermography is usually able to pick up low back disorders independently diagnosed as being related to nerve problems but is not sensitive to pain due to muscle tension in the low back. Surface EMG is sensitive in the opposite way. When the two tests are used together, they are very efficient at quickly and noninvasively determining the physiological cause of the back pain.

The recorder portion of this study has been completed. The MMPI portion is proceeding according to the approved addendum.

Publications:

Arena J, Sherman R, Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in different positions. *Pain*, 37:57-65, 1989.

Arena J, Sherman R, Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in six different positions. *Pain*, 1990.

Arena J, Sherman R, Bruno G: Professionals and low back pain patients expectations of differences in response patterns on the MMPI as a function of presence or absence of chronic pain. *Biofeedback and Self-Regulation*, 1989.

Arena J, Sherman R, Bruno G: Reliability of multiple surface electromyographic recordings of the paraspinal muscles among subjects with and without low back pain. *Int. J. Psychophysiology*, 1989.

Sherman R, Arena J, Bruno G: Electromyographic recordings of low back pain subjects in different positions during low and high pain levels. *Biofeedback and Self-Regulation*, 1989.

Arena J, Sherman R, Bruno G, Young T: Temporal stability of paraspinal electromyographic recordings in low back pain and non-pain subjects. *Int. J. of Psychophysiology*, 9:32-37, 1990.

Presentations:

Arena J, Sherman R, Bruno G, Young T: Reliability of paraspinal electromyographic recordings in low back pain and non-pain subjects. Presented: *Am. Psychological Assoc.*, 1988.

Sherman R, Arena J, Bruno G, Young T: Electromyographic recordings of low back pain subjects in different positions vs. results of standard diagnosis. Presented: *Am. Psychological Assoc.*, 1988.

Sherman R, Arena J, Bruno G, Young T: A comparison of surface EMG and thermographic evaluations of five diagnostic categories of low back pain subjects. Presented: *Proceedings of the American Pain Society's 1989 annual meeting, Phoenix, AZ October 1989.*

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/207 (3) Status: Ongoing

(4) Title: Determination of Mechanisms of Phantom Limb Pain:
Phase 2

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators

Michael D. Getter, MAJ, MC

(11) Key Words:
phantom limb pain
mechanisms

Timothy Young, MD, Augusta, VAMC

Robert Rodinelli, MD, Ph.D.,
Denver, VAMC

Jeffrey Ginther, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 24 _____

d. Total Number of Subjects Enrolled to Date: 24 _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To use MRI, nerve recording, and other techniques to monitor veteran and active duty amputees who report shocking, shooting, and stabbing descriptors of phantom limb pain while they are experiencing various intensities of pain in order to ascertain the physiological changes which are related to changes in pain intensity.

(16) Technical Approach: We will carry out the pilot for a full proposal in which we would record groups of twenty active duty or veteran amputees four times. In the pilot, only two amputees from each group will participate. Two of the recordings will be at one particular pain intensity while the other two will be at two different intensities. This will permit factoring changes due to time from those due to changes in pain intensity. Each subject will be recorded at about weekly intervals but the exact timing will have to depend on when their pain intensity changes. The groups will consist of two amputees with (1) only stabbing phantom pain, (2) only shooting phantom pain, (3) only shocking phantom pain, (4) a combination of all three (which is common), and (5) no phantom pain. The fifth group of amputees without phantom pain is necessary

to further evaluate changes which occur in the normal stump over time so we can differentiate them from abnormal changes. We know from our experience in Phase I of this study that twenty is the minimum number of amputees we can have in a group due to normal physiological variability and in variability in reporting pain intensity. However, two per group will give us an idea of whether the following techniques are likely to show any differences at all. We propose to use MRI to record overall stump anatomy, plethysmography to record swelling and internal stump pressure, and signals from the neuroma to record responses to mechanical and other stimuli. Because of its invasive nature, we will carry out only one nerve signal study from the stump. For subjects who report phantom pain, we will perform the test on a day when they report the maximum phantom pain they usually experience. We will compare the results of this recording with those from pain free amputees. Due to its cost, we will do MRI recordings of only one subject per pilot group. Two MRI's will be done for each pilot subject. One will be while the subject is as pain free as they get and the other will be while they are experiencing the most pain they generally expect.

(17) Progress: Four amputees experiencing numerous acute episodes of cramping phantom pain had the surface muscle tension in their residual limbs recorded. They pressed a button during episodes of phantom pain. Temporal relationships between initiation of episodes and spasms in the limb were established. Spasms precede start of pain by more than reaction time so causes the phantom pain. FY 90, no new patients or progress.

Publications:

Sherman R, Sherman C, Grana A: Occurrence of acute muscle contractions in the residual limbs of amputees preceding acute episodes of phantom limb pain. *Biofeedback & Self-Regulation* 14(2):169, 1989.

Sherman R, Bruno G: Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. *Orthopedics*, 10:1395-1402, 1987.

Sherman R, Sherman C, Bruno G: Psychological factors influencing chronic phantom limb pain: An analysis of the literature. *Pain*, 28:285-295, 1987.

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. *Biofeedback and Self-Regulation*, 1988, (Abstract).

Presentations:

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Presented at the 19th Annual meeting of the Society for Applied Psychophysiology in Colorado Springs, CO, March 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/20x-003 (3) Status: Ongoing

(4) Title: Evaluation of the Goat as a Model for Bone Grafting Studies

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
David B. Hahn, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
Richard Sherman, MAJ, MS
Ross M. Wilkins, MD
Presbyterian Hospital

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The overall objective is to determine the suitability of the goat as a model for studies on bone grafting.

(16) Technical Approach: See protocol

(17) Progress: We created 2cm defects in ulna in three goats. The goats were radiographed at three week intervals. Two out of three went on to heal their defects, thus bone grafts were not performed. We feel it is necessary to create a model that would consistently result in non-union. Plans are to do another preparatory study. Study in progress, principal investigator on temporary duty elsewhere.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/20x-004 (3) Status: Ongoing

(4) Title: Development of an Animal Model for the Study of Anterior Cruciate Ligament Repairs

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Steven D. Pals, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic Surgery (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Resident on rotation. Gone from FAMC for the summary period. No progress.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/200 (3) Status: Ongoing

(4) Title: ALCON Surgical Intraocular Lens Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Floyd M. Cornell, LTC, MC

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators
Jonathan Stock, MAJ, MC
Ricardo J. Ramirez, MAJ, MC
Robert W. Enzenauer, LTC, MC
Thomas A. Gardner, CPT, MC
Margaret B. Lisecki, CPT, MC
Joseph E. O'Boyle, CPT, MC
Robert W. Weller, CPT, MC
William Walton, CPT, MC
Roger K. George, CPT, MC

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 11 _____
d. Total Number of Subjects Enrolled to Date: _____ 25 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Adjunctive study with FDA for intraocular lenses used following cataract extraction.

(16) Technical Approach: Intraocular lenses are implanted into the anterior segment of the eye following cataract extraction either as a primary procedure or as a secondary procedure.

(17) Progress: All lenses in place are doing well. No adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/201A (3) Status: Ongoing

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Stephen M. Fall, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Cardiothoracic (10) Associate Investigators
Dick R. Smith, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To conduct training courses in Advanced Trauma Life Support (ATLS).

(16) Technical Approach: See protocol

(17) Progress: 32 ATLS provider/instructors trained this calendar year.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/202 (3) Status: Ongoing

(4) Title: A Comparison of Clinical Features of Ulnar Nerve
Compression at the Elbow Before and After Medial
Epicondylectomy

(5) Start Date: 1989 (6) Est Compl Date: 1990

(7) Principal Investigator: David Bizousky, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
James C. Johns, MAJ, MC
Douglas Hemmler, CPT, MC

(11) Key Words:
nerve compression
conduction velocity

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 6 _____
d. Total Number of Subjects Enrolled to Date: _____ 21 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: Assess results of medial epicondylectomy in the
treatment of cubital tunnel syndrome.

(16) Technical Approach: Comparison of preoperative and postoperative
and electrical parameters.

(17) Progress: Approximately 21 patients have undergone the procedure
of medial epicondylectomy. Clinical impression is that operation is
working well. No adverse reactions recorded. Data continues to be
collected.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/203 (3) Status: Ongoing

(4) Title: Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective) Utilizing Anterior Rhinometric Techniques

(5) Start Date: 1988 (6) Est Compl Date: 1992

(7) Principal Investigator: Michael L. Lepore, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Otolyn/Hd&NkSur. (10) Associate Investigators

(11) Key Words:
rhinomanometry
nasal obstruction
nasal surgery

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (a) to utilize anterior rhinometric principles in the pre-op assessment of patients prior to nasal surgery, (b) to utilize anterior rhinometric principles in the post-op evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery (opened or closed), and (c) to determine, utilizing anterior rhinomanometric techniques, if the unobstructive nasal cavity after nasal surgery (opened or closed) is significantly altered at the expense of correcting the pre-op obstructive side, and is this subjectively noted by the patient to the point of causing secondary obstructive symptoms, of any degree on the unobstructive side which will be objectively measured.

(16) Technical Approach: Measurements of nasal airflow utilizing anterior rhinomanometry will be performed before surgery and after surgery

at definite periods. Correlation will be made between the various surgical procedures and the measured test results to note if any significant alterations on the unobstructed side have resulted from the surgical procedures.

(17) Progress: This protocol has not been started due to multiple administrative problems and inability to set aside the appropriate research time because of lack of staff. It is hopeful, that when my operation is stable, I will be able to begin my endeavors. I would appreciate having the project open, so when I am able to begin, I will not have any particular delays.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/206A (3) Status: Terminated

(4) Title: An Analysis of the Effect of Nonsteroidal Anti-Inflammatory Medications on Regeneration of Articular Cartilage in New Zealand White Rabbits Treated by Intermittent Active Motion and Continuous Passive Motion

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Alexander Pruitt, MAJ, MC
Anthony W. Colpini, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
Joe K. Ozaki, COL, MC
Cris Myers, CPT, MC

(11) Key Words:
articular cartilage regeneration
continuous passive motion
nonsteroidal anti-inflammatory

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The object of this protocol is to determine whether non-steroidal anti-inflammatory medications have an effect upon the regeneration of articular cartilage in rabbit knees. We are also attempting to delineate whether two separate nonsteroidal anti-inflammatories have different effects on regenerative of articular cartilage treated with continuous passive motion.

(16) Technical Approach: The rabbit knees will be arthrotomized and pieces of the articular cartilage will be moved and the knees will be closed, and then the rabbits will either be put on continuous passive motion on one leg and active intermittent motion on the other, after both arthrotomies. Then they will be reoperated at 4, 8 & 12 weeks, and one group will get no nonsteroidal, one group will get Piroxicam, one group will get Acetylsalicylic acid.

(17) Progress: Project terminated, was never started as resident left.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/208 (3) Status: Completed

(4) Title: A Retrospective Analysis of the Incidence of Pseudarthrosis in Posterior Spine Fusion Done Between 1971 and 1986, at St. Anthony's Hospital and Denver Children's Hospital

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Alexander Pruitt, MAJ, MC
John A. Odom, MD (8) Facility: FAMC
Lakewood Clinic, Denver, CO

(9) Dept/Svc: SUR. Orthopedic (10) Associate Investigators
John L. Brugman, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this study is to evaluate those patients with pseudarthrosis and compare them with an age, sex, and diagnosed matched group of controls who also underwent posterior spine fusion but did not develop pseudarthrosis. We propose to evaluate the contributions of several factors which may effect the incidence of pseudarthrosis in these patients.

(16) Technical Approach: See protocol.

(17) Progress: Data is currently being put into the computer. Charts are still being reviewed. Project completed. No significant information derived. No further plans for progression, presentation or publications.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/209 (3) Status: Ongoing

(4) Title: A Comparison of Percutaneous Repair Versus Open Repair
of Achilles Tendon Ruptures

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
R. Todd Hockenbury, CPT, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

James C. Johns, MAJ, MC
Rick Wilkerson, MAJ, MC

(11) Key Words:
achilles tendon ruptures
percutaneous repair of achilles
tendon ruptures

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: (a) To compare the clinical results of per-
cutaneous repair to open repair of achilles tendon rupture and to inves-
tigate the complications and long-term outcome of these techniques. (b)
To compare the initial repair strengths of these techniques.

(16) Technical Approach: Patients are now being randomized into 2
separate groups and surgery is being performed. The cadaver study is
completed.

(17) Progress: Only 4 additional patients enrolled.

Publications:

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" (Submitted for publication, Journal of Foot and Ankle Surgery).

Presentations:

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: The Western Orthopaedic Society National Meeting. Honolulu, Hawaii, October 1988. Winner of the Vernon P. Thompson Award.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Foot and Ankle Society Section of The National Academy of Orthopedics Meeting. Las Vegas, Nevada, February 1989.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Rocky Mountain Chapter Meeting of the Western Orthopedic Society Barnard Lecture Competition. February 1988, and was selected as one of the five finalist papers.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/210A (3) Status: Completed

(4) Title: Delayed Repair of Traumatic Intratemporal Facial
Nerve Palsy in the Pig

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: David M. Barrs, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Otolaryngology (10) Associate Investigators:

(11) Key Words:
traumatic facial palsy
nerve graft

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: a. Determine optimal timing for facial nerve
repair following temporal bone trauma; b. measure effect of stretch
injury to facial nerve in cerebellopontine angle; c. refine direct
facial nerve stimulation technique in the temporal bone; and d. develop
an animal model for facial nerve study in the temporal bone.

(16) Technical Approach: The facial nerve is cut in the temporal bone
and nerve grafted at intervals from immediately to three months after
trauma. Histologic and electrophysiologic examinations will determine
differences in return of function for different times of repair.

(17) Progress: Protocol is completed. Dr. Barrs received an honorable
mention at the Triologic Society meeting.

Publications and Presentations: A thesis for the American
Laryngological, Rhinological, and Otolological Society has been completed
and forwarded September 5, 1989. If accepted, the thesis will probably
be broken into two separate publications due to its length. Several
other publications may also be written concerning the electrophysiologic
testing. This was presented at the Triologic Society and will be
published in the future.

(1) Date: 30 Sep 90 (2) Protocol #: 88/211 (3) Status: Terminated

(4) Title: Double Blind Crossover Study of Cyclobenzaprine Versus Placebo in Patients with Primary Fibrositis: Correlation of Symtomatic Verus Thermographic Criteria of Improvement

(5) Start Date: Jan '90 (6) Est Compl Date: June '90

(7) Principal Investigator: Robert A. Coe, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedic

(10) Associate Investigators:
Alexander Pruitt, MAJ, MC
Richard A. Sherman, MAJ, MS
Douglas Hemler, MAJ, MC
Sterling West, COL, MC

(11) Key Words:
fibrositis
flexeril
thermography

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objectives of this study are to compare Flexeril versus Placebo in the treatment of fibrositis, and to evaluate how subjective improvement of either drug or placebo corresponds to normalization of the thermogram.

(16) Technical Approach: Forty patients will be randomized to either the placebo or Flexeril (30mg qhs) group for a seven week period. Pain logs will be used by the subjects. PIs will assess subjects using subject interview, MMPI, pain log, physical exam and thermogram. After a one month washout period, the subjects will be crossed over.

(17) Progress: Protocol was withdrawn and terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/212 (3) Status: Terminated

(4) Title: Prevention of Nosocomial Pneumonia and Gastroduodenal
Ulcer Prevention in Mechanically-Ventilated Patients

(5) Start Date: Oct 89 (6) Est Compl Date: Oct 92

(7) Principal Investigator: Phillip L. Mallory, II, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Intensive Care (10) Associate Investigators:
Kevin Dwyer, MD
Brant Thrasher, MD
William Marx, MAJ, MC

(11) Key Words:
nosocomial pneumonia
gastroduodenal ulcer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To decrease the incidence of pneumonia
(nosocomial) in mechanically ventilated patients receiving antiulcer
prophylaxis.

(16) Technical Approach: 4 groups of patients will be sequentially
assigned to high, low, and moderate risk (based on APACHE) score) to
receive either Cimetidine and antacids; Cimetidine, antacids,
Tobramycin, Polymixin B, Amphotericin; Famotidine or Sulcralfate; GI
bleeding will be noted; routine cultures will be performed.

(17) Progress: No progress as of this date. Medical Research and
Development Command recently funded this project. FY 90, no progress
as of this date so will terminate the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/213 (3) Status: Ongoing

(4) Title: Investigational Plan for the Clinical Study of Silicone Intraocular Lenses Sponsored by Allergan Medical Optics

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Floyd M. Cornell, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology (10) Associate Investigators:
Robert W. Enzenauer, LTC, MC
Thomas A. Gardner, MAJ, MC
Jonathan Stock, MAJ, MC
William Walton, CPT, MC
Ricardo J. Ramirez, MAJ, MC

(11) Key Words:
silicone IOL

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0
d. Total Number of Subjects Enrolled to Date: _____ 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to establish the safety and efficacy of the silicone intraocular lens according to FDA regulations.

(16) Technical Approach: The technical approach is the standard surgical method of cataract extraction and lens implantation to treat visually disabling cataracts.

(17) Progress: Although no patients have been enrolled to date, we anticipate beginning patient enrollment during the period November 1989 through October 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/214 (3) Status: Ongoing

(4) Title: Clinical Investigation of Intraocular Lenses in Minors
Sponsored by COBURN Optical IND, Inc/Storz Ophthalmics
Inc.

