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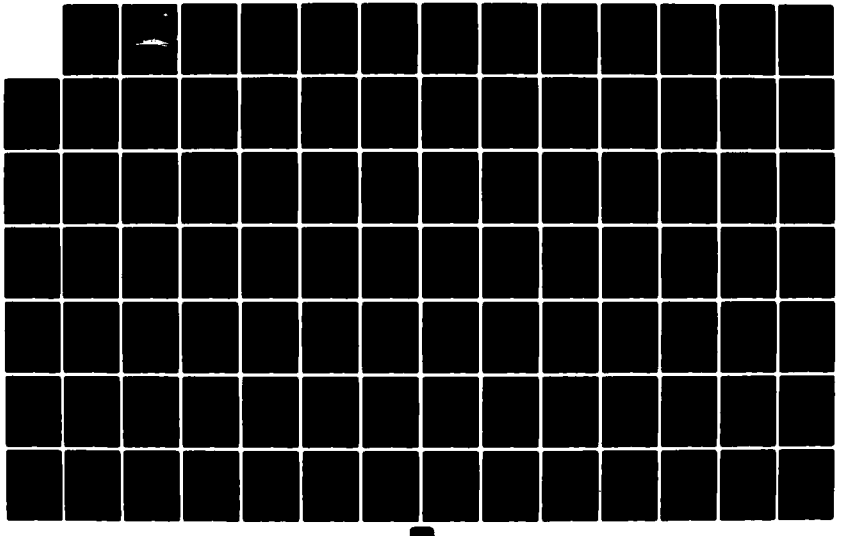

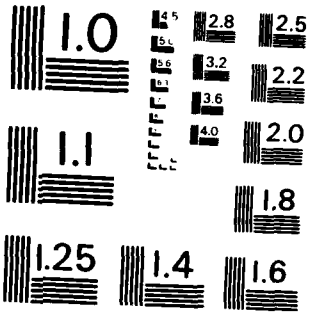

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CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT

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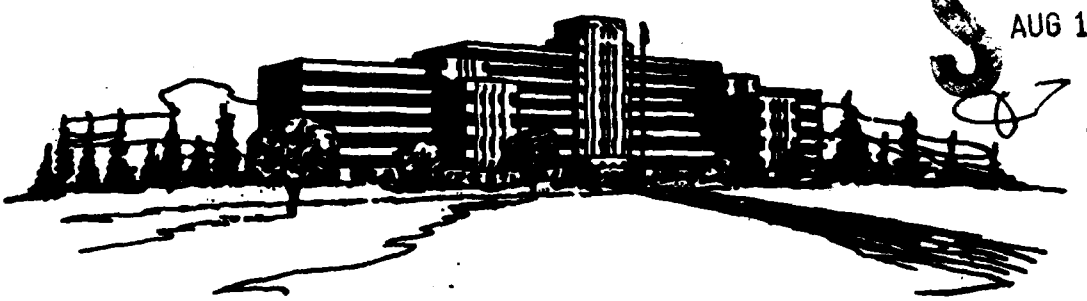

DEPARTMENT OF CLINICAL INVESTIGATION

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18. SUPPLEMENTARY NOTES

The findings of subject 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)

Clinical Investigations, all medical specialties
Experimental Projects (planning, coordination, staff supervision, execution, review and monitoring)
Research Protocols
In-house Research

(continued on reverse side)

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Subject 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 1982 and other known presentations and publications by the Fitzsimons Army Medical Center professional staff. The research protocols described were conducted under the provisions of AR 40-38, as amended, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, HSC Reb 40-23, as amended (continued on reverse side)

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Block 19. Key Words

Publications, Presentations of research data (at national, international and regional science meetings)
Post Graduate Educational Programs
Protocol Training and Support Programs
Protocol Registration
Protocol Status (ongoing, completed, terminated)
Technological Base (personnel and equipment)
Experimental Design (statistical tools, etc.)

Block 20. Abstract

Management of Clinical Investigation Protocols and Reports, Use of Volunteers as subjects of research and AR 40-38, as amended, Department of Clinical Investigation, policies and procedures, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigations.