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Floyd Cornell, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology (10) Associate Investigators:
Robert W. Enzenauer, LTC, MC

(11) Key Words:
minors
IOL
cataract extraction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to evaluate the
safety and efficacy of intraocular lenses in children.

(16) Technical Approach: Patients are selected based on inability to
utilize spectacles, contact lenses, or the use of epikeratoplasty. Only
posterior chamber lenses are utilized. The lenses are placed in the
capsular bag when available, into the ciliary sulcus when appropriate,
or sutured into place when sulcus fixation is otherwise not achievable.

(17) Progress: There have been two patients enrolled because of
traumatic cataracts, two patients enrolled because of irregular
astigmatism and/or lack of iris support. All patients were enrolled
because of cataract formation to one degree or another as a result of
trauma. All patients are achieving their preoperative best corrected
visual acuity and having no adverse reactions to the lens implant.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol WU#: 88/215 (3) Status: Ongoing

(4) Title: Continuous Environmental Recording of Activity, Headache, and Muscle Contraction Level Among Subjects with Tension, Migraine or No Headache

(5) Start Date: 1988 (6) Est Compl Date: 1992

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators
Richard Calkins, COL, MC
David Hahn, LTC, MC
Crystal Sherman,

(11) Key Words:
headache
muscle tension
environmental recording

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine relationships between motion, muscle tension in the frontal and trapezius muscles, and onset and intensity of headaches among subjects recorded in their normal environments.

(16) Technical Approach: Subjects wear a small EMG and motion recorder during all working hours for one week. They keep an hourly log of types and activity and pain intensity while wearing the recorder.

(17) Progress: The patterns of muscle tension and movement were virtually identical for all back pain subjects during pain free periods and for the pain free control. The subjects with back pain almost always showed increases in muscle tension preceding increases in pain and decreases preceding decreases in pain. All six headache subjects showed relationships in which both stress and upper back muscle tension increased prior to increases in headache intensity and decreased prior to decreases in pain. Trial results indicate that changes in muscle tension precede changes in pain so are causative rather than reactive.

Minimal progress this fiscal year due to lack of manpower. Protocol will be restarted after the end of the hiring freeze.

Publications: None

Presentations: Presented at the Annual Meeting of the Association for Applied Psychophysiology in San Diego, CA 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/20x-001 (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer, and Vessel and Nerve Repair Utilizing the Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Glen Y. Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Surgery/Otolary. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This training protocol is to attain and maintain proficiency in microvascular surgical repair of small nerves and blood vessels. The femoral artery and nerve of the rat is well suited for this type of study.

(16) Technical Approach: See protocol.

(17) Progress: The maintenance of microvascular proficiency has been accomplished. Each year new residents are provided basic skills in their training. Twenty hours of training was received for two personnel.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 89/202 (3) Status: Ongoing

(4) Title: The Effect of Harvesting the Central One-third of the Patellar Tendon and Reapproximating the Medial and Lateral Edges of Patellofemoral Joint Mechanics in Cadavers

(5) Start Date: 1989 (6) Est Compl Date: 1990

(7) Principal Investigator: Richard A. Schaefer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:

Scott D. Gillogly, MAJ, MC
Alexander Pruitt, MAJ, MC

(11) Key Words:
arthroscopy
anterior cruciate ligament

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine differences in patellofemoral joint contact area and pressure resulting from two standard treatments after harvesting the central third of the patellar tendon for ACL reconstruction (suturing versus not suturing the cut edges).

(16) Technical Approach: The radiographic and patellofemoral joint contact area and pressure changes in cadavers pre- and post harvesting the central one-third of the patellar tendon will be investigated.

(17) Progress: No progress.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/203 (3) Status: Ongoing

(4) Title: Rates of Occurrence of Simultaneous and Independent Low Back Pain and Headache Among Patients with and without Chronic Pain

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Richard A. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators: John G. Arena, Ph.D. Jeffrey R. Ginther, MAJ, MC Melissa Damiano, M.S.

(11) Key Words: low back pain tension headache incidence

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 44 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the temporal relationships between the above pain problems among subjects with and without chronic pain.

(16) Technical Approach: Survey deers eligible people with and without pain while they are waiting for appointment at FAMC.

(17) Progress: No results yet as surveys are still being distributed. Study has been stopped by the hiring freeze.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 89/204 (3) Status: Completed

(4) Title: Incidence of Multiresistance in Serial
Gram-Negative Isolates from ICU's

(5) Start Date: 1989 (6) Est Compl Date: 1989

(7) Principal Investigator: Phillip Mallory, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/SICU

(11) Key Words:

(10) Associate Investigators:
Jeffrey R. Clark, COL, MC
Harris W. Hollis, Jr., LTC, MC
Leo A. Andron, LTC, MS
William H. Marx, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to develop an antibiogram for
the SICU.

(16) Technical Approach: Specimens will be analyzed using Merck, Sharp
& Dohme protocol.

(17) Progress: No specimens were studied.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/205A (3) Status: Ongoing

(4) Title: Correlation of the Vocal Fold Vibratory Pattern to the Post Operative Surgical Wound in the Porcine Model

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Vincent D. Eusterman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryngology (10) Associate Investigators: Don B. Blakeslee, RET, COL

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Study was delayed due to equipment purchase. Awaiting equipment which as been ordered by contracting.

Publications and Presentations:

(1) Date: 30 Sep 90 (2) Protocol #: 89/206A (3) Status: Completed

(4) Title: The Effect of Liposuction on Myocutaneous Flaps in the Yucatan Micro Pig

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Terence R. Woods, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryngology (10) Associate Investigators: Michael L. Lepore, COL, MC

(11) Key Words:
swine
liposuction
myocutaneous flaps

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effect of the timing of liposuction on the viability of the cutaneous portion of trapezius myocutaneous axial flaps created on the Yucatan Micro Pig.

(16) Technical Approach: See protocol

(17) Progress: This project is completed. We are awaiting Pathology's review of the biopsies before any formal evaluation of our results. The project was completed in May 1990.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/207 (3) Status: Ongoing

(4) Title: Etiology and Progression of Acute Muscle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercises

(5) Start Date: Oct 1989 (6) Est Compl Date: Sep 1992

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC & Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:

(11) Key Words: low back pain EMG (10) David Hahn, LTC, MC Jeffrey R. Ginther, MAJ, MC John G. Arena, Ph.D. (VA, Augusta, GA)

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the etiology and progression of acute muscle tension related low back pain occurring during sustained activity including combat training exercises.

(16) Technical Approach: Use ambulatory recorders to make second by second records of bilateral surface paraspinal EMG and back movement as well as hourly back pain and fatigue rating entries for 20 hours per day while subjects function in their normal environment.

(17) Progress: All equipment has been purchased and tested. Staff has been hired and trained. The study is underway.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-2³ as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/209 (3) Status: Terminated

(4) Title: Clinical Investigation of the Synthes Spinal
Internal Fixator

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: David B. Hahn, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:
Michael Getter, MAJ, MC
Anthony P. Dwyer, MD
(UCHSC)

(11) Key Words:
spinal fixator

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To verify the improved results of the surgical
management of spinal fractures, that has been reported in Europe, with
the use of the Synthes spinal internal fixator.

(16) Technical Approach: Phase II clinical trial to meet FDA
requirements for release of this investigational new medical device.

(17) Progress: Terminated.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/210 (3) Status: Ongoing

(4) Title: Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 92

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedic Svc (10) Associate Investigators: Allyn Woerman, LTC, PT

(11) Key Words: thermography
lower extremity pain
surface temperature

Ft. Sill, OK
Kent Karstetter, CPT, MC
FAMC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 11
d. Total Number of Subjects Enrolled to Date: 11
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide immediate, on-site diagnosis of stress fractures in the lower extremities of active duty soldiers using a comparison of high technology videothermography and bone scan with filed viable contact thermography and surface temperature probes.

(16) Technical Approach: Phase I) Use videothermography and standard physical evaluations to establish baselines for trainees initially entering service at Ft. Sill, OK. Repeat thermograms will be performed on all trainees reporting to the troop medical clinic for treatment of pain in their knees, lower legs, and feet. Thermography will be performed on a matched group of trainees who come in to the clinic for other problems. This will permit differentiation of changes which occur among most trainees from pathological changes.

Phase II) Compare videothermograms, contact thermograms, bone scan and other recordings of 100 trainees and 100 relatively senior soldiers suspected of having stress fractures with similar evaluations of matched controls to establish the efficacy of low technology contact thermography for evaluation of stress fractures.

(17) Progress: All equipment has been purchased. Staff has been hired and trained and the study is underway.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/211 (3) Status: Ongoing

(4) Title: Randomization Study of Transurethral Resection of the Prostate vs Balloon Dilation of the Prostate for Symptomatic Benign Prostatic Hyperplasia in Men

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 90

(7) Principal Investigator: Craig Donatucci, MAJ, MC
Karl Kreder, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Urology Svc (10) Associate Investigators: Michael Raife, COL, MC

(11) Key Words: transurethral resection of prostate (TURP)
balloon dilation of prostate (BDP)

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 39
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effectiveness of balloon dilation of the prostate (BDP) to TURP in moderately symptomatic men over 45 who suffer from benign prostatic hyperplasia (BPH).

(16) Technical Approach: This is a multi-center, two-arm, randomized study to examine the efficacy of BDP in improving symptoms of urinary outlet obstruction and urinary flow in men with symptomatic BPH, and compare and contrast the results with those of men undergoing TURP. Men with urinary outlet obstruction who need TURP and meet the protocol entrance criteria will be randomly assigned to TURP or BDP. After operation the patients will be followed for 1 year to determine improvement in symptoms, urinary flow parameters and post void residual urines. Groups will be compared to determine whether any beneficial effects from BDP have occurred.

(17) Progress: First patient underwent TUP 11/89 - to complete 1-yr. follow-up in 11/90.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/20x-001 (3) Status: Ongoing

(4) Title: Evaluation of the Goat as a Model for ACL Reconstruction
Fixation Studies

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
R. Todd Hockenbury, CPT, MC
Scott D. Gillogly, MAJ, MC

(9) Dept/Svc: Surgery/Ortho (10) Associate Investigators:
Steven Pals, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: The overall objective is to determine the
suitability of the goat as a model for ACL reconstruction.

(16) Technical Approach: Three goats will be anesthetized and open ACL
reconstruction will be performed on one of the hindlegs, using a
different graft fixation technique on each goat. Following surgery the
goats will be housed in Bldg 610 in large animal enclosures, which
permit the animals full freedom of movement. No postoperative
immobilization will be used. They will be euthanatized at one week
postop and the knee will be harvested and subjected to biomechanical and
histologic testing.

(17) Progress: Progress report is due October 90.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/200A (3) Status: Ongoing

(4) Title: Comparison of ACL Graft Fixation Techniques in a Goat Model

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Scott D. Gillogly, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic Svc (10) Associate Investigators: Todd Hockenbury, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine which of three standard ACL graft fixation techniques provides the best graft fixation in reconstruction of the anterior cruciate ligament utilizing the central one-third of the patellar tendon.

(16) Technical Approach: See protocol.

(17) Progress: Data from the testing of Groups I and II under this protocol has been completed. Requested purchase of sufficient goats to support completion of protocol. The requested goats would allow completion of the testing of Group III.

Publications and Presentations: Accepted for presentation for FY 91.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/201A (3) Status: Ongoing

(4) Title: Use of Tetrograde Cardioplegia in the Pig Model

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Thomas Gaines, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Cardiothor. Surg. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: New study and will be reported on in Nov 90.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/202 (3) Status: Ongoing

(4) Title: Non-Surgical Treatment of Morton's Neuroma with Injection of Vitamin B-12/Lidocaine/Solumedrol Combination

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Paul Spezia, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The aim of the first phase is to determine whether the injection produces good enough results with a sufficient percent of the patients to be worth giving as a simple first try prior to offering surgery.

(16) Technical Approach: Our plan is to inject a combination of 0.5cc of lidocaine, 0.5cc solumedrol, and 0.5cc of vitamin B-12 into the interdigital neuroma of all patients in a series of two injections.

(17) Progress: The study injection works as a temporary measure at the 90-day followup. Long-term effects cannot yet be determined as the on-year followup data is pending.

Publications and Presentations: Presentation in 1989 at the Barnard Residents's competition.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/203 (3) Status: Ongoing

(4) Title: Synovial and Serum Keratan Sulfate Levels and Their Correlation with Arthroscopically Determined Articular Damaged Chronically Deficient Cruciate Ligament Knees

(5) Start Date: 1990 (6) Est Compl Date: 1993

(7) Principal Investigator: Paul Spezia, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic (10) Associate Investigators: Scott Gillogly

(11) Key Words:
keratan sulfate
arthroscopic cruciate deficient

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 18 _____
d. Total Number of Subjects Enrolled to Date: _____ 18 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if there is a correlation between keratan sulfate and cruciate deficient knees as determined by arthroscopy and bone scan.

(16) Technical Approach: No significant data.

(17) Progress: Currently 36 samples, ongoing harvesting.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/204 (3) Status: Ongoing

(4) Title: A Clinical Comparison of a Hydroxylapatite Coated Versus Porous Coated Total Hip Implant for Use in Arthritic Human Hips

(5) Start Date: 1990 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Edward Lisecki, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: James Wolfe, CPT, MC
Frederick Coville, COL (RET)

(11) Key Words: hydroxyapatite

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 29
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Compare results of two porous ingrowth hip components to improve amount of ingrowth, thereby, reduce the need for revisions.

(16) Technical Approach: Posterior approach to the hip routine implantation of a porous femoral/acet. component.

(17) Progress: Hip scores on hydroxy apatite hips is consistently higher than the non HA coated hip.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/205A (3) Status: Completed

(4) Title: Investigation of the Radiology and Anatomy of the Origin of the Anterior Cruciate Ligament

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Brent McIntosh, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish accurate anatomic and radiologic correlation of the origin of the anterior cruciate ligament.

(16) Technical Approach: See protocol.

(17) Progress: The study has been completed, awaiting report from Ft. Leavenworth.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/206 (3) Status: Ongoing

(4) Title: Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electromagnetic Fields

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Kent Karstetter, CPT, MC (8) Facility: FAMC Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: Orthopedics (10) Associate Investigators:

(11) Key Words: stress fractures pulsing magnetic fields
Allyn Woerman, LTC, MC
Richard Sherman, MAJ, MS

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate that a full study of pulsing magnetic fields is warranted for treatment of stress fractures.

(16) Technical Approach: Double-blind, placebo controlled study. Electrical stimulators will be used in half of the subjects.

(17) Progress: No progress, funding pending.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/207A (3) Status: Ongoing

(4) Title: Patellar Tendon Healing and Strength Following Patellar Tendon Autograft Harvest in Goats

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: David Bizousky, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: See protocol.

(16) Technical Approach: See protocol.

(17) Progress: Initial surgeries just done in early October 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/208A (3) Status: Ongoing

(4) Title: Development of an Implanted, Hydroxyapatite Coated, Titanium Limb Prosthetic Through Tests in Tissue Culture, Then in Goats, and Finally in Humans

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators:

(11) Key Words:
percutaneous implant
prosthetic
amputees
goats

Philip Deffer, CPT, MC
Ronald L. Jackson, CPT, MS
Edward J. Lisecki, MAJ, MC
William Hall, MD
Stephen Cook, PhD
Paul Glick MAJ, DC
Donald Mercill, DAC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test a percutaneous implant in a goat model to evaluate long term (a) infection through the skin - implant interface, (b) strength of the interface, and (c) ability of the goat to walk on the implanted prosthesis.

(16) Technical Approach: Tissue culture will be used to refine methods for evaluating tissue growth into the prosthesis. A goat model will be used to test which combination of coatings and materials give the best skin adhesion with the least infection and formation of fistulas. The optimal combination will be used to produce a percutaneously implanted prosthetic which will be implanted into several goats to test the above objective.

(17) Progress: None.

Publications and Presentations: None.

(1) Date: 20 Sep 90 (2) Protocol #: 90/209 (3) Status: Ongoing

(4) Title: Reliability of Psychophysiological Measures Used to Evaluate Pain

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: John Arena, Ph.D.

(11) Key Words: chronic pain psychophysiological responses comprehensive assessment Carson Henderson, Psy.D. Richard Calkins, COL, MC Kimford Meador, MD Jeffrey Ginther, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: to evaluate the test/retest reliability of several commonly used psychophysiological measures when used with patients and controls.

(16) Technical Approach: Three groups of chronic low back pain subjects, two groups of tension headache and 75 age-matched controls will be assessed five times. The pain groups will be seen three times when at no or low pain levels and twice when at high pain levels. The assessments will consist of the standard six position measurement of surface EMG patterns, standard psychophysiological evaluations and cold presser test.

(17) Progress: To date no progress pending funding. This is a VA-DoD grant application which cannot be performed unless it is funded.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/210 (3) Status: Ongoing

(4) Title: Effectiveness of Treatments for Reflex Sympathetic
Dystrophy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:
Douglas Hemler, MAJ, MC
Kent Karstetter, MAJ, MC
Muhammad Shaukat, LTC, MC
Mary Brinkman, MAJ, RPT
Darlene Mullon, MAJ, MC
Robert Ketchum, COL, MC

(11) Key Words:
reflex sympathetic dystrophy
nerve block
corticosteroids
physical therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective of the standard
treatments for reflex sympathetic dystrophy.

(16) Technical Approach: After standard workup and videothermography,
subjects will be randomized to one of the three standard treatments--
corticosteroids, multiple nerve blocks or vigorous physical therapy.
Patients will be followed at 3-mo intervals for one year. If there is
no improvement, the patient will be randomized to one of the remaining
treatments.

(17) Progress: Patients are currently being enrolled on this study
which was approved in Aug 90.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/211A (3) Status: Ongoing

(4) Title: Effects of Coumadin and Methotrexate on Bone Ingrowth and Fixation in Hydroxyl Apatite Coated Porous Implants in a Goat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: James Wolff, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: Edward Lisecki, MAJ, MC Stephen Cook, Ph.D.

(11) Key Words:
coumadin
methotrexate
bone ingrowth
hydroxyl apatite implants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To quantify the biomechanical histological effects of coumadin and methotrexate on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Thirty-six adult goats will be randomized to treatment groups 1-6. Of the coumadin and methotrexate animals, one will be given the medication beginning one month prior to surgery and the other will not receive the medication until the day of surgery. Five transcortical rods will be placed in the femur. Each rod is coated for half its length so each acts as its own comparison control. Specimens will be collected, radiographed and prepared for biomechanical and histological evaluation from 3 to 104 weeks postoperatively.

(17) Progress: No progress, LACUC approved in Sep 90.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/212A (3) Status: Ongoing

(4) Title: The Evaluation of Bone Ingrowth in Hydroxyl Apatite and
in Non-Hydroxylapatite Porous Implants in a Goat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Richard Schaefer, CPT, MC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:
Edward Lisecki, MAJ, MC

(11) Key Words: bone ingrowth implants
Stephen Cook, PhD
Jerome Weidel, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To quantify the biomechanical and histological
effects of hydroxyl apatite on bone growth into porous-coated implants.

(16) Technical Approach: The following parameters will be evaluated
in a weight loaded goat hip: (a) the interface attachment shear strength
and stiffness; (b) rate of development of interfasciary strength and
stiffness; (c) the amount, rate and organization of bone ingrowth.

(17) Progress: No progress, LACUC approved Sep 90.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/213 (3) Status: Ongoing

(4) Title: Eaton Trapezial Implant Long-Term Follow-up

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Phillip Deffer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:

James Johns, MAJ, MC

(11) Key Words: eaton trapezialimplant

Frank Scott, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate through long-term followup that the Eaton trapezial implant provides a strong, stable, mobile and useful thumb without significant complications.

(16) Technical Approach: Retrospective analysis of postoperative records; subjective questionnaire; clinical exam; radiographic evaluation to look for evidence of implant failure, osseous changes or arthritic progression.

(17) Progress: No progress, newly approved study.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION

(1) Date: 30 Sep 90 (2) Protocol #: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults.
I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977 (6) Est Compl Date: Open-Ended

(7) Principal Investigator: Robert S. Stewart, MAJ, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
Shannon M. Harrison, LTC, MC

(11) Key Words:
immunologic diseases

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct 87 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 199
d. Total Number of Subjects Enrolled to Date: 1328
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: Serum gammopathics evaluated by SPEP, IEP, and rate nephelometry. Lymphocyte phenotyping, DNA analysis, and neutrophil activation potential by flow cytometry. Lymphocyte activation determined by quantitative mitogenesis.

(17) Progress: We continue to provide specialized immunological evaluations and testing with this protocol.

Presentations:

(1) Brown, G.L., and Hegggers, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Acquired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy--Immunology Symposium, Aurora, CO, 21-23 January 1986.

(3) Rickman, W.J., Lima, J.E., and Muehlbauer, S.L.: U.S. Army HTLV-III Testing Program Flow Cytometry Workshop. Presented: 11th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, San Antonio, TX, 18-20 March 1986.

(4) Rickman, W.J.: Epidemiology, Pathogenesis and Military Implications of HTLV-III Infection. Presented: Health Service Command Annual Pharmacy Conference. Aurora, CO, 5-9 May 1986.

(5) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Lymphocyte Subsets in Human Immunodeficiency Virus Infection: A Prospective Study. Presented: 2nd Annual Symposium of the Rocky Mountain Flow Cytometry Users Group, Albuquerque, New Mexico, 10-11 September 1986.

(6) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Human Immunodeficiency Virus (HIV) Natural History Study: Abnormal Proliferation of Leu-7 Positive Suppressor T Cells in Asymptomatic Seropositive Patients. Presented: United States Army AIDS Conference, Arlington, VA, 16-18 September 1986.

Publications:

Smolin, M.R., Hasbargen, J., and Rickman, W.J.: Profound Panhypogammaglobulinemia in a Renal Transplant Recipient. Ann. Int. Med.

(1) Date: 30 Sep 90 (2) Protocol #: 82/302 (3) Status: Ongoing

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Pari L. Morse (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words:
microbiology
microbiological techniques

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 5/90 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: FY 90 - Evaluation of a kit for the measurement of Beta 2 Microglobulin in sera. This has been useful in the evaluation of HIV patients. Evaluation of a ELISA kit (ortho) for the measurement of antibody to hepatitis C (formerly non-A, non-B). Testing of this kit is still underway, but it appears useful in current hepatitis and HIV patients. Evaluation of a western blot kit (CHIRON-RIBA) for the measurement of antibody to Hepatitis C in sera. This kit appears to be more specific than the ELISA. Further testing is required.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985;) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/300 (3) Status: Ongoing

(4) Title: Early Identification of *Borrelia burgdorferi* Antibody
in Human Sera

(5) Start Date: 1986 (6) Est Compl Date:

(7) Principal Investigator: Leo A. Andron, LTC, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
Sandy L. Tessier

(11) Key Words:
borrelia
lyme disease
spirochete

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To develop a sensitive and specific screening
assay to detect human IgM directed against *B. burgdorferi*. The
procedure proposed here will determine if the avidinbiotin system can
detect IgM antibody bound to *B. burgdorferi* on nitrocellulose paper
(NCP).

(16) Technical Approach: Preliminary studies confirmed that the probes
currently available against IgG are more sensitive and much more
specific than the anti IgM probes. A new IFA kit using the FIAX
fluorometer system that detects IgG/IgM antibodies to *B. burgdorferi* was
found to have the best sensitivity and specificity of currently
available commercial kits.

(17) Progress: Tests for Ab to tick antigens and direct tests for *B.*
burgdorferi antigens are in planning stages.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/30X (3) Status: Ongoing

(4) Title: Veterinarian and Veterinary Support Personnel Training in
Emergency Care Procedures for Laboratory Animals

(5) Start Date: Jul 88 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Ron E. Banks, MAJ, VC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:
Terrie R. Clark

(11) Key Words:
laboratory animals
emergency procedures
veterinary personnel training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: N/A b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To provide veterinary resources personnel
training in routine and emergency medical procedures in government owned
animals.

(16) Technical Approach: See Protocol.

(17) Progress: No animals used under this protocol, to date.
Fortunately, we have been able to conduct training on animals being
terminated for other research protocols.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/300A (3) Status: Completed

(4) Title: The Effect of the Topical Application of Minoxidil on Hair Growth in the "Nude" Mouse

(5) Start Date: 1989 (6) Est Compl Date: Dec. 1989

(7) Principal Investigator: Charles F. Ferris, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: T.P. O'Barr, Ph.D., DAC
(11) Key Words: James E. Fitzpatrick, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To use athymic mice as a model to determine the possible method of action of minoxidil in the promotion of hair growth.

(16) Technical Approach: Minoxidil applied 2X daily on the 5 treatment mice, carrier on the 5 control animals. Biopsies taken baseline and at 3 week intervals for 12 weeks. Comparisons of hair growth will be made histologically.

(17) Progress: Histologic evaluations have been made and all technical work has been completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

Date: 30 Sep 90 (1) (2) Protocol #: 89/301 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: I Skin Lesion Examination

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators:

(11) Key Words:
lupus erythematosus
immunofluorescence
icam

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ f. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether systemic lupus erythematosus, discoid lupus erythematosus, and subacute lupus erythematosus can be differentiated by specific auto-antibody binding patterns in the skin using immunofluorescent staining techniques.

(16) Technical Approach: Direct immunofluoresence, immunoperoxidase staining, H&E histology.

(17) Progress: In addition to the original IF studies we have been performing on the specimens, we are studying the tissue for the presence of intracellular adhesion molecule. This molecule is thought by many to be important in the trafficking of inflammatory cells through the epidermis.

Publications: 2 papers in progress - 3 abstracts given.

Presentations: Western Regional Meeting of the American Federation of Clinical Research.

National Meeting of the Society of Investigative Dermatology.

National Meeting of the American College of Rheumatology.

Poster presentation at the annual meeting of the American Society of Dermatopathology.

FAMC A.P.R. (RC: MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/302 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: Charles F. Ferris, MAJ, MS
Lela Lee, MD, UCHSC

(11) Key Words:
neonatal lupus erythematosus
autoantigens
autoantibodies
Ro

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The major objectives of this project are to characterize the autoantigens and autoantibodies involved in neonatal lupus erythematosus (NLE) and subacute cutaneous lupus erythematosus (SCLE) and to determine if certain characteristics of the autoantigens or autoantibodies can be related to the major clinical findings in these diseases.

(16) Technical Approach: Immunoblotting technique, cloning of Ro, rabbit immunization with Ro to attempt to produce animal model.

(17) Progress: It has been found that the La RNA-binding antigen is present in greater quantities in neonatal than in adult tissues. (These studies were done using antisera from patients who were from the Univ. of Colorado Medical Center.) There have been no direct benefits to the human subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/303 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: III The Study of the Effects of Ultraviolet Light on the Skin of Lupus Erythematosus Patients

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Scott Bennion, LTC, MC
Lela Lee, MD (8) Facility: FAMC
UCHSC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators:

(11) Key Words:
ultraviolet light
cutaneous lupus

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate and better correlate the cutaneous lupus subsets with their respective responses to ultraviolet light to be performed by phototesting patients with systemic lupus erythematosus (SLE), discoid lupus erythematosus (DLE) and subacute cutaneous lupus erythematosus (SCLE) then analyzing tissue and serologic specimens.

(16) Technical Approach: UV exposure followed by immunfluorescent.

(17) Progress: No progress. Currently we are having difficulty in determining the appropriate dosage of UV light. We are utilizing one patient who is at the UCHSC to adjust the area and time of UV light exposure. Until we feel comfortable with the UV dosage we are not going to begin a large study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/304 (3) Status: Ongoing

(4) Title: Evaluation of the Protofluor-Z as a Screening Tool for Lead Intoxication in Children

(5) Start Date: 30 Aug 89 (6) Est Compl Date: 30 Aug 91

(7) Principal Investigator: Joseph C. White, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: COL Askold Mosijczuk David B. Burgess, MD

(11) Key Words: blood lead heated graphite atomiztaion atomic absorpction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1000
d. Total Number of Subjects Enrolled to Date: 1400
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to reduce the cost of blood lead screening by placing hematofluorometers in a clinic setting. Only samples that fail the screening criteria need be analyzed further for anemia or lead intoxication.

(16) Technical Approach: Blood lead assayed by the gold standard method: atomic absorption, then reuslts compared with hematofluorometers measuring ZPP.

(17) Progress: 1000 samples assayed by aa; 800 samples assayed by hematofluorometer; methods developed for both instruments; survey certification complete in March, 1990. CDH portion complete. Army participation open.

Publications: Abstract Mar, 1990, Society of Armed Forced Medical Laboratory Scientists. Baltimore, MD.

Presentations: "Aqueous vs. Whole Bllood Calibration for Blood Lead by Electrothermal Zeeman Background Corrected Atomic Absorption", presented at the above cited meeting.

(1) Date: 30 Sep 90 (2) Protocol #: 90/300 (3) Status: Status

(4) Title: Videx (2', 3'dideoxyinosine, ddi) Treatment IND Protocol
No. 454-999-001 (Bristol-Myers Co)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Robert H. Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI/MDI (10) Associate Investigators:
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC
Rowland N. Hannon, PA-C/IDS

(11) Key Words:
HIV therapy
anti-retroviral therapy
reverse transcriptase inhibitor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment with ddi in patients with severe ARC or AIDS who clinically deteriorate on Zidovudine therapy and cannot participate in NIAID phase II study.

(16) Technical Approach: Study design is an open label salvage treatment using 2', 3' dideoxyinosine (ddi), in patients with advanced HIV disease. These patients are followed in the Infectious Disease Clinic at Fitzsimons Army Medical Center, and treated according to protocol, and in coordination with the sponsor.

(17) Progress: To date, one patient has been treated with ddi on this protocol. This patient has noted improved energy, appetite, and sense of well-being. A laboratory improvement in the CD4 helper cell count has been noted. This patient remains clinically stable, without obvious adverse side effects. This patient has returned to work full-time.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/301 (3) Status: Ongoing

(4) Title: Videx (2', 3'dideoxyinosine, ddI) Open Label Study
Protocol No. 454-999-002 (Bristol-Myers Co)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Robert H. Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC
Rowland N. Hannon, PA-C

(11) Key Words:
HIV therapy
anti-retroviral therapy
reverse transcriptase inhibitor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" **Peripheral neuropathy, which developed in one subject, was reported to the sponsor.**

(15) Study Objective: Treatment with ddi in patients with severe ARC or AIDS who clinically deteriorate on Zidovudine therapy and cannot participate in NIAID phase II study.

(16) Technical Approach: Study design is an open label salvage treatment using 2', 3' dideoxyinosine (ddi), in patient with advanced HIV disease. These patients are followed in the Infectious Disease Clinic at Fitzsimons Army Medical Center, and treated according to protocol, and in coordination with the sponsor.

(17) Progress: To date, one patient has been treated with ddi. This patient as noted above, had the drug discontinued secondary to peripheral neuropathy. this peripheral neuropathy has improved greatly off drug.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary

Two Advanced Trauma Life Support (ATLS) exercises were conducted during the year, using eight goats in the training of 40 staff physicians in the emergency management of casualties. 80-plus hours of training were provided, requiring 100 hours of support by Animal Resources Service personnel for planning, preparation, pre-op anesthesia induction, surgical preps, anesthesia monitoring, circulating, and cleanup.

Two pigs were used by the Urology Service in the training of two staff physicians and three residents in the management of renal trauma. Forty-five hours of training were received, requiring thirty hours of support by Animal Resources Service personnel.

Two kittens were used by the Neonatology Service for the training of 18 members of their staff in methods of resuscitation, which included endotracheal intubation and chest tube placement. Forty-five hours of training were received, requiring 12 hours of support by Animal Resources Service personnel.

Fifty-six rats were utilized in support of microsurgery training in the re-anastomosis of small vessels, providing 180-plus hours of training to 19 staff surgeons and residents. Orthopedic Surgery Service conducted 26 sessions; Plastic Surgery Service, 19; Urologic Surgery Service, nine; and Otolaryngology Service, two. Support of this training by Animal Resources Service personnel totalled nearly 270 hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and resterilization.

Ten enlisted members of Emergency Medicine Service, in MOS 91A, 91B, or 91C, were trained in suturing techniques. Training consisted of an overview of operating room procedure, including aseptic technique, operating room rules of etiquette, instruction in the surgical hand scrub, and gowning and gloving, and hands-on experience in dry and wet labs. Training was conducted on two days and utilized ten rats. Thirty-plus hours of training were received, requiring fifty-plus hours of support by Animal Resources Service personnel.

One exercise was conducted in "Resuscitation of Newborn" for the American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Ninety physicians and nurses received 135 hours of training in methods of resuscitation and endotracheal intubation, using 16 kittens and requiring sixty hours of support by Animal Resources Service personnel.

One goat was utilized under the Animal Resources Service training protocol for the training and evaluation of skills of personnel of this service. Four people participated in the exercise, including the staff veterinarian, two 91T animal specialists, and the 91D operating room specialist, receiving 36 hours of training. Preparation and cleanup contributed an additional 12 hours.

Cost of Training

ATLS Exercises	\$375/animal x 8 animals = \$ 3,000
In-service Training	375/animal x 1 animal = 375
Renal Trauma Exercises	290/animal x 2 animals = 580
Kitten Intubation, FAMC	270/animal x 2 animals = 540
Kitten Intubation, IHS	51/animal x 16 animals = 816
Rat Microsurgery	117/animal x 56 animals = 6,552
Suture Labs (Rats)	15/animal x 10 animals = 150
	<u>\$12,013</u>

There were no high school students trained during the year under the memorandum of agreement with Aurora Public Schools T.H. Pickens Technical Center.