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DEPARTMENT OF CLINICAL INVESTIGATION

REPORT CONTROL SYMBOL MED-300

CLINICAL INVESTIGATION PROGRAM

ANNUAL PROGRESS REPORT

30 SEPTEMBER 1982

CLINICAL INVESTIGATIONS (U)

FITZSIMONS ARMY MEDICAL CENTER

AURORA, COLORADO 80045

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

FORWARD

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 1982 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, as amended, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, Use of Volunteers as Subjects of Research, and HSC Reg 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 especially grateful to BRIGADIER GENERAL William R. Dwyre, MC, Commanding General of Fitzsimons Army Medical Center, his professional and administrative staff, and to the Commanding Officers and staffs of other supporting activities for the cooperation and assistance provided this Department of Clinical Investigation in our efforts to accomplish our mission. Finally, I would like to recognize the outstanding work, dedication, and wholehearted corroboration of my entire staff. I would especially like to thank my Proto/Ed Asst., Ms. Val McCrill and Mrs. Nancy Moran, Secy, without whose assistance and support this report would not have been possible.

DONALD G. CORBY, M.D.
Colonel, MC
Chief, Department of Clinical
Investigation

UNIT SUMMARY

UNIT SUMMARY

Clinical Investigation Program, FAMC

Clinical Investigation efforts by FAMC personnel in FY 82 culminated in the publication of 126 articles and 121 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1982, there were 142 research protocols on the DCI register. Of these, 97 projects were ongoing and 45 were 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, direction and management is carried out under the aegis of AR 40-38, as amended, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 15-2, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters and other facilities.

Manpower: Current authorized strength is outlined.

Description	Grade	MOS	Br	Auth	Act	Name
C, Dept of Clin Investi	06	60P9B	MC	1	1	Corby
C, Micro Svc	05	68A00	MSC	1	1	Engelkirk
Lab Resources Mgr	04	68F00	MSC	1	1	Quigg
C, Biochem Svc	04	68C00	MSC	1	1	Zolock
C, Immunol Svc	03	68A00	MSC	1	1	Whiteaker
C, Surg Res Labs Svc	03	68J00	MSC	1	1	Harbell
Veterinarian	03	68F00	VC	1	1	Smith
NCOIC - Med Lab NCO	E7	92B4R		1	1	Engle
Sr Med Lab SP	E6	92B30		1	1	Fernandez
Operating Rm SP	E5	91D2R		1	1	Robbins
Bio Sci Asst	E5	01H2R		1	1	Kramer
Bio Sci Asst	E5	01H20		1	1	Kessens
Bio Sci Asst	E6	01H20		1	1	Chadwick
Bio Sci Asst	E5	01H2R		1	1	Jones
Bio Sci Asst	E4	01H20		0	1	Nicholson
Vet SP	E6	91T3R		1	1	Alford
Supv Res Chem	13	1320	GS	1	1	O'Barr
Microbiologist	11	0403	GS	2	2	Lima Paine
Microbiologist	09	0403	GS	5	5	Feuerstein Koester Morse Nelson Rothlauf
Med Technologist	09	0644	GS	1	1	Rush
	07	0644	GS	1	1	Mueller
Med Technician	07	0645	GS	2	2	Hakes Rameriz

Description	Grade	MOS	Br	Auth	Act	Name
Research Chemist	09	1320	GS	4	4	Noble Springs Swanson Waldrup
Bio Lab Tech (animal)	08 09	0404 0404	GS GS	1 1	1 1	Jones Mercill
Ed Assist	06	0318	GS	1	1	McCrill
Animal Caretaker	05	7706	WG	2	2	Beltran Hitchcock
Clerk-Steno	05	0318	GS	1	1	Moran

	FY 80	FY 81	FY 82
Civilian Pay	434,911	474,832	526,991
Travel	5,240	7,629	5,350
Supplies	189,998	222,999	239,833
Equipment	104,311	153,912	201,002
Contracts	18,598	23,540	25,592
Other(Military)	345,859	417,320	470,174

PROGRESS

Biochemistry Service

The development of a PCP assay using gas chromatographic procedures has provided a technique for evaluating hemoperfusion as a means of removing toxic levels of this debilitating drug. Prostaglandin F_2alpha assay was initiated for use in evaluating OB-GYN patients. More red blood cell metabolites and more enzyme assays were initiated in the continued evaluation into the ontogenesis of opossum hemoglobin. The glucagon assay used in the analysis of the interrationship between glucose, insulin and glucogan was modified to increase the assay's sensitivity down to 25 pg. Progress has been made on the development of an assay for gastric inhibitory protein (GIP) which will be used by endocrinology in their study of reactive hypoglycemia. New techniques were developed for studying the vitamin D - calcium metabolism in the chick model. Methodologies for evaluating the relationship of the diglyceride pathway to platelet aggregation is almost complete.