DEPARTMENT OF OB-GYN

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/351 (3) Status: Ongoing

(4) Title: Section A: Master Protocol for Phase II Drug Studies in the
Treatment of Advanced Recurrent Pelvic Malignancies
GOG 26 A

(5) Start Date: 4/14/86 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol

(17) Progress: Ongoing

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/352 (3) Status: Ongoing

(4) Title: Section C: A Phase II Trial of CIS-Platinum
GOG 26 C

(5) Start Date: 4/27/77 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients; one partial remission. No serious adverse reactions.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/359 (3) Status: Ongoing

(4) Title: Section S: A Phase II Trial of VM26
GOG 26

(5) Start Date: 7/9/84 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Four patients, three progressive disease, 1 stable. No adverse reactions.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/378 (3) Status: Ongoing

(4) Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease

GOG 72

(5) Start Date: 12/20/83 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients, surgical-pathological study only, no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/379 (3) Status: Completed

(4) Title: Early Stage I Vulvar Cancer Treated with Ipsilateral
Superficial Inguinal Lymphadenectomy and Modified
Radical Hemivulvectomy (Phase III)

GOG 74

(5) Start Date: 10/17/83 (6) Est Compl Date: Unknown

(7) Principal Investigator: (8) Facility: FAMC
Mark E. Potter, MAJ, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results Completed
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol

(17) Progress: Closed, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/380 (3) Status: Ongoing

(4) Title: A Clinical Pathologic Study of Primary Malignant Melanoma
of the Vulva Treated by Modified Radical Hemivulvectomy
GOG 73

(5) Start Date: 11/1/83 (6) Est Compl Date: 1990

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol

(17) Progress: No patients entered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 82/35X-001 Status: Terminated

(4) Title: Repair of Femoral Artery and Fallopian Tube of Rabbit and Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Edward G. Lundblad, COL, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: No response for request of progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 83/351 (3) Status: Terminated

(4) Title: Danazol in the Treatment of Premenstrual Syndrome

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:
Diane C. Garrow, CPT, MS

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators
Edward Lundblad, COL, MC

(11) Key Words:
pms
therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 5 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if Danazol is effective in treating symptoms of pre-menstrual syndrome.

(16) Technical Approach: A double-blind, cross-over, placebo study in which patients who have documented PMS are treated for 2 months with Danazol and 2 months with placebo. While being treated, patients keep a diary of thier symptoms.

(17) Progress: No progress.

Publications and Presentations: Obstetrics and Gynecology, July 1987.

(1) Date: 30 Sep 90 (2) Protocol #: 87/351 (3) Status: Completed

(4) Title: A Randomized Comparison of Hydroxyurea Versus 5-FU
Infusion and Bolus Cisplatin as an Adjunct to Radiation
Therapy in Patients with Stages II-B, III and IV-A
Carcinoma of the Cervix and Negative Para-Aortic Nodes

GOG 85

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Mark E. Potter, MAJ, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group in the study
of malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/353 (3) Status: Ongoing

(4) Title: Evaluation of Cisplatin, Etoposide, and Bleomycin
Induction Followed by Vincristine, Dactinomycin and
Cyclophosphamide Consolidation in Advanced Ovarian
Germ Cell Tumors

GOG 90

(5) Start Date: 9/18/86 (6) Est Compl Date: 1991

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/354 (3) Status: Ongoing

(4) Title: Randomized Clinical Trial for the Treatment of Women with Selected Stage IAi & IAii & IBii Ovarian Cancer (Phase III) GOG 95

(5) Start Date: 9/22/86 (6) Est Compl Date: 1994

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words: pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/356 (3) Status: Completed

(4) Title: A Phase III Randomized Study of Cyclophosphamide and Cisplatin in Patients with Suboptimal Stage III and State IV Epithelial Ovarian Carcinoma Comparing Intensive and Non-Intensive Schedules

GOG 97

(5) Start Date: 12/1/86 (6) Est Compl Date: 1990

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words: pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Completed
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Seven patients; 1 complete response, 3 alive with no evidence of disease; 5 dead of disease. No adverse reactions.

Publication and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

1) Date: 30 Sep 90 (2) Protocol #: 87/358 (3) Status: Ongoing

(4) Title: Evaluation of Intraperitoneal Chronic Phosphate After
Negative Second-Look Laparotomy in Ovarian Carcinoma

GOG 93

(5) Start Date: 6/1/87 (6) Est Compl Date: 1992

(7) Principal Investigator: (8) Facility: FAMC
Mark E. Potter, MAJ, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/359 (3) Status: Ongoing

(4) Title: Adjunctive Radiation Therapy in Intermediate Risk
Endometrial Carcinoma

GOG 99

(5) Start Date: 6/1/87 (6) Est Compl Date: 1991

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/350 (3) Status: Ongoing

(4) Title: Radiation Therapy vs No Further Therapy in Selected Patients with Stage IB Invasive Carcinoma of the Cervix

GOG 92

(5) Start Date: 3/9/88 (6) Est Compl Date: 1992

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words: pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/351 (3) Status: Ongoing

4) Title: A Phase II Study of the Treatment of Stage III and IV
Disease of Advanced Endometrial Carcinoma and All Stages
of Papillary Serious Carcinoma and Clear Cell Carcinoma
of the Endometrium with Total Abdominal Radiation Therapy
GOG 94

(5) Start Date: 12/22/86

(6) Est Compl Date: 1990

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/355 (3) Status: Ongoing

(4) Title: Intraperitoneal (SWOG8501) Intraperitoneal Cis-Platinum
and Cyclophosphamide IV vs Intravenous Cis-Platinum
and Cyclophosphamide IV in Patients with Optimal
Stage III Ovarian Cancer

GOG 104

(5) Start Date: 6/15/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/358 (3) Status: Ongoing

(4) Title: Monoclonal Antibody Against Free Beta HCG to Predict
Development of PGTD in patients with Hydaditoform Mole

GOG #100

(5) Start Date: 1/88 (6) Est Compl Date: 1/92

(7) Principal Investigator: (8) Facility: FAMC
Mark E. Potter, MAJ, MC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or s
ponsor for studies conducted under an FDA-awarded IND. May be continued
on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/359 (3) Status: Ongoing

(4) Title: GOG Protocol I02A - Master Protocol for Intraperitoneal Drug Studies in Residual Ovarian Malignancies after Second-Look Surgery

(5) Start Date: 1/4/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators: Francis J. Major, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/360 (3) Status: Ongoing

(4) Title: A Phase II Trial of hydroxurea, DTIC and VP-16
in Patients with Advanced Uterine Sarcomas

87C

(5) Start Date: 3/7/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/350 (3) Status: Completed

(4) Title: A Phase II Trial of Echinomycin (NSC#E526417) in Patients with Advanced Squamous Cell Carcinoma of the Cervix

GOG 76H

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
echinomycin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Completed
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluation of the efficacy and safety of echinomycin in the treatment of patients with advanced squamous cell carcinoma of the cervix.

(16) Technical Approach: This is a non-randomized study; all patients will be treated identically.

(17) Progress: Closed, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/351 (3) Status: Ongoing

(4) Title: A Phase II Trial of VP-16 in Patients with Advanced
or Recurrent Uterine Sarcoma

GOG 87D

(5) Start Date: Aug 89 (6) Est Compl Date: 1994

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
VP-16
uterine sarcoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To identify active drugs against each of the two major types of sarcomas which have a high recurrence rate and against which combination chemotherapy has not been effective. VP-16 has been included because it has been shown to have elicited some response in a very small sample and the data suggest the need for study in previously untreated patients.

(16) Technical Approach: This is a non-randomized study which will involve treating an average sample size of 30 evaluable patients per drug. This method allows for rapid replacement of ineffective agents.

(17) Progress: No patients have been enrolled at FAMC to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/352 (3) Status: Ongoing

(4) Title: A Phase II Evaluation of Preoperative Chemoradiation
for Patients with Advanced Vulvar Cancer
GOG 101

(5) Start Date: Aug 89 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
preoperative chemoradiation
vulvar cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if using preoperative chemoradiotherapy will obviate the need for pelvic exenteration in patients with advanced vulvar cancer; will its use allow less extensive surgical resection without compromising survival or cure.

(16) Technical Approach: All patients will be treated with split-course radiotherapy to the primary lesion as well as chemotherapy. Only patients with positive groin nodes will receive additional radiotherapy to the groin and pelvic nodes. Four to eight weeks after radiotherapy is completed, all patients will have surgical resection of the primary tumor plus bilateral groin node dissection.

(17) Progress: No FAMC patients enrolled to date on this recently approved protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/353 (3) Status: Completed

(4) Title: A Phase II Study of Intraperitoneal Administration of
Cisplatin (NSC#119875) and Recombinant Alpha 2 Interferon
in Residual Ovarian Carcinoma

GOG 102C

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
cisplatin
interferon
ovarian carcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Completed
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of these two drugs used
in combination when there has been a partial response to Cisplatin as
determined by second-look surgery.

(16) Technical Approach: All patients accepted for inclusion in this
study will receive the above-named drugs. Any dosage modifications will
be based on the type and degree of toxicity, if any, and is carefully
defined in the body of the protocol.

(17) Progress: Closed, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/354 (3) Status: Ongoing

(4) Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus
Cisplatin in Recurrent Endometrial Adenocarcinoma
Previously Diagnosed as Primary Stage III or IV
(Phase III)

GOG 107

(5) Start Date: Aug 89 (6) Est Compl Date: 6/92

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

doxorubicin
cisplatin
endometrial adenocarcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Ongoing_
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether the addition of cisplatin
to doxorubicin offers significant improvement in the frequency of
objective response, in the duration of progression-free interval and the
length of survival as compared with the administration of doxorubicin
alone.

(16) Technical Approach: Patients will be randomized to one of the two
regimens and will be treated until the maximum tolerated dose of
doxorubicin is reached or until there is progression of disease.

(17) Progress: No FAMC patients enrolled.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/355 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Cisplatin (NSC#119875)
and Etoposide (VP-16) (NSC #141540) in Patients with
Residual Ovarian Carcinoma (Phase II)
GOG 102E

(5) Start Date: 1989 (6) Est Compl Date: 2/91

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:
cisplatin
etoposide
carcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of these two drugs used
in combination when there has been a partial response to Cisplatin as
determined by second-look surgery.

(16) Technical Approach: 200 mgm/M2 of Etoposide and 100 mgm/M2 of
Cisplatin every 4 weeks for six doses.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/356 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Alpha Recombinant Interferon (aIFN) in Residual Ovarian Carcinoma (Phase II)
GOG 102F

(5) Start Date: 1989 (6) Est Compl Date: 2/91

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:
Interferon
carcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 4/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of this agent when it is administered directly into the area where the tumor is localized when there has been a partial response to Cisplatin.

(16) Technical Approach: 50x10⁶ units of Interferon administered IP in 250ml NS after 1750 ml dialysate solution is given IP via the IP catheter. Therapy is given weekly for 12 weeks.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/350 (3) Status: Ongoing

(4) Title: Ifosfamide and the Uroprotector Mesna, with or without
Cisplatin, in Patients with Advanced or Recurrent Mixed
Mesodermal Tumors of the Uterus

GOG 108

(5) Start Date: 1990 (6) Est Compl Date: 10/93

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: New study, not yet open.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/351 (3) Status: Ongoing

(4) Title: A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

GOG 109

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in teh GOG protocol in the study of Cancer.

(16) Technical Approach: See protocol.

(17) Progress: New study, not yet open.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/352 (3) Status: Ongoing

(4) Title: A Phase II Trial of Didemnin B in Patients with Advanced Pelvic Malignancies

GOG #26EE

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14) _____"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/353 (3) Status: Ongoing

(4) Title: A Phase II Trial of Fazarabine in Patients with
Advanced/Recurrent Pelvic Malignancies
GOG 26GG

(5) Start Date: 1990 (6) Est Compl Date: Undetermined

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/354 (3) Status: Ongoing

(4) Title: A Phase II Trial of 5-Fluorouracil and Leucovorin in
Advanced Metastatic or Recurrent Pelvic Malignancies

GOG #26HH

(5) Start Date: 1990 (6) Est Compl Date: Undetermined

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate
Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: New study, no patients.

Publications and Presentations: None.

(1) Date: 30 Sep 90 (2) Protocol #: 90/355 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Cisplatin (NSC#119875)
and Thiotepa in Residual Ovarian Carcinoma

GOG 102G

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: New study not yet started.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/356 (3) Status: Ongoing

(4) Title: A Phase III Randomized Study of Cyclophosphamide (NSC#26271) and Cisplatin (NSC#19875) Versus Taxol (NSC#125973) and Cisplatin (NSC#119875) in patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma

GOG 111

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 0 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: New study, no patients.

Publications and Presentations: None

DEPARTMENT OF PEDIATRICS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 78/40X-001 (3) Status: Ongoing

(4) Title: Use of Laboratory Animals (Cats) to Teach Medical Skills

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Beverly A. Anderson, MAJ, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

John P. Kinsella, MAJ, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Teaching protocol.

(16) Technical Approach: See protocol.

(17) Progress: Annual laboratory exercise continues to be successful in teaching intubation/chest tube placement skills to Pediatric House Officers. This remains an excellent model for teaching skills.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 82/403 (3) Status: Ongoing

(4) Title: Rare Tumor Protocol for Childhood Solid Tumor
Malignancies, Ancillary
POG 7799

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators
Thomas Carter, COL, MC
(11) Key Words: drug therapy Jeffrey Clark, COL, MC
Randal Henderson, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___0_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Two patients have been registered at FAMC, one pt. with
superficial melanoma of the eye is continuing to do well, in complete
remission. The other patient, a newborn with metastatic
undifferentiated sarcoma of the face has died. The study remains open
for new patient entry.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 82/414 (3) Status: Ongoing

(4) Title: NWTs Long Term Follow-Up Study: A Non-therapeutic Study
POG 8158

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the P group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons, the study remains open to new patient registrations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 82/420 (3) Status: Ongoing

(4) Title: Intergroup Rhabdomyosarcoma Study III

POG 8451

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators

(11) Key Words:
drug therapy

Dr. Clark
Dr. Reddy
Dr. Henderson
Dr. Bodlien

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Four patients have been entered at FAMC. The first patient has relapsed with metastatic disease after having completed the prescribed two years of chemotherapy and has died. Another patient, who entered in 1987 achieved complete remission status of his undifferentiated sarcoma of the pelvis region, but has subsequently died of overwhelming sepsis as a result of severe myelosuppression from chemotherapy; another patient entered in October 1986 had pulmonary metastases of chest and died on 10 July 1990. The other patient who was entered in 1988 with nasopharyngeal rhabdomyosarcoma is currently in complete remission status having completed chemotherapy. The study remains open to new patient entry.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 83/401 (3) Status: Terminated

(4) Title: Prevalence of Endometriosis Externa in Adolescent Women Complaining of Severe Dysmenorrhea

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:
David W. Wells, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
endometriosis
dysmenorrhea

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 622
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: An epidemiologic survey of young women will document the prevalence of symptomatic endometriosis externa in a middle class primary care population of adolescent women complaining of dysmenorrhea. This prevalent figure will tell the health care provider how alert he has to be to this condition.

(16) Technical Approach: This retrospective stage of epidemiologic survey is designed to isolate by questionnaire those young women who might have endometriosis and subject them to laparoscopy.

(17) Progress: No progress has been made on this protocol since the departure of the original principal investigator.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/403 (3) Status: Completed

(4) Title: Prophylactic Intravenous Immunoglobulin for Infections
in High Risk Neonates

(5) Start Date: March 86 (6) Est Compl Date: 1989

(7) Principal Investigator: C. Gilbert Frank, LTC, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators
Beverly A. Anderson, MAJ, MC

(11) Key Words:
high risk neonates
prophylactic IVIG

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 4423
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To evaluate in a double blind manner the
effectiveness compared to an albumin placebo of IVIG preventing
infectious disease and/or reducing morbidity and mortality in the high
risk neonate.

(16) Technical Approach: < 2,000g, < 34 wks gestation are eligible for
the study. Routine evaluations and therapy will be given as necessary
to all infants. IgG antibody titers will be drawn pre and post infusion
as well as at 1, 2, and 8 weeks. The incidence of infection as well as
mortality and morbidity will be evaluated.

(17) Progress: An FDA advisory panel reviewed study data and recommeded
conclusion of the study and analysis and publication of results. Data
collection was completed in July 1989 and additionnal study material
returned to Sandoz per protocol. Study presently in evaluation stage.

Publications and Presentations: Prophylactic Intravenous Immunoglobulin
(IVIG) in High Risk Neonates. Presented. 16th Aspen Conferece on
Perinatal Research (ACPR) Aspen, CO July, 1987.

Abstracts and presentations "Intravenous Immunoglobulin Therapy of Neonatal Sepsis" and "Intravenous Immunoglobulin Prophylaxis of Late-Onset Septicemia in Neonates", Society for Pediatric Research meeting, Anaheim, CA, May 90.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/408 (3) Status: Ongoing

(4) Title: Laboratory Classification in Acute Lymphoid Leukemia of
Childhood (ALinC 14C) Phase III
POG 8600

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words: drug therapy (10) Dr. Reddy
Dr. Bodlien
Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: During the past fiscal year, two new patients have been
entered on study. Eight patients at FAMC are on this study. One of
those patients was entered at Walter Reed and transferred here. Another
patient was entered at Keesler AFB, transferred here and subsequently
transferred to Prince Charles Hospital in Salt Lake City, Ut. Since
this is a laboratory classification study, there is no toxicity. The
study is ongoing and is open to new pt. entry. One of the patients (MP)
entered on study one year ago has a unique ALL phenotype. The patient
has markers of T-cell ALL as well as being Philadelphia chromosome
positive. This is a new finding in the protocol and in the Pediatric
Oncology Group. The study is ongoing and is open to new patient entry.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 86/410 (3) Status: Ongoing

(4) Title: ALinC #14: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALinC#14) - A Pediatric Oncology Group Phase III Study
POG 8602

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators
Dr. Reddy
(11) Key Words: drug therapy Dr. Boulien
Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: There are currently eight patients on this study. One of the 8 patients on study was entered at Walter Reed and transferred to FAMC. This patient has subsequently transferred to Roswell Park Memorial Institute in Buffalo, New York. Another patient was entered at Keesler AFB, transferred here and recently transferred to Prince Charles Hospital. Responsibility for POG data will remain with Dr. Mosijczuk. A previous patient diagnosed at FAMC has subsequently been transferred to Travis Air Force Base and continues on protocol with information being related periodically to principal investigator at Fitzsimons. Significant toxicity in two of the 8 patients has included severe myelosuppression, septicemia in one patient, secondary to high-dose Methotrexate and high-dose Ara-C chemotherapy as per protocol. Otherwise, patients are tolerating therapy well and all remain in complete remission status, some having completed treatment. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/401 (3) Status: Ongoing

(4) Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA Hodgkins Disease in Pediatric Patients, A Pediatric Oncology Group Phase III Study
POG 8625/26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators

(11) Key Words: drug therapy Dr. Reddy
Dr. Bodlien
Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient has been entered at FAMC. The patient achieved complete remission status and is currently doing well, having completed all therapy as per protocol. No unusual toxicities have been encountered. The study remains open to new patient entry.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/403 (3) Status: Completed

(4) Title: Randomized Phase II Study of Carboplatin (CBCDA) vs. CHIP in Treatment of Children with Progressive or Recurrent Brain Tumor
POG 8638

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Carter
(11) Key Words: drug therapy Dr. REddy
Dr. Bodlien

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient, a 14-year-old girl with recurrent pontine glioma was entered on this study in November of 1986. The patient is currently off chemotherapy, doing well with stable disease. Toxicity has been limited to moderate myelosuppression. The study is closed to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/404 (3) Status: Ongoing

(4) Title: A Study of Childhood Soft Tissue Sarcomas (STS) Other than Rhabdomyosarcoma and Its Variants, A Pediatric Oncology Group Phase III Study
POG 8653/54

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Clark
(11) Key Words: drug therapy Dr. Reddy
Dr. Bodlien

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/405 (3) Status: Completed

(4) Title: Front Loading Chemotherapy in Children with Increased Risk Medulloblastoma
POG 8695

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Carter

(11) Key Words: drug therapy
Dr. Reddy
Dr. Bodlien
Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 1 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. M / be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient was entered at FAMC in April of 1987. The patient suffered severe grade IV myelosuppression secondary to the high-dose Cyclophosphamide as per protocol but recovered. However, during subsequent radiation therapy, the patient developed severe bone marrow hypoplasia lasting for two months but eventually recovered and refused further radiation therapy. He is currently off study, and is alive with recurrent tumor. Nationally, 39 patients have been entered on protocol. 30 patients are evaluable for response. Of these, the following post chemotherapy responses have been documented prior to radiation therapy: CR 10 patients, PR 5 patients, SD (stable disease) 17 patients, progressive disease 4 patients. Most important toxicity has been severe myelosuppression due to the high dose Cyclophosphamide which is expected. Although there have been 2-3 week delays in radiation therapy because of the myelosuppression, most patients have been able to complete chemotherapy and radiation as intended. The study is closed to new patient entry.

Publications and Presentations:

Dr. Mosijczuk presented an update on the status of the study at the Annual UCHSC Pediatric Hematology Seminar in Aspen, Colorado on March 31, 1989.

Dr. Mosijczuk presented an update on the status of the study at the Semi-annual Pediatric Oncology Group Meeting in Clearwater, Florida, April 1989.

Dr. Mosijczuk presented a poster abstract of the protocol results at the International Pediatric Neuro-Oncology meeting in Seattle, Washington on 2 June 1989.

Dr. Mosijczuk presented an update on the study at the semi-annual Pediatric Oncology Meeting, Orland, FL, April 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/406 (3) Status: Completed

(4) Title: Effects of Oral Contraceptive Agents on Coagulation
Parameters in the Adolescent Patient

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Patrice T. Gaspard, MAJ, MC
Vishnu Reddy, LTC, MC
Judy Barber, DAC
Patricia Rush, DAC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators

(11) Key Words:
oral contraceptive agents
thromboembolic disorders
clotting factors

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 1990 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 45
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To assess if the newer oral contraceptive agents
used today have effects on the levels of clotting factors in adolescent
patients (specifically Factor VIII, PT, PTT, fibrinogen, Antithromb III,
and protein C).

(16) Technical Approach: Patients have the above studies measured at
baseline, then 3 months, 6 months and one year after being on oral con-
traceptives.

(17) Progress: Currently in process of analyzing data on computer
patients to assess any trends. Following patients already enrolled but
not entering any new patients until stats on current patients are
analyzed. Statistics revealed difference between smokers and nonsmokers
in SATT III and fibrinogen. Completed study.

Publications and Presentations: Presented but not published.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 87/408 (3) Status: Terminated

(4) Title: Efficacy of Prophylactic Anti-Migraine Therapy in the Adolescent Therapy Patient - A Double Blinded Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Sharon Freeman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators

(11) Key Words: migraine headaches verapamil
MAJ Miller, MD
LTC Dorsett, MD
Michael G. Schaffrinna, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Terminated
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine efficacy of prophylactic verapamil in a double blinded study in adolescent migraine sufferers. At the same time this study would establish a per kilogram dose for younger adolescents.

(16) Technical Approach: Patients will be evaluated at entry for the diagnosis of migraine headaches with a frequency per history of at least two events per month. Presence of organic disease will be evaluated via physical and laboratory evaluation. If no contraindications to verapamil exist then enrollment will occur. Over the next two months no medications will be given. The patient will see two different neurologists who will again evaluate them and fill out an interval history sheet. If both concur with the diagnosis, the patient will be randomly assigned by the pediatric pharmacy to receive either verapamil or placebo for two months. The patient will be seen every month for evaluation of therapy. At the end of two months, they will have a 7 day washout period. Then they will take the counterpart placebo or verapamil depending on which they were initially assigned. They will again take the drug for two months at which time the study will be completed.

(17) Progress: No progress was made due to inability to obtain the placebo. No publications or presentations.

(1) Date: 30 Sep 90 (2) Protocol #: 88/400 (3) Status: Ongoing

(4) Title: T Cell#3 Protocol - A Pediatric Oncology Group Phase III Study

POG 8704

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL,MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
B. Vishnu Reddy, LTC, MC
Randal Henderson, MAJ, MC
John M. Bodlien, CPT, MS

(11) Key Words:
T cell ALL

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 1 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The one patient entered at FAMC (MP) is an eight-year-old girl who presented with an extremely high white count at diagnosis (852,000) and was found to have T-cell ALL. The patient responded well to initial leukopheresis and chemotherapy according to protocol. She relapsed 8 months from diagnosis and died. Toxicity has been the expected severe myelosuppression. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/401 (3) Status: Completed

(4) Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma
in Children > 365 Days at Diagnosis

POG 8741/42

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
B. Vishnu Reddy, LTC, MC
Randal Henderson, MAJ, MC
John M. Bodlien, CPT, MS
Jeffrey R. Clark, COL, MC

(11) Key Words:
treatment of stage D
neuroblastoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC on this study.
The study is closed to new patient entry.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/402 (3) Status: Ongoing

(4) Title: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma POG 8759

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
B. Vishnu Reddy, LTC, MC
David Hahn, LTC, MC
John M. Bodlien, CPT, MS
Jeffrey R. Clark, COL, MC

(11) Key Words:
phase II agents in untreated
or recurrent osteosarcoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC on this study. The study remains open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/403 (3) Status: Completed

(4) Title: Evaluation of Response and Toxicity of Ifosfamide and
VP-16-213 in Children with Resistant Malignant Tumors
POG 8763

(5) Start Date: Dec 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators
John M. Bodlien, CPT, MS

(11) Key Words:
ifosfamide
VP-16

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 2 _____
d. Total Number of Subjects Enrolled to Date: 1 _____ 3 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". ONE PATIENT WAS STARTED ON
TREATMENT ACCORDING TO PROTOCOL ON A COMPASSIONATE BASIS FROM THE NCI.
HE IS NOT OFFICIALLY ENTERED ON PROTOCOL.

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Three patients have been entered at FAMC on this study.
Patient (PA) has had progressive tumors and died. Patient (DS) had
recurrent osteosarcoma and showed no response on this study and died.
Patient (NO) with recurrent metastatic hepatoblastoma, developed sudden
coma after only one dose of Ifosfamide. This was due to a silent
cerebral metastasis. Patient recovered and was taken off study. Study
recently closed to new patient entry.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/404 (3) Status: Ongoing

(4) Title: Ceftriaxone vs Amoxicillin/Clavulanate for Initial Empirical Therapy of Occult Bacteremia in Children

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Frederic W. Bruhn, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
bacteremia
Ceftriaxone
Clavulanate

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if one of the antibiotic regimens used for the emperic therapy of occult bacteremia will be more effective in preventing serious complications.

(16) Technical Approach: See protocol.

(17) Progress: Patient enrollment ongoing, 180 nationwide/2 at FAMC; preliminary data shows both therapies effective.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/405A (3) Status: Ongoing

(4) Title: Macromolecular Absorption in the Post-Asphyxiated
Small Intestine of the Adult Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Kevin J. Kelly, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
macromolecular absorption
asphyxial injury

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 48
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This protocol will attempt to demonstrate the mechanism of movement of whole protein macromolecules through small intestinal absorptive cells which have been subjected to an asphyxial injury, as compared to controls.

(16) Technical Approach: No new experimental techniques have been introduced. The animals are still anesthetized and subjected to laparotomy, as previously approved. The intestinal sacs constructed post-removal are now subjected to a new experimental variable. They are being incubated in the same nutrient media as previously described with the addition of a metabolic inhibitor 2,4 dinitrophenol. This will attempt to determine active vs. passive transport.

(17) Progress: To date, 48 animals have been used to expand the N values of both the control and experimental groups. To date, we have data on 16 gut sacs per group. It is very apparent that the experimental groups transport whole protein at a rate three times greater than the control groups. In addition, the metabolic inhibitor experiments preliminarily demonstrate total cessation of transport in both the experimental and control groups suggesting an active transport mechanism in both. These findings need to be confirmed in a larger sample of control and experimental animals as well as by light and electron microscopic evaluation. Once these experiments are completed, the gut sacs need to be then incubated from rats that have been pre-treated with therapeutic doses of theophylline. The sacs will then be exposed to the non-absorbable carbohydrate lactulose. No new data for FY 90.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/408A (3) Status: Ongoing

(4) Title: The Effect of Human/Animal Interaction on Stress Levels During Outpatient Pediatric Oncology Visits

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator: Mary Woolverton, MSW
Terri R. Clark, CPT, VC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Askold Mosijczuk, COL, MC

(11) Key Words:
animal interaction
stress reduction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 5/90 b. Review Results: Ongoing_
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's stress level as measured by blood pressure and fingertip temperature; b. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's anxiety level (as measured by behavioral questionnaires) or discomfort as measured by the visual analog pain scale).

(16) Technical Approach: Blood pressure, temperature and questionnaire will be used to evaluate stress levels in study subject.

(17) Progress: A total of 12 patients have been entered into the study. Due to investigators' time constraints we have not been able to gather data as projected. Hope is to start enrolling patients in fall of 1990.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 88/409 (3) Status: Terminated

(4) Title: The Correlation of Perinatal Events with Neonatal Morbidity: A Scoring System

(5) Start Date: Oct 88 (6) Est Compl Date: Oct 90

(7) Principal Investigator: Brian S. Carter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Neonatal (10) Associate Investigators: C. Gilbert Frank, LTC, MC

(11) Key Words:
neonatal morbidity
scoring system

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 200
d. Total Number of Subjects Enrolled to Date: 3000
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test the hypothesis that the combination of 3 commonly used means of fetal and neonatal assessment (fetal heart-rate tracings, umbilical arterial base deficit, and the 5 min. Apgar score) when combined in a scoring system can allow for the prediction of neonatal morbidity in the first 28 days of life.

(16) Technical Approach: A prospective, observational study. Enrollment is by chart review on all near-term (> 36 weeks gest.) newborns that had umbilical cord blood drawn in the delivery room, and were monitored in utero. Scores are assigned and the clinical courses observed for outcome.

(17) Progress: Due to lack of interest the protocol became inactive in December 1989. As the Labor & Delivery service at FAMC experienced a decline in the number of births of prospective eligible study patients since the initiation of the protocol an alternate Labor & Delivery service was identified and is currently being studied.

Publications and Presentations: None

FAMC A.P.R. (RCS MFD 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/400 (3) Status: Ongoing

(4) Title: Protocol for Second Induction and Maintenance in
Childhood Acute Lymphoblastic Leukemia (SIMAL #5)

POG 8710

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Hemo/Oncol (10) Associate Investigators:
Dr. Reddy
Dr. Bodlien

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/401A (3) Status: Ongoing

(4) Title: An Observational Study on the Response of Children to the Presence of a Stuffed Animal VS a Live Animal During a Neuromuscular Exam

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: Mary Woolverton, MSW
Terri R. Clark, CPT, VC (8) Facility: FAMC

(9) Dept/Svc: PEDS/EFMP (10) Associate Investigators: David Hahn, LTC, MC

(11) Key Words:
animal interaction
stress reduction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 36
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: By introducing an interaction with an animal we may be able to decrease anxiety and lessen the apprehension associated with potentially uncomfortable hospital visits.

(16) Technical Approach: See protocol

(17) Progress: Children seen in neuromuscular clinic are introduced first to a large white stuffed rabbit and later a dog/or cat to see how it effects their stress level during their physical exam in the clinic. This is documented on films and by independent observation. A total of 26 patients have been observed. This study is being actively pursued with more patients enrolled each month as they qualify by age and mental capacity. Children who have been to the clinic and around the animals now ask for them as soon as they come in.

Publications and Presentations: 3 presentations.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/402 (3) Status: Completed

(4) Title: Newborn Informed Consent Study

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: C. Gilbert Frank, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Newborn Svc (10) Associate Investigators:
Brian Carter, CPT, MC
Patti Paige, MAJ, AN

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluation of parental understanding of procedures and counseling performed following admission of their infant to the Newborn Intensive Care Unit.

(16) Technical Approach: Interview technique by single investigator with correlation of interview information with the medical record.

(17) Progress: Patient enrollment and parent interviews are complete. Data accumulation phase complete. Anticipate interpretation to begin in the summer of 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/403A (3) Status: Ongoing

(4) Title: Effect of Inflammation in Chronic Pneumonia in Rats Due to Pseudomonas Aeruginosa----Medication by Bacterial Exoproducts

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: LeRoy M. Graham, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Pulmonary (10) Associate Investigators:
Michael L. Vasil, PhD
Norbert F. Voelkel, MD
Kurt R. Stenmark, MD

(11) Key Words:
pneumonia
pseudomonas aeruginosa
rats

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish an animal model for cystic fibrosis using rats.

(16) Technical Approach: See protocol

(17) Progress: Equipment being manufactured/purchased. Clinical duties have precluded work on this project to date. It is anticipated work may begin in the next 6 months.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/404 (3) Status: Ongoing

(4) Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD)
+ or - Low Dose Total Nodal Radiation Therapy in the
Treatment of Stages IIB, IIIA-2, IIIB, IV Hodgkin's
Disease in Pediatric Patients
POG 8725

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Hemo/Oncol (10) Associate Investigators:
Dr. Reddy
(11) Key Words: Dr. Clark
Dr. Henderson
Dr. Bodlien

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/405 (3) Status: Ongoing

(4) Title: Clonidine Treatment of Constitutional Delay of Growth and Puberty--A Prospective Double Blind Study

(5) Start Date: Sep 89 (6) Est Compl Date: Mar 92

(7) Principal Investigator: Robert Slover, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Adol Med (10) Associate Investigators:
Linda Brantner, CPT, MC
Linda Ikle, PhD

(11) Key Words:
growth delay
clonidine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 5/90 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether chronic oral clonidine therapy is effective when compared to placebo in accelerating linear growth in constitutionally delayed pre-pubertal pediatric and adolescent patients.

(16) Technical Approach: Double-blind crossover study of 20 subjects.

(17) Progress: Dr. Brantner who originally submitted the protocol has moved to Tyler AMC. I plan to start enrolling patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/406 (3) Status: Completed

(4) Title: A Phase I Study of Hyperfractionation Radiation in Brain Stem Glioma in Children

POG 8495

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS\Hema/Oncol (10) Associate Investigators:
Dr. Carter
(11) Key Words: Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 3 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Three patients have been entered at FAMC. 2 patients with classic signs of high grade pontine glioma responded initially but subsequently relapsed. Another patient with symptoms consistent with low grade pontine glioma continues to do well two years after completing radiation treatment. Study is closed for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/407 (3) Status: Ongoing

(4) Title: Baby Development Follow-up Network Project

(5) Start Date: (6) Est Compl Date: Dec 90

(7) Principal Investigator: Beverly A. Anderson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Newborn (10) Associate Investigators: Majorie Feinberg EFMP
C. Gilbert Frank, MD

(11) Key Words: developmental evaluation
high risk infants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Developmental evaluation of all infants with birth weight of 1,000 to 1,500 grams who are Colorado residents.

(16) Technical Approach: The examinations will be done at 36-40 weeks post-conceptual age and eight months corrected age by physical or occupational therapists with at least one year experience in the Newborn Nursery who have been given special training sessions for this project.