Immunology Service

A microtiter ELISA procedure for quantitating platelet antibodies has been developed and tested against patient samples with excellent results. Additional microtiter ELISA procedures for quantitating circulating immune complexes and antitetanus antibodies have been developed and are giving reliable results. A microtiter adaptation of the Bio-Rad protein assay has also been developed. An immunocytochemical staining procedure using alkaline phosphatase conjugated second antibody has been developed and is being used successfully along with monoclonal antibodies to type T and B lymphocytes.

Microbiology Service

During the fiscal year, the Microbiology Service participated in a total of 13 clinically-oriented infectious diseases protocols, which involved 12 FAMC physicians, 11 DCI personnel, one nurse, 2 Department of Pathology employees, 2 Fitzsimons Army Health Services Region physicians, and 4 persons from the civilian community.

Evaluation of counterimmunoelectrophoresis (CIE) as a routine diagnostic procedure at FAMC was completed, and Department of Pathology personnel were trained to assume CIE responsibilities.

Giardia research was expanded to include 4 separate protocols, covering such areas as immunodiagnosis, in vivo and in vitro interactions between trophozoites and host leukocytes, and antigenic analysis. In June 1982, LTC Engelkirk was a guest speaker at the Denver Giardia Symposium sponsored by the Colorado Department of Health and the University of Colorado; the title of his presentation was "Recent advances in the immunodiagnosis of giardiasis".

Arrangements were made to replace our 20-year-old RCA transmission electron microscope with a 9-year-old Siemens TEM which will be transferred from William Beaumont Army Medical Center in early FY 83.

Surgical Research Laboratories Service

A 600 MA X-ray Unit, from the Hospital, complete with research fluoroscopic capabilities, was installed during the 2nd quarter FY 82. This acquisition increased the radiographic diagnostic and research capabilities.

Construction of a new 7,000 square foot laboratory animal housing facility was approximately 75% completed by the end of FY 82. The new facility has a capacity to house 3,100 animals and is equipped with a modern cage washer, automatic watering systems, new cages, and timed lighting to control light and dark cycles. The new building makes it possible for DCI at FAMC to pursue AALAC accreditation by allowing separation of species, proper ventilation with 15 air changes per hour and more efficient cleaning and sanitization of cages through the use of a cage and rack washer.

Funding

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

MEDCASE items purchased for protocols and general laboratory use are listed as follows:

ITEM	COST
Beckman L8-80 Centrifuge	$27,556.00
Refrigerator Freezer	4,702.76
Circon Micro Video	23,837.00
TRS-80 Model 16	21,502.00
Liquid Scintillation	30,360.00
Biofeedback	12,121.00
Inverted Microscope	7,876.96
Mettler Balance	3,937.97
Forma Incubator	4,555.00
Laminar Flow Hood	5,022.00
Laminar Flow Hood	5,625.00
-85 C Freezer	4,987.95
Steam Sterilizer	21,159.65
J6B Centrifuge	9,930.90
J21M Centrifuge	17,520.00

PUBLICATIONS

PUBLICATIONS

DEPARTMENT OF MEDICINE

Allergy Service

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Kilbride, H., et al: Transcutaneous Oxygen Monitoring in the Acute Management of Infants with RDS. Presented: The Aspen Military Conference on Perinatal Research, Aspen, CO, July 1982.(C)

Merenstein, G.B.: Level I and II Issues. Presented: American Academy of Pediatric Course on Perinatal Pediatrics, Denver, CO, October 1981.

Merenstein, G.B.: Neonatal Jaundice. Presented: Quarterly Update in Pediatrics, Denver, CO, September 1982.

Merenstein, G.B.: Perinatal Infectious Disease Workshop. Presented: American Academy of Pediatrics Course on Perinatal Pediatrics, Denver, CO, October 1981.

Merenstein, G.B.: Oxygen Tension Changes during Lumbar Puncture of the Neonate and Mechanisms of Action. Presented: Second International Symposium on Continuous Transcutaneous Blood Gas Monitoring, Zurich, Switzerland, October 1981.(C)

Merenstein, G.B.: Transcutaneous Monitoring of the Infant with Apnea. Presented: Second International Symposium on Continuous Transcutaneous Blood Gas Monitoring, Zurich,Switzerland, October 1981.