(17) Progress: The infants enrolled in the followup study have continued to receive both medical and developmental evaluations routinely and per protocol. The occupational/physical therapists have been allowed to utilize current testing materials in a controlled manner and the communication between health care givers and the families of this high risk population has been optimized.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/408 (3) Status: Ongoing

(4) Title: Comparison of Cotinine Hair and Saliva Analysis in
the Determination of Passive and Active Cigarette
Smoking Exposure in Adolescents

(5) Start Date: Oct 89 (6) Est Compl Date: 6/91

(7) Principal Investigator: Neil Goodman, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:
Joseph White, MAJ, MS
Ian Stewart, M.S.

(11) Key Words:
cigarette smoke exposure
passive smoking

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if commercially available EIA
techniques for detecting cotinine correlate with historical survey to
determine if the values accurately reflect the smoking history.

(16) Technical Approach: Small amounts of hair and saliva will
obtained for EIA assay of cotinine from an adolescent population. A
self-administered questionnaire detailing history of passive and active
smoking over the preceding 3 months will also be given.

(17) Progress: Assay method for cotinine in hair has been developed
and is extremely sensitive and reliable. This is the first such assay
that will allow cotinine measurement from hair via a monoclonal antibody
technique. Subject sampling will begin in Aug 90. Initial publication
of assay technique is being sought at this time.

Publications and Presentations: None at present time.

(1) Date: 30 Sep 90 (2) Protocol #: 90/400 (3) Status: Terminated

(4) Title: A Treatment IND for Retrovir Brand Zidovudine (AZT)
Therapy of Pediatric Patients with HIV Disease
(TX 304-IND-33,760)

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Shannon M. Harrison, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI/PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: This protocol was cancelled.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/401 (3) Status: Ongoing

(4) Title: Experience with Multiple Doses of Survanta in Premature Infants

(5) Start Date: 1990 (6) Est Compl Date: Indefinite

(7) Principal Investigator: John Kinsella, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Neonatal/PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment IND; surfactant therapy for premature infants with hyaline membrane disease.

(16) Technical Approach: Surfactant is instilled through the endotracheal tube; up to four doses may be given as indicated by respiratory status.

(17) Progress: No progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HCCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/402A (3) Status: Ongoing

(4) Title: Training for Pediatricians in Emergency Procedures

(5) Start Date: 1990 (6) Est Compl Date: Indefinite

(7) Principal Investigator: John Kinsella, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Neonatal/PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To train pediatricians in invasive emergency procedures.

(16) Technical Approach: Goat, swine, and rabbits are to be used for training in intubation, femoral venous and arterial cutdown procedures, thoracostomy tube placement, and percutaneous jugular venous catheter placement.

(17) Progress: First training course is to be scheduled for Fall 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/403A (3) Status: Ongoing

(4) Title: Studies of the Hemodynamic Consequences of Partial
Cardiopulmonary Bypass in the Lamb

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: John Kinsella, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Neonatal/PEDS (10) Associate Investigators:
Adam A Rosenberg, MD

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To study the distribution of blood flow during
partial cardiopulmonary bypass in lambs.

(16) Technical Approach: Blood flow will be measured using
microspheres during control period and at two levels of cardiopulmonary
bypass (50 and 100 ml/kg/min).

(17) Progress: This protocol is scheduled for funding in FY 91.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/404 (3) Status: Completed

(4) Title: Revision of Bayley Scales of Infant Development

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Linda Ikle, Ph.D. (8) Facility: FAMC

(9) Dept/Svc: Excep. Fam. Mbr/PEDS (10) Associate Investigators:

(11) Key Words:
bayley scales
human infants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 60
d. Total Number of Subjects Enrolled to Date: 60
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The primary objective of this study is to assist the psychological corporation in the restandardization of the bayley scales of infant development by providing critical feedback of the tryout version of the revised instrument and by providing approximately 50 subjects whose data will contribute to the development of the revised version of the scale.

(16) Technical Approach: See protocol.

(17) Progress: We have completed the protocol on the subjects whom we arranged to do for the psychological corporation. All data has been mailed in. Payments for subjects will probably all be disbursed by the end of September by T.P.C. Our portion of this nationwide study is complete. We are considering being involved in the standardization trials next year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/405 (3) Status: Ongoing

(4) Title: Followup of the NICU Graduate in Military Medical Facilities

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Beverly Anderson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Newborn/PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 123
d. Total Number of Subjects Enrolled to Date: 123
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance of NICU graduates in military medical facilities.

(16) Technical Approach: Information retrieved through questionnaire sent to every military facility serving a pediatric population.

(17) Progress: Information from questionnaire is currently being assessed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/406 (3) Status: Ongoing

(4) Title: POG 8788 Intergroup Rhabdomyosarcoma Study IV: A Pilot Study for Clinical Group III Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/407 (3) Status: Ongoing

(4) Title: POG 8821 AML#3: Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/408 (3) Status: Ongoing

(4) Title: POG 8823/24 Recombinant Alpha Interferon in Childhood
Chronic Myelogenous Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/409 (3) Status: Ongoing

(4) Title: POG 8827 Treatment of Children with Hodgkin's Disease
in Relapse - Phase I:

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/410 (3) Status: Ongoing

(4) Title: POG 8829 A Protocol for a Case-Control Study of Hodgkin's Disease in Childhood: A Non-Therapeutic Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/411 (3) Status: Ongoing

(4) Title: POG 8832 Pre-XRT Cisplatin and Ara-C for Children with
Imcompletely Resected Supratentorial Malignant Brain
Tumors

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 90/412 (3) Status: Ongoing

(4) Title: POG 8850 Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/413 (3) Status: Ongoing

(4) Title: POG 8889 Intergroup Rhabdomyosarcoma Study-IV Pilot
Study for Clinical Group IV Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 90/414 (3) Status: Ongoing

(4) Title: POG 8828 Late Effects of Treatment of Hodgkin's Disease:
A Pediatric Oncology Group Non-Therapeutic Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/415 (3) Status: Ongoing

(4) Title: POG 8650 National Wilms' Tumor Study - 4 (NWTS-4), A
Pediatric Hematology-Oncology Group Phase III Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, one patient enrolled at FAMC.

Publications and Presentations: None

DEPARTMENT OF PATHOLOGY

(1) Date: 30 Sep 90 (2) Protocol #: 89/450 (3) Status: Completed

(4) Title: Evaluation of the Available Plasma Separator Tubes
for Storage of Patient Specimens

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Alan F. Weir, CPT, MS (8) Facility: FAMC

(9) Dept/Svc: Pathology (10) Associate Investigators:
Margaret Zakroff, MT

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the difference between the current
method and the newer serum separator tubes and the length of time serum
can be stored using the new serum separator tubes.

(16) Technical Approach: See protocol.

(17) Progress: Data has been collected and is being evaluated.
Manuscript will be submitted upon completion of evaluation of data.

Publications and Presentations: None.

DEPARTMENT OF RADIOLOGY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Peter W. Blue, COL, MC (8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators

(11) Key Words:
adosterone
adrenal glands

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep 89 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: No studies were performed this period. One negative study performed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/600 (3) Status: Terminated

(4) Title: a. The Usefulness of MRI and Transrectal Ultrasound in the Staging of Prostatic Cancer: Comparison to 1mm Whole Gland Mounts. b. Artifacts and Variants of the Normal Prostate Seen by MRI and Transrectal Ultrasound: Comparison to 1mm Whole Gland Mounts

(5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:
Kenneth D. Hopper, MAJ, MC
Daniel Horne, LTC, MC
David Thickman, MD
Gary Miller, MD
Gail Weingast, MD
Michael Manco-Johnson, MD

(8) Facility: FAMC

UCHSC
UCHSC
UCHSC
UCHSC

(9) Dept of Radiology

(10) Associate Investigators
Michael Raife, LTC, MC
Edward Pienkos, LTC, MC
Steve Parker, MAJ, MC
Merlyn Gibson, MAJ, MC
Jerry Sims, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 42 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Within the past two years, the usefulness of transrectal ultrasound and MRI in the diagnosis and staging of prostatic cancer has been well demonstrated. There are numerous artifacts and variants within the prostate as seen with these two modalities, however, which are poorly understood. In addition, no study evaluating the efficacy of transrectal ultrasound and MRI in prostate cancer has compared the radiographic findings with histological mounts of the entire gland. We intend to correlate the results of the MRI and transrectal ultrasound to 1mm whole gland mounts in order to better understand the aforementioned artifacts/variants as well as tumor extension.

(16) Technical Approach: See original protocol.

(17) Progress: Terminated due to PCS of principal investigators and budget exhaustion.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/601 (3) Status: Ongoing

(4) Title: Body Fat Determination by Dual Photon Absorptiometry

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Peter W. Blue, COL, MC (8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators
Harry N. Tyler, Jr.

(11) Key Words:
absorptiometry
body fat

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 89 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: approx.
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate body fat composition by absorptiometry and other current modalities.

(16) Technical Approach: Each patient will be studied by four methods and the methods compared.

(17) Progress: No progress. To date funding is not available.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/602 (3) Status: Ongoing

(4) Title: The Comparative Renal Clearances of Disofenin and
Mebrofenin

(5) Start Date: (6) Est Compl Date: July 1991

(7) Principal Investigator: Jay Cook MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators:
Peter Blue, COL, MC

(11) Key Words:
renal clearance
disofenin
mebrofenin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: The intent of the study is to objectively
compare the renal serum clearance of each of the agents in the most
optimally controlled environment possible, the individual patient. In
this manner, the claims of the manufacturer can be established or
refuted and the best agent determined.

(16) Technical Approach: The subjects will be categorized into normal
(total serum bilirubin of less than 2.0), and four groups of abnormal
(greater than 2.0, 5.0, 10.0 and 20.0). Each patient will then be given
the minimal suggested dose (4 millicuries to 10 millicuries) and renal
and hepatic clearances will be calculated. Hepatobiliary scans will
also be performed on the patients with each agent. The abnormal group
with bilirubins greater than 20 will receive the mebrofenin first
followed by the disofenin to asses for competitive binding interference.

(17) Progress: Projects has not started yet, no patients have been
tested.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/602 (3) Status: Ongoing

(4) Title: The Utility of the Bard "Biopty" Gun in the Breast:
Correlation with Surgical Excisional Specimens

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: James Leuthke, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators:

Steve H. Parker, MAJ, MC

(11) Key Words:
Bard "biopty" gun
breast biopsy

Jeffrey Lovin, CPT, MC
Wayne Yakes, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 105
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To ascertain the accuracy of breast biopsies performed with the Bard "Biopty" biopsy gun utilizing stereotaxic mammagraphic and ultrasonographic guidance.

(16) Technical Approach: As outlined in objective.

(17) Progress: Results indicate that Bard "biopty" gun produces specimens as good as surgical biopsy.

Publications and Presentations: Abstract to be presented at the Radiological Society of North America 75th Annual Meeting, 26 Nov-1 Dec 89, Chicago, IL, and to be published in Radiology.

DEPARTMENT OF PRIMARY CARE & COMMUNITY MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 80/650 (3) Status: Ongoing

(4) Title: A Study of Hemoglobin and of Red Cell Metabolism in the American Opossum (*Didelphis virginiana*)

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators: J.E. Lima

(11) Key Words:
opossums
marsupial
erythrocytes
purine metabolism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: An inquiry into the energy metabolism of opossum erythrocytes (glucose, purines and pyrimidines) and factors involved which maintain cell viability and function.

(16) Technical Approach: Radiolabelled purine and pyrimidinenucleosides, bases and glucose are provided to red cells in-vitro and synthetic/catabolic pathways are determined with the aid of HPLC/radiochromttography.

(17) Progress: Study results to date: In contrast to human red cells, opossum RBC effectively salvage hypoxanthine for the production of ATP and GTP (J. Cell Physiol. 1990). Formate and AICA are also incorporated into ATP and GTP indicating that the last steps of de-novo nucleotide synthesis is active in these cells (Comp. Biochem. Physiol., 1990).

Progress - continued

The amounts of NAD are directly proportional to intra cellular ATP concentrations in opossum red cells. In the presence of glutamine, both nicotinic acid and nicotinamide are substrates for the synthesis of NAD, indicating the presence of nicotinamide deamidase in these cells. This enzyme is not active in human red cells under physiologic conditions.

Collaborative Efforts:

1. Division of Clinical Pharmacology, Department of Medicine, Brown University, Providence, RI - Isoenzymes of adenosine deaminase (40.000 and 100.000 Dalton species) were isolated from red cells, plasma, spleen and liver of *D. virginiana*. Their activities in these tissues, and their kinetic constants (K_m and V_{max}) to adenosine and deoxyadenosine were determined. A paper is in preparation for publication.

2. Department of Biology, Federal University of Santa Catarina, Florianopolis, Brasil - Purine nucleotide patterns of red cells of *D. marsupialis* and of *D. albiventris* have been determined. *D. marsupialis*, from which *D. virginiana* has evolved, does not have detectable deoxy ATP in its erythrocytes suggesting interesting genetic and evolutionary possibilities. A paper is in preparation for publication.

3. Department of Pharmacology, University of Columbia-Missouri, Columbia, MO - Cation transport in red cells of *D. virginiana* containing ATP/dATP, or dATP alone is being investigated. Membrane Na, K, Mg and Ca ATPase(s) are also being investigated using ATP and dATP as substrates.

4. Department of Physiology, University of New England, Armidale, Australia - A study of red cell nucleotide patterns and cation ATPase(s) of small Australian marsupialia is intended to commence in the Spring of 1991.

Abstracts of two papers will be submitted for consideration for presentation at the 7th International Symposium on Purine and Pyrimidine Metabolism in Man, Bournemouth, England, July 1991.

Publications:

1. Petty C, Bethlenfalvay NC, and Bageant T: Spectrophotometric measurement of hemoglobin oxygen saturation in the opossum, *Didelphis virginiana*. *Comp. biochem. Physiol.* 50:273, 1975.

2. Bethlenfalvay NC, Block M, and Brown GB: Hemoglobins of the opossum (*Didelphis Virginia Kerr*) I. Developmental changers from yolk sac to definitive erythropoiesis. *Lab. Animal Sci.* 26:106-165, 1976.

3. Bethlenfalvay NC, Brown GL, and Waterman M: I. Hemoglobins of the opossum (*Didelphis marsupialis*) II. Electrophoretic and chromatographic observations. Lab Animal Sci. 26:908-912, 1976.
4. John ME, Bethlenfalvay NC, and Waterman MR: Oxidation - reduction properties of the hemoglobin of the opossum Didelphis Virginiana. Comp. Biochem. Physiol. 73B:585-591, 1982.
5. Bethlenfalvay NC, Waterman MR, Lima JE, and Waldrup T: Cystolic and membrane bound methemoglobin reductases in erythrocytes of the opossum Didelphis virginiana. Comp. biochem. Physiol. 738:594, 1982.
6. Bethlenfalvay NC, Waterman MR, Lima JE, and Waldrup T: Comparative aspects of methemoglobin formation and reduction in opossum Didelphis Virginiana and human erythrocytes. Comp. Biochem. Physiol. 75A:635-639, 1983.
7. Bethlenfalvay NC, Lima JE, and Waldrup T: Studies on the energy metabolism of opossum (*Didelphis Virginiana*) erythrocytes. I. Utilization of carbohydrates and purine nucleosides. J. Cellular Physiol. 120:69-74, 1984.
8. Bethlenfalvay NC, Lima J, Waldrup T, and Chadwick E: Studies of the energy metabolism of opossum *Didelphis virginiana* erythrocytes. II. Comparative aspects of 2-deoxy-D-glucose catabolism in opossum and human red cells in-vitro. Comp. biochem. Physiol. 89A:113, 1988.
9. Bethlenfalvay NC, Lima J, Stewart I, and Chadwick E: Studies on the energy metabolism of opossum *Didelphis virginiana* erythrocytes. III. Metabolic depletion with 2-deoxyglucose markedly accelerates methemoglobin reduction in opossum, but not in human erythrocytes. Comp. Biochem. Physiol. 89A:119, 1988.
10. Bethlenfalvay NC, Lima JE, Chadwick E: Studies on the energy metabolism of opossum *Didelphis virginiana* erythrocytes -IV. Half-millimolar levels of deoxy adenosine triphosphate in red cells are found associated with low adenosine deaminase activity. Life Sciences 44: 963-970, 1989.
11. Bethlenfalvay NC, White JC, Chadwick E, Lima JE: Studies on the Energy Metabolism of Opossum (*Didelphis virginiana*) Erythrocytes: V. Utilization of Hypoxanthine for the Synthesis of Adenine and Guanine Nucleotides in-vitro. J. Cell Physiol. 143:563-568, 1990.
12. Bethlenfalvay NC, White JC, Chadwick E, Lima JE: Studies on the Energy Metabolism of Opossum (*Didelphis virginiana*) Erythrocytes: VI. De-Novo Purine Nucleotide Biosynthesis is Limited to the Final steps of the Pathway In-vitro. Comp. Biochem. Physiol. 97B: 193-196, 1990.

Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 87/650 (3) Status: Terminated

(4) Title: Clonal Fidelity of Erythroid Lineage in
Dyserythropoiesis: An Inquiry Into Ultrastructure

(5) Start Date: 1987 (6) Est Compl Date: Indefinite

(7) Principal Investigator: N.C. Bethlenfalvay, MD
V.V. Reddy, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators:
C.F. Ferris, MAJ, MS
D.B. Mercill

(11) Key Words:
dyserythropoiesis
ultrastructure
x-ray microanalysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 6/90 b. Review Results: Terminated
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate the aspects of ultrastructural components of erythroid precursors to include elemental composition of these components for determination of their role on erythroid maturation, morphology, the process of erythroid denucleation, and functional differentiation in various dyserythropoietic states.