Merenstein, G.B.: Where We're Going. Presented: Aspen Conference on Perinatal Research, Aspen, CO, July 1982.

Moffitt, D.R., Parry, W.H., Merenstein, G.B.: Transcutaneous Monitoring of tne Infant with Apnea. Presented: Second International Symposium on Continuous Transcutaneous Blood Gas Monitoring, Zurich, Switzerland, October 1981.

Mosijczuk, A.D.: Total Body Irradiation and Autologous Bone Marrow Transplantation for Metastatic Rhabdomyosarcoma. Presented: Annual Medical Seminar, 8th Medical Command and 38th Parallel Medical Society, Seoul, South Korea, April 1982.

Mosijczuk, A.D.: Triage and Care of Pediatric Refugees and Victims of Disasters. Presented: Uniformed Services Pediatric Seminar, Bethesda, MD, March 1982.

Pierce, J.R.: Neonatal-Perinatal Workshop. Presented: American Academy of Pediatric Course on Perinatal Pediatrics, Denver,CO, October 1981.

Pierce, J.R.: Neonatal Polycythemia Debate. Presented: American Academy of Pediatric Course on Perinatal Pediatrics, Denver, CO, October 1981.

(C) Direct result of approved registered protocol.

Sanders, J.M.: Adolescent Medicine. Presented: Pediatric Postgraduate Conference, University of Iowa, October 1981.

Sanders, J.M.: Adolescent Medicine. Presented: University of Colorado Conference on Pediatric Disease, Aspen, CO, August 1982.

Sanders, J.M.: Adolescent Medicine in the 1980's. Presented: Michigan State University, November 1981.

Sanders, J.M.: Aspects of Adolescent Medicine. Presented: Visiting Professor, Department of Pediatrics, Keesler AFB, Biloxi, MI, 1981.

Sanders, J.M.: Family Planning and the Adolescent. Presented: Family Planning Maternal and Child Health Conference, Des Moines, IA, April 1982.

Sanders, J.M.: Perspectives in Adolescent Medicine. Presented: Annual Conference of the North American Medical/Dental Association, Snowmass, CO, February 1982.

Sanders, J.M.: The Adolescent and Practicing Pediatricians. Presented: Spring Meeting, Colorado Chapter of the American Academy of Pediatrics, May 1982.

Steenbarger, J.R.: Oxygen Tension Changes during Lumbar Puncture of the Neonate and Mechanisms of Action. Presented: Perinatal Section Meeting District VIII, AAP, Jackson Hole, WY, May 1982.(C)

Weisman, L.E.: Human Colostral T-Lymphocytes: Comparative Analysis with Maternal Peripheral Blood T-Lymphocytes. Presented: Military Section, American Academy of Pediatrics, November 1982.(C)

Weisman, L.E.: Oxygen Tension Changes during Lumbar Puncture of the Neonate and Mechanisms of Action. Presented: Uniformed Services Pediatric Seminar, Bethesda, MD, 16 March 1982.(C)

Wells, D.W.: Adolescent Pregnancy Workshop. Presented: Rocky Mountain Chapter Society for Adolescent Medicine Conference, Denver, CO, May 1982.

DEPARTMENT OF SURGERY

Ophthalmology Service

Cottingham, A.J.: Endophthalmitis. Presented: Postgraduate Course in Military Ophthalmology, Walter Reed Army Medical Center, Washington, DC, April 1982.(C)

Cottingham, A.J.: Endophthalmitis - Diagnosis and Treatment. Presented: 9th Biennial Walter ReedOphthalmology Post Graduate Course and Alumni Meeting, April 1982.(C)

(C) Direct result of approved registered protocol.

Cottingham, A.J.: Ocular Trauma for the Non-Ophthalmologist. Presented: Gary Wratten Surgical Symposium, San Antonio, TX, March 1982.(C)

Cottingham, A.J.: Posterior Chamber Implantation of Intraocular Lenses. Presented: Letterman Army Medical Center, San Francisco,CA, April 1982.(C)

Otolaryngology Service

Aldes, M.E., Lowry-Romero, F.: Protocol for Delivery of Services to the Laryngectomized Population and Their Families. Presented: American Speech and Hearing Association, South Central Regional Conference, Colorado Springs, CO, March 1982.