(16) Technical Approach: Burst forming erythroid colonies will be grown in semi-solid tissue-culture media. Bursts will be isolated, fixed, embedded and evaluated by electron microscopy and concurrent x-ray microanalysis of metallic cellular inclusions.

(17) Progress: Growth of erythroid colonies and of bursts was never achieved, project was therefore terminated.

Publications and Presentations: None

DEPARTMENT OF NURSING

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 86/700A (3) Status: Ongoing

(4) Title: Introduction of Suturing Techniques Using Outbred Adult Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: LTC Debra J. Walker (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:
suture techniques training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 11/89 b. Review Results: Ongong
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To instruct selected department of nursing personnel to properly suture traumatic lacerations, to establish and maintain a sterile field during the suturing procedure, to cleanse traumatic lacerations, to instruct the patient to manage the wound and facilitate healing, and to correctly remove suture when healing is complete.

(16) Technical Approach: Students are detailed to perform at least 1 successful suturing episode under direct supervision of an Emergency Medical Service staff physician to validate learning and clinical competence. Once certified, suturing activities become a part of the staff members' scopes of nursing practice. Skills are revalidated annually to ensure continued competence.

(17) Progress: Seventeen department of nursing personnel have completed the protocol during reporting period. All have been subsequently certified to perform basic suturing techniques in the FAMC Emergency Medical Service. No clinical practice deficiencies have been observed/reported which would indicate a problem with the revised protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/700 (3) Status: Completed

(4) Title: A Study of the Clinical Nurse Specialist in the AMEDD

5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:
A.J. Frelin, COL, AN

(8) Facility: FAMC

(9) Dept/Svc: Nursing

(10) Associate Investigators
Nancy Staggers, MAJ, AN

(11) Key Words:
role development

Ass. Prof., School of Nursing
Univ. of California

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this descriptive study is to explore the role of the clinical nurse specialist (CNS) as implemented by the ANC from the perspective of the CNSs now in practice as well as the Nurse Managers where the roles are or could be implemented. (a) to describe the role of the CNS in HSC from the perspective of the practicing CNSs; (b) to describe the role of the CNS in HSC as perceived by ANC officers who rate/senior rate them and by Chiefs of Nursing Departments; (c) to compare the perceptions of these groups regarding role implementation; (d) to describe a normative profile of the ANC officer practicing in the CNS role and (e) to assess potential for the future implementation of this specialty in the ANC.

(16) Technical Approach: Each group will be surveyed using a written mailed survey instrument constructed for this purpose. Data analysis will be directed to describing the role and the normative characteristics of those practicing in the role.

(17) Progress: Principal data collection and analysis has been completed.

Presentations: Presented: 6th Annual Research Conference sponsored by the VA Medical Center and University of Utah, 17 Feb 89.

Publications: Accepted for publication in CNS, Fall 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/700 (3) Status: Ongoing

(4) Title: A Pilot Study: A Comparison of Subarachnoid Block Anesthesia with Tetracaine and Epidural Anesthesia with Lidocaine and the Effects on the Umbilical Artery Acid-Base Results and Five Minute Apgar Scores of Neonates Following Uncomplicated Cesarean Section

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: William Gillis, CPT, AN (8) Facility: FAMC

(9) Dept/Svc: Anesthesia/Nursing (10) Associate Investigators: Arthur Brehn, CPT, An Arthur Bryson, CPT, An Jenifer Crawford, CPT, An John Wong, CPT, AN

(11) Key Words: subarachnoid block epidural anesthesia apgar scores cesarean section umbilical artery acid-base

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: Via a process of random selection compare 2 groups of 10 patients, 1 group to receive subarachnoid block anesthetic the other an epidural anesthetic for cesarean section, and compare the 5 min. apgar scores and umbilical artery acid-base results from the infants of the two groups.

(16) Technical Approach: Refer to "6.c. Evaluations" of the protocol.

(17) Progress: We have recently completed our subject data gathering and are compiling the data in preparation for statistical analysis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/701 (3) Status: Ongoing

(4) Title: Assessment of Post Myocardial Infarction Patients
Learning Needs During Hospitalization and Post Discharge

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Greg Cannon, 1LT, AN

(9) Dept/Svc: NURSING (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the priority of learning needs of the cardiac patient.

(16) Technical Approach: Utilize questionnaire developed by Peggs S. Gerard, RN, MS.

(17) Progress: Performed study to satisfy requirements for graduation from coronary care nursing course.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/702 (3) Status: Ongoing

(4) Title: The Impact of Practice at Fitzsimons Army Medical Center
Upon Registered Nurses Professional Role Conception

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator: A.J. Frelin, COL, AN (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:
registered nurses
role conception

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: a) Compare the role conception of neophyte RNs
upon their assignment to FAMC and one year after assignment. b) Compare
the role conception of experienced RNs upon their assignment to FAMC and
one year after assignment. c) Assess similarities and dissimilarities
between the two groups. d) Evaluate especially items of role discrepancy
among all groups with the intent of making decisions regarding possible
system changes which could decrease role conflict and impact positively
on retention.

(16) Technical Approach: Comparative study using questionnaires
distributed over an 18-month period.

(17) Progress: Recently approved study, no progress to date.

Publications and Presentations: None

PHYSICAL MEDICINE SERVICE

(1) Date: 30 Sep 90 (2) Protocol #: 90/750 (3) Status: Ongoing

(4) Title: Onset-to-Onset Difference Between the Median Motor Nerve and the Anterior Interosseous Nerve Using a Common Stimulation at the Antebubital Fossae

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Douglas Hemler, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Phy. Med. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To mathematically define the temporal relationship between the anterior interosseous nerve and the median nerve.

(16) Technical Approach: Volunteers with no known neurologic pathology will be used. Stimulation by standard surface electrodes with cathode placement medial to the biceps tendon at the flexion crease of the antebubital fossae. Standard adjustment of the stimulus to achieve maximal responses from the Abductor Pollicis Brevis and Pronator Quadratus is performed.

(17) Progress: Fifteen subjects have been studied. Current data is insufficient for analysis.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/751 (3) Status: Completed

(4) Title: The Frequency that Physicians Recommend Aerobic Exercise
for Patients with Rheumatoid Arthritis

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: C.L. Lewis, CPT, SP (8) Facility: FAMC

(9) Dept/Svc: Occupational Therapy (10) Associate Investigators:

(11) Key Words:
aerobic exercise
rheumatoid arthritis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to determine if
aerobic exercise is recommended by physicians for patients with
rheumatoid arthritis.

(16) Technical Approach: One hundred and sixty-five military
physicians were surveyed using a written mailed questionnaire developed
for this purpose. The study looked at the frequency and percentages
that physicians recommended aerobic exercise for patients with RA, the
exercise modes recommended, the benefits and contraindications of
aerobic exercise for RA patients, the tests recommended prior to
starting an exercise program, and the method of explaining the exercise
program to the patient.

(17) Progress: Principal data collection has been completed. Analysis
of the data is ongoing.

Publications and Presentations: None.

MEDDAC

(1) Date: 30 Sep 90 (2) Protocol #: 83/902A (3) Status: Ongoing

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: 1982 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Mark A. Larsen, COL, MC (8) Facility: FAMC
Ft. Carson Vet. Activity &
Ft. Carson MEDDAC Emergency
Medical Service
A-691-7226/7111

(9) Dept of Emerg Med & Vet Svc (10) Associate Investigators:
MAJ Irwin Rubin

(11) Key Words:
emergency medical services

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 78 _____
d. Total Number of Subjects Enrolled to Date: _____ 85 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: This project is a refresher/teaching course in
emergency medicine operative procedures. It is conducted on a monthly
basis for EMS physicians and PAs'.

(16) Technical Approach: Under general anesthesia animals are
subjected to common emergency medicine operative procedures including
venous cutdown, peritoneal lavage, chest tube insertion, and thorocotomy
with aortic cross clamp with cardiac laceration repair. At the end of
the exercise, the animals are disposed of by lethal injection.

(17) Progress: Training program, good utilization and training
continues.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/900 (3) Status: Ongoing

(4) Title: IOLAB Investigational Plan for the Clinical Study of Intraocular Lenses

(5) Start Date: 8/87 (6) Est Compl Date: Indefinite

(7) Principal Investigator: David Pernelli, MAJ, MC (8) Facility: FAMC
Fort Leonard Wood, MO
65473-5700

(9) Dept/Svc: Ophthalmology Svc (10) Associate Investigators

(11) Key Words:
IOL (posterior chamber)

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 46
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient.

(16) Technical Approach: Extracapsular cataract extraction with PC IOL secondary intraocular lens (IOL) implants.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 88/901 (3) Status: Ongoing

(4) Title: Coburn Intraocular Lens Study AT GLWACH

(5) Start Date: 8/87 (6) Est Compl Date: Indefinite

(7) Principal Investigator: David Perenelli, MAJ, MC (8) Facility: FAMC Fort Leonard Wood, MO 65473-5700

(9) Dept/Svc: Ophthalmology Svc (10) Associate Investigators

(11) Key Words:

IOL (anterior chamber)

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient.

(16) Technical Approach: Secondary intraocular lens implant.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/900 (3) Status: Ongoing

(4) Title: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610)
for Immunization Against Q Fever

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Steven White, LTC, MC

(8) Facility: FAMC
US Army Health Clinics
Dugway Proving Grounds
Dugway, Utah 84022

(9) Dept/Svc:

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/901 (3) Status: Ongoing

(4) Title: Continued Evaluation of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83 Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Steven White, LTC, MC (8) Facility: FAMC Director of Health Services US Army Health Clinic, DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached. No new enrollments authorized.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/902 (3) Status: Ongoing

(4) Title: Evaluation of New Lots of Tularemia Vaccine, Protocol B:
Comparative Assessment of Francisella tularensis
Vaccine, Live, NDBR 101, IND 157

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Steven White, LTC, MC (8) Facility: FAMC
Dugway Proving Grounds
US Army Health Clinic

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Reserach Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached. No new enrollments authorized.

Publications and Presentations: None

(1) Date: 30 Sep 90 (2) Protocol #: 89/903 (3) Status: Ongoing

(4) Title: Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel, IND 914

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Steven White, LTC,MC (8) Facility: FAMC
Director of Health Services
DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 20 _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached. No new enrollments for this reporting period.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/904 (3) Status: Ongoing

(4) Title: Use of the Sixteen Personality Factor Questionnaire
to Predict Susceptibility to Occupational Stress
Among US Army Recruiters

(5) Start Date: Aug 89 (6) Est Compl Date: Aug 90

(7) Principal Investigator: John Kaicher, CPT, MC (8) Facility: FAMC
US Army Health Clinic
Ft. Sheridan, IL

(9) Dept/Svc: (10) Associate Investigators:
Peter Orris, MD, MPH and
Robert Moretti, PhD,
Northwestern University
Medical School
Walter Teachout, CPT, MS, FAMC

(11) Key Words:
occupational stress
Army recruiters
personality factors

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine a mechanism to identify those
soldiers who are predisposed to disabling occupational stress problems,
considerable psychopathological morbidity and its attendant costs.

(16) Technical Approach: To determine the validity of the 16PF to
predict Army Recruiters predisposed to occupational stress related
psychological and behavioral problems.

(17) Progress: To date 180 subjects were tested. Enrollment will
continue through the end of September 1990.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 89/905 (3) Status: Completed

(4) Title: Comparative Evaluation of Jet Injected PPD Based on the Mantoux Response in Initial Entry Training Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Jul 90

(7) Principal Investigator: Linda J. Andersen MAJ, AN (8) Facility: FAMC Ft. Leonard Wood, MO

(9) Dept/Svc: Immunization Clinic (10) Associate Investigators:

(11) Key Words:
TB testing

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To directly compare the jet-injected intradermal PPD to the stanedard Mantoux method for detection of TB exposure among IET soldiers at Fort Leonard Wood, MO.

(16) Technical Approach: Phase I) Jet injected response is compared to the Mantoux response in a convenience sample of known positive Mono-Vaccs assessing for the sensitivity and specificity against the gold standard. Phase II) Jet injected PPD is administered simultaneously with the Mono-Vacc to soldiers of unknown Mono-Vacc response and is evaluated as the single process of determining TB exposure among the IET soldiers at FLW.

(17) Progress: I completed the study as principal investigator after CPT Luther PCS'd. All data has been mailed to her at her new duty station.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/900 (3) Status: Ongoing

(4) Title: Iron Deficiency Anemia in 11-14 Month Old Infants at 6,000 Feet (1830m) Elevation. A Study to Evaluate the Response to a Therapeutic Trial of Iron

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Steve Lang, MAJ, MC (8) Facility: FAMC Ft. Carson, CO Family Practice

(9) Dept/Svc: Ft. Carson (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether one year old infants at higher altitudes are more likely than children at sea level to be iron deficient.

(16) Technical Approach: Hemoglobin response in healthy 11-14 month old infants living at altitude to 3-month oral iron treatment will be assessed using A HemoCue hemoglobin measuring instrument.

(17) Progress: None to date, due to recent assignment of principal investigator to long-term TDY.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: 90/950A (3) Status: Ongoing

(4) Title: Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care. Resuscitation of the Newborn Utilizing Young Cats

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
To be announced.

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skill of neonatal endotracheal intubation to Indian Health Service (IHS) personnel newly assigned to remote Service Units where successful resuscitation of asphyxiated infants may depend on their ability to intubate.

(16) Technical Approach: Animal models will be used to teach the skills of neonatal endotracheal intubation and bag and mask ventilation.

(17) Progress: This is a recurring post graduate course, the yearly outline will determine the principal and associate investigator and the number of course attendees.

Publications and Presentations: None.

EMERGENCY USE PROTOCOLS

(1) Date: 30 Sep 90 (2) Protocol #: EU-89-1 (3) Status: Completed

(4) Title: POG 8633/34 Treatment of Children Less than Three Years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation.

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Ped Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Patient treatment with NCI approved protocol.

(16) Technical Approach: See protocol.

(17) Progress: Closed to patient accrual.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: EU-89-2 (3) Status: Ongoing

(4) Title: POG 8743

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Ped Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment study for stage IV neuroblastoma sponsored by NCI.

(16) Technical Approach: See protocol.

(17) Progress: Open to patient accrual. One patient enrolled at FAMC. Clinically doing well, stable disease.

Publications and Presentations: NA

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: (3) Status: Completed

(4) Title: Compassionate Enrollment in POC 8696/97

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: COL Askold Mosijczuk (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Closed to patient accrual. One patient entered. Achieved a complete response after chemo but relapsed 6 months later and was taken off the study.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: One (3) Status: Completed

(4) Title:
Compassionate/One Time Use Protocol - Ribovirin (2-wk course)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Dr. Byrne

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Compassionate/one time use protocol (2-wk course).

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: Two (3) Status: Completed

(4) Title:
Tc99m Antimony - Trisulfide Colloid

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Fortenbury (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Completed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: Three (3) Status: Terminated

(4) Title:
Itraconazole

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Jerry Pluss, MAJ, MC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Drug discontinued in patient.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: Four (3) Status: Terminated

(4) Title:
POG 8751

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress:

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: Five (3) Status: Completed

(4) Title:
Intravenous Ciprofloxacin

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Byrne

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Course completed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 90 (2) Protocol #: Six (3) Status: Completed

(4) Title:
Strontium Chloride Sr-89

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Fortenbury

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: One time only.

Publications and Presentations:

INVESTIGATORS INDEX

INVESTIGATORS INDEX

NAME	PAGE
Abrams, L.F. -----	147,165
Andersen, L. -----	430
Andersen, P.A. -----	69,88
Anderson, B. -----	348,353,380,387
Andron, L.A. -----	78,94,169,273,300
Anman, W. -----	168
Arena, J. -----	246,248,272,276,290
Aronson, C.E. -----	237
Ashley, D.D. -----	159,169
Asp, A. -----	93
Atchley, S.H. -----	112
Banks, R.E. -----	301
Barber, J. -----	362
Barrett, J.R. -----	100
Barrs, D.M. -----	262
Bennion, S. -----	40,42,111,225,303,305,306
Bergstrom, -----	162
Bethlenfalvay, N.C. -----	408,411
Bezier, J.L. -----	236
Bianchi, A.M. -----	127
Bizousky, D. -----	256,288
Blakeslee, D.B. -----	274
Blue, P. -----	71,77,103,122,128,135, 136,199,401,404
Brantner, L. -----	378
Bray, V. -----	108,163
Brehn, A. -----	415
Bright, K. -----	214
Brinkman, M. -----	291
Brown, J.S. -----	131,137,143,179
Brugman, J.L. -----	260
Bruhn, F.W. -----	368
Bryson, A. -----	415
Bunker, D. -----	159
Burgess, D.B. -----	307
Byrne, W.R. -----	78,178,226,308,309
Calkins, R. -----	268,290
Campbell, R.L. -----	105
Cannon, G. -----	416
Caras, W.E. -----	133
Carter, B. -----	372,375
Carter, T. -----	229
Casserly, J. -----	78
Clark, J.R. -----	93,241,273
Clark, T. -----	301,371,374
Cobb, P.W. -----	114

Coe, R.A. -----	264
Colpini, A.W. -----	259
Cook, S. -----	289, 292, 293, 405
Copeland, T. -----	44
Cornell, F.M. -----	232, 254, 266, 267
Corpe, R.S. -----	283
Cosgriff, T. -----	53, 54, 56, 58, 59, 60, 61, 63, 64, 72, 74, 79, 80, 81, 82, 83, 84, 85, 92, 95, 96, 103, 114, 119, 125, 139, 172-177, 178, 181, 183-197, 201, 212, 217-223
Coulter, S. -----	111
Coville, F. -----	285
Cravero, J. -----	431
Crawford, J. -----	415
Cremins, J.E. -----	135
Crosby, B.L. -----	67
Cruz-Saez, J.A. -----	42
Culclosure, T.F. -----	152
Damiano, M. -----	272
David, K. -----	40, 215, 225
Davis, R.C. -----	120
Deffer, P. -----	289, 294
Dengenhardt, E. -----	163
Dirks, M. -----	233
Dolton, H. -----	168
Donatucci, C. -----	180, 238, 239, 279
Dorogy, M. -----	112, 181
Dorsett -----	363
Dothager, D. -----	122, 146, 198
Dunkelberg, J. -----	129, 135, 182
Dwyer, A.P. -----	216
Dwyer, K. -----	263, 265, 277
Enzenauer, R.J. -----	140, 141
Enzenauer, R.W. -----	232, 254, 266, 267
Eusterman, V.D. -----	274
Fall, S. -----	255
Feinberg, M. -----	380
Ferris, C.F. -----	39, 50, 73, 302, 305, 411
Fisher, M. -----	154, 171, 182
Fitzpatrick, J.E. -----	111, 225, 302
Fortenberry, E.J. -----	86
Frank, C.G. -----	353, 372, 375, 380
Freeman, S. -----	129, 135, 140, 150, 154, 169, 171, 182, 363
Frelin, A.J. -----	414, 417

Gaines, T.	282
Gardner, T.A.	232, 254, 266
Garrow, D.C.	320
Gaspard, P.T.	362
Gates, R.H.	78, 94, 99, 105, 119, 145, 178, 226, 308, 309
Gates, R.	145
Gentry, R.	40
George, R.K.	254
Georgitis, W.J.	71, 93, 100, 123, 134, 160, 164, 179
Getter, M.D.	250, 261, 277
Gibson, M.	402
Gillis, W.	415
Gillogly, S.D.	271, 280, 281, 284, 286
Ginter, J.	250, 272, 276, 290
Glassheim, J.	213
Glick, P.	289
Goodman, N.	381
Graham, L.M.	376
Green, E.W.	104, 143
Hahn, D.B.	246, 248, 252, 261, 268, 276, 277, 374
Hall, W.	289
Hallgren, S.E.	129, 135, 171
Hannon, R.N.	78, 94, 308, 309
Harrison, S.M.	78, 94, 99, 105, 133, 169, 178, 226, 296, 308, 309, 382
Hasbargen, B.	199
Hasbargen, J.A.	108, 152, 157, 162, 170, 199, 200, 224
Hemler, D.	256, 264, 291, 419
Henderson, C.	290
Henry, A.R.	75, 213
Hockenbury, R.T.	240, 261, 280, 281
Hofeldt, F.D.	32
Hollis, H.W.	241, 273
Hopper, K.	402
Horne, D.	402
Hull, R.W.	112
Ikle, L.O.	378, 386
Jackson, R.L.	42, 289
Jarek, M.J.	158
Johns, J.	228, 256, 261, 294
Johnson, R.C.	133, 136, 158
Jones, T.A.	238, 239
Jordon, L.W.	112
Judson, P.	151

Kaicher, J. -----	429
Karstitter, K. -----	278, 283, 287, 291
Kelly, K.J. -----	369
Ketchum, R. -----	291
Kidd, G.S. -----	32, 34, 36, 37, 46, 71, 77, 86, 90, 93, 100, 103, 128, 131, 134, 147, 164, 168
Kinsella, J.P. -----	348, 383, 384, 385
Kollef, M.H. -----	133, 138, 144, 146, 155, 158, 178, 198, 214
Kreder, K. -----	238, 239, 279
Kozlowski, C. -----	181
Kristo, D. -----	155
Kruger, M. -----	141
Kuck, P. -----	234
Kudryk, B. -----	181
Lang, S. -----	431
Lanier, D. -----	114
Larsen, M.A. -----	164
Larsen, L.V. -----	117
Lawrence, S.P. -----	129
Ledoux, R.A. -----	67, 137, 213
Lee, L. -----	215, 305, 306
Lemar, H.J. -----	160, 164
Lepore, M.L. -----	214, 257, 275
LeSueur, C. -----	62
Leuthke, J. -----	155, 406
Lewis, C.L. -----	429
Lima, J. -----	408
Lin, E. -----	134, 419
Lisecki, M.B. -----	254, 285, 289, 292, 293
Lovin, J. -----	406
Lundblad, E. -----	319, 320
Maco-Johnson, M. -----	402
Madonna, J. -----	142
Mallory, P.L. -----	198, 263, 265, 273
Manier, S.M. -----	71
Marx, W.H. -----	263, 265, 273
McCormack, M. -----	214
McDermott, M.T. -----	34, 36, 37, 48, 52, 65, 71, 77, 86, 90, 93, 100, 103, 128, 147, 149, 159, 164, 179
McIntosh, B.R. -----	286
McNalley, P.J. -----	159, 171
Meador, K. -----	290
Meiklejohn, G. -----	148
Mercill, D.B. -----	73, 111, 289, 411
Merenich, J. -----	77, 93, 100, 134, 14, , 159, 164, 179
Meyers, J.I. -----	138, 144, 156

Miles, F.W. -----	105
Miller, G. -----	402
Moretti, R. -----	429
Morse, P.L. -----	298
Morton, B.E. -----	230
Moses, T.A. -----	238, 239
Mosijczuk, A.D. -----	307, 349-351, 355-361, 364-367, 371, 373, 377, 379, 388-397
Mullon, D. -----	291
Myers, C. -----	259
Negron, F. -----	77
Nelson, H.S. -----	48
Nordstrom, D. -----	69
O'Barr, T.P. -----	73, 302
O'Connell, M.A. -----	75
O'Connor, J. -----	168
Odom, J.A. -----	260
Orris, P. -----	429
Ow, C.L. -----	97, 161
Ozaki, J.K. -----	259
Paige, P. -----	375
Pals, S.D. -----	253, 280
Parker, S. -----	402, 406
Pernelli, D.P. -----	231, 423, 424
Perry, M.E. -----	77, 122, 136, 138, 156, 168, 214
Pfander, N. -----	127, 134
Potter, M.E. -----	313-318, 321-326, 327-332, 333-346
Pruitt, A. -----	259, 260, 264, 271
Raife, M.J. -----	238, 239, 279, 402
Ramirez, R.J. -----	232, 254, 266
Reddy, V. -----	101, 144, 159, 362, 411
Rodinelli, R. -----	243, 246, 250
Rosenberg, A.A. -----	385
Rothschild, B. -----	246
Roy, C.R. -----	134
Rush, P. -----	362
Santoro, T. -----	215
Schaefer, R.A. -----	271, 293
Schaffrinna, M.G. -----	363
Schleve, M.M. -----	40, 225
Scott, F. -----	294
Shanefield, C. -----	62
Shaukat, M. -----	291
Sherman, K. -----	140, 150, 169
Sherman, R.A. -----	143, 242, 243, 248, 250, 252, 264, 268, 272, 276, 278, 287, 289, 290, 291

Simcic, K. -----	100
Sims, J. -----	402
Singleton, J.D. -----	88,115,140,179
Sjoberg, R.J. -----	32,100
Skavlen, P. -----	215
Sklarew, P.R. -----	104,153,180
Slover, R. -----	378
Spaulding, H.S. -----	166,167,180
Spezia, P. -----	283,284
Staggers, N. -----	414
Stenmark, K.R. -----	376
Stewart, I.B. -----	381
Stewart, R.S. -----	132,296
Stock, J. -----	254,266
Sutherland, R. -----	238,239
Szefler, S. J. -----	48
Tell, D.T. -----	55,56,241
Tessier, S. -----	300
Teuton, C. -----	215
Thickman, D. -----	402
Thrasher, J.B. -----	180,238,239,263,265
Travis, P.S. -----	157
Truxal, A.R. -----	52
Tyler, H.N. -----	128,404
Urry, L. -----	111
VanDeren, J.M. -----	120,129,142
Vasil, M.L. -----	376
Voelmeck, W. -----	416
Vollkel, N.F. -----	376
Vaughan, R. -----	44,48,75,104,109,117,126, 130,213
Walden, T. -----	71
Walker, D.J. -----	413
Walton, W. -----	254,266
Ward, F. -----	112
Wartofsky, L. -----	52
Weaver, M. J. -----	97,116,145,163
Weber, R.W. -----	132,143
Weidel, J. -----	293
Weingast, G. -----	402
Weir, A. -----	399
Weller, R.W. -----	254
Wells, D.W. -----	352
West, S.G. -----	62,69,88,115,140,179,264
Weston, W. -----	111
White, J.C. -----	131,147,200,307,381

White, S. -----	425,428
Wilkerson, P. -----	261
Wilkins, R.M. -----	252
Williams, K. -----	148
Williams, R.F. -----	42
Winn, R. -----	99,133,148
Woerman, A. -----	278,287
Wolfe, J. -----	285
Wolff, J. -----	292
Wong, J. -----	415
Woods, T.R. -----	275
Woolverton, M. -----	371,374
Yakes, W. -----	406
Yoshidja, G. -----	270
Young, T. -----	243,246,248,250
Zakroff, M. -----	399

KEY WORD INDEX

KEY WORD INDEX

KEY WORDS	Page
absorptiometry	404
access	162
acclimatization	168
achilles tendon rupture	261
adosterone	401
adrenal glands	401
aerobic exercise	420
age	163
alcohol	160
allergens	67
allergenicity	213
altitude	156
effects	168,431
amputees	289
angina pectoris	120
animal interaction	371,374
anterior cruciate ligament	271
arthroscopy	271
anticoagulation	152
antigenicity	213
antihistamine	104,180
antiinflammatory	216
agent	240
antiretroviral therapy	308,309
antitussive	160
aphakia	232
apgar scores	415
army recruiters	429
arthroscopic cruciate deficient	28
articular cartilage regeneration	259
asphyxial injury	369
asthma	109,130
asymptomatic HIV	94
atrial natriuretic peptide	142
atomic absorption	307
autoantibodies	305
autoantigens	305
bacteremia	368
baird biopsy gun	406
balloon dilitation of prostate	279
basal cell CA	39,40,50
bayley scales	386
bladder augmentation and substitution .	239
blood lead	307
body fat	404

bone density	34,103,128
ingrowth	292,293
borrelia	300
breast biopsy	406
calcium	77,86,200
calcitonin deficiency	34
carbohydrate	32
cardiopulmonary resuscitation	145
cataract	232
extraction	233,267
ceftriaxone	368
cesarean section	415
chemotherapy	63,79
chronic pain	290
cigarette smoking exposure	381
clavulanate	368
clindamycin	226
clonidine	378
clotting factors	362
comprehensive assessment	290
congestive heart failure	141
cognitive, moral & faith development .	105
continuous passive motion	259
contract vs noncontract	127
copd	126
coronary disease	181
corticosteroids	126,130,291
coumadin	103,292
cross reactivity	213
cutaneous lupus	396
cyclic oxygen therapy	136
cyclosporin	52
d-dimer	112
d-penicillamine	115
development evaluations	380
diabetes	131,134
mellitus	160
dialysis	157,162,199
disofen	405
do not resuscitate order	145
drug induced lupus	88
drug sensitivity	75
drug therapy	53-61, 64,72,74, 80-85 92,95,96,119,349-351 355-361,364-367
dyserythropoiesis	411
dysmenorrhea	352

eaton trapezial implant	294
emergency medical services	422
emergency procedures	301
management	130
emg	276
endometriosis	352
endoscopy	129
environmental recording	246, 268
eosinophilia	167
nyalgia syndrome	166
epidural anesthesia	415
erythrocytes sedimentation rate	141
erythropoietin	224
estrogen	73
exercise	156
eye disease	52
fibrin monomer	112
fibrinopeptide analysis	181
fibrositis	264
flexeril	264
food hypersensitivity	44
gastric emptying	135
gastroduodenal ulcer	263, 265
gastrostomy tube	135
glucose	200
goats	289
gonadal dysgenesis	36, 37
gonadotropins	36
gram-negative shock	99
gram-negative sepsis	99
growth delay	378
ha-1a, monoclonal antibody	99
headaches	268
heated graphite atomization	307
hematuria	152
hepatitis	169
b vaccine	167
hepatotoxicity	182
herpes zoster	225
high risk neonates	353
infants	380
hip fracture	90
histones	88
HIV virus	78
infection	226
therapy	308, 309
HLA antigens	62

human infants	386
humanistic qualities	97
hydroxyapatite	285
implants	292
hypercalcemia	157
hypersensitivity	67
hypertension	108,157,200
hyperthyroidism	32,48
hypothyroidism	36,37,46,48
hypoxia	129
icam	303
ige	167
immunofluorescence	303
immunologic diseases.....	296
immunotherapy	132
implants	293
impotence	134
incidence	272
infants	431
intraocular lens	231,234,236,237,254
implanting	233
intravenous fat emulsion therapy	144
iodine	100
iol	267,423,424
iron deficiency	431
IVIG	178
keratin.....	42
sulfate	284
laboratory animals	301
limulus	150
liposuction	275
locus of control	127
low back pain	246,248,272,276
lower extremity pain	278
l-tryptophan	166
lung	163
volume	198
lupus erythematosus.....	62,215,303
lyme disease.....	300
macromolecular absorption	369
malignant melanoma.....	73
marsupial	408
mebrofenin	405
mechanisms.....	250
mediators.....	44
medical residents.....	97
MMPI.....	248

methotrexate	109,115,182,292
methylprednisolone	48
microbiological techniques.....	298
microbiology.....	298
microsurgery.....	238
microvascular education & training	228,229
migraine	44
headaches.....	363
minor	267
minor determinants	137
monoclonal antibody	99
morton's neuroma	283
muscle tension.....	268
myocutaneous flaps	275
nasal obstruction.....	257
nasal surgery.....	257
neonatal lupus erythematosus	305
neonatal morbidity	372
nephropathy	131
nerve block	291
graft	262
nifedipine.....	65,108
nifedipine GITS.....	120
non-insulin dependent diabetes	127
non-steroidal	240,259
noscomial pneumonia.....	263,265
nude mice	50
obstructive lung disease	126
occupational stress	429
octreotide	171
opossum	408
oral contraceptives agents	362
orem's self-care model	127
osteocalcium	103
osteoporosis.....	34,90,179
oxygen kinetics	156
pacemaker syndrome	142
pain.....	242
pancreatitis	171
passive smoking	381
peak bone mass	128
pelvic neoplasms.....	313-318, 322-326,327-332, 333-346
penicillin	137
pentoxifylline	134
percutaneous implant	289
tendon ruptures.....	261
personality factors	429

phantom limb pain.....	243,250
treatments	243
phenindamine.....	104
physical therapy	291
pituitary	36
pms.....	320
pneumonia	376
pollen	67
positive end expiratory pressure	214
prednisone.....	52
procainamide.....	88
progesterone.....	73
prophylactic IVIG	353
prostaglandins synthetics	461
prosthetic	289
pseudomonas aerugenosa	376
psychophysiological responses	290
psycho-social-spiritual.....	105
pulmonary abnormalities	144
purine metabolism.....	408
pulsing magnetic fields	287
pyrimethamine	226
rats	376
reactive arthritis.....	69
receptors.....	73
recirculation	162
reflex sympathetic dystrophy	291
registered nurses	417
reiter's disease.....	69
renal clearance	405
failure	157,170,224
function	199
trauma	239
renovascular surgery.....	239
retinoids	40
reverse transcriptase inhibitor	308,309
ro	305
role conception	417
development	414
rheumatoid arthritis	115,420
rhinomanometry.....	257
SBP	150
scoring system	372
serum creatinine	170
silent ischemia.....	120
silicone iol	266
skin test	143
smoking cessation	163
spinal fixator	261,277

spirochete.....	300
steroid	179,216
dependent	109
stress fractures	287
subarachnoid block	415
sucrose	160
surface EMG.....	246,248
temperature	278
suture techniques training.....	413
swine	275
tamponade	146
tb testing	430
tendon healing.....	240
tension headache	272
theophylline	48,65,86
therapy.....	320
thermography.....	143,242,248,264,278
thromboembolic disorders.....	362
thoracostomy	146
thyroid function tests.....	71,100
gland	71
hormones.....	34
disease	71
tonsillectomy	216
toxoplasmic encephalitis	226
transplantation.....	50
transurethral resection of prostate ...	279
traumatic facial palsy.....	262
ultrastructure	411
ultraviolet light	306
umbilical artery acid-base	415
unstable coronary aretery disease.....	112
urodynamics	180
variceal hemorrhage	154
vasopressin	154
verapamil.....	363
veterinary personnel training	301
vitamin b-12	283
d	86
vitamin d rifampin.....	77
deficiency.....	77
water electrolyte balance.....	46
imbalance.....	46
water purification tablets	100
x-ray microanalysis.....	411
ZDV	94

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