Hasbrouck, J.M.: Speech Production and Perception as Related to the Assessment and Remediation of Auditory Perceptual Disorders. Presented: Wyoming Speech-Language-Hearing Association Annual Convention, Laramie, WY, September 1982.

Hasbrouck, J.M.: An Intensive Therapy Approach to Eliminating Stuttering and Maintaining Fluency. Presented: American Speech and Hearing Association, South Central Regional Conference, Colorado Springs, CO, March 1982.(C)

Urology Service

Donohue, R.E., Fauver, H.E.: Unilateral Absence of the Vas Deferens - A Significant Physical Finding. Presented: 77th Annual American Urological Association Meeting, Kansas City, MO, May 1982.

Donohue, R.E., Mani, J.H., Biber, R.J., Whitesel, J.A., Augspurger, R.R., Scanavino, D.J., Fauver, H.E., Pfister, R.R.: Complications of the Staging Pelvic Lymphadenectomy in Prostatic Adenocarcinoma. Presented: 77th Annual American Urological Association Meeting, Kansas City, MO, May 1982.

Horne, D.W.: Primary Signet Ring Adenocarcinoma of the Bladder: The Fitzsimons Experience. Presented: 29th Annual Kimbrough Urological Seminar, Denver, CO, November 1981.

Mani, J.H.: Leiomyolipoma: Preoperative Diagnosis and Conservative Surgery. Presented: 29th Annual Kimbrough Urological Seminar, Denver, CO, November 1981.

Osborne, M.L.: Genito-Urinary Neurofibromatosis. Presented: 29th Annual Kimbrough Urological Seminar, Denver, CO, November 1981.

Whitesel, J.A., Donohue, R.E., Mani, J.H., Fauver, H.E., Augspurger, R.R., Biber, R.J., Scanavino, D.J., Pfister, R.R.: Acid Phosphatase - It's Influence on Pelvic Lymph Node Dissection. Presented: 77th Annual American Urological Association Meeting, Kansas City, MO, May 1982.

(C) Direct result of approved registered protocol.

EXPLANATION of ANNUAL PROGRESS REPORT DETAIL SHEETS

(1) DATE: Fiscal Year ending date.

(2) PROTOCOL NO: FAMC Work Unit Number of the study.

(3) STATUS: Indicates if the study is Ongoing, Completed or Terminated.

(4) TITLE: Project title of the study.

(5) START DATE: The date the study started.

(6) ESTIMATED COMPLETION DATE: The projected completion date of the study.

(7) PRINCIPAL INVESTIGATOR(s): List of all Principal Investigator(s) involved in the study.

(8) FACILITY: Fitzsimons Army Medical Center

(9) DEPARTMENT/SECTION: Department or Service the protocol originated from.

(10) ASSOCIATE INVESTIGATOR(9): List of all Associate Investigator(s) involved in the study.

(11) KEY WORDS: Key words pertaining to the particular area of research involved in the study.

(12) ACCUMULATIVE MEDCASE COST: See Unit Summary Sheet - Funding.

(13) ESTIMATED ACCUMULATIVE OMA COST: See Unit Summary Sheet - Funding

(14) PERIODIC REVIEW RESULTS: Date of the continuing review by the Institution Review Committee.

(15) STUDY OBJECTIVE: A summary of objectives to be accomplished during the study.

(16) TECHNICAL APPROACH: A brief summary of the technical approach to be taken during the study.

(17) PROGRESS: A summary of prior and current progress since inception of of the study.

The Continuation Sheets are used as extensions for (1) - (17) and as an accumulative listing for Publications and Presentations that are a direct result from the study.

The Detail Sheets were submitted in final form by the Principal Investigators and have not been edited.

DETAIL SUMMARY SHEETS

MEDICINE

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 74/110 (3) Status: Ongoing

(4) Title:

Reactive Hypoglycemia: An Analysis of Glucose-Insulin-Glucagon Interrelationships and Counter Hormonal Regulatory Factors

(5) Start Date: FY71

(6) Est Compl Date: Indefinite

(7) Principal Investigator:

Fred D. Hofeldt, M.D., COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine Service

(10) Assoc Investigators:
Gerald S. Kidd, M.D., LTC,MC
David Zolock, MAJ, MS
T. P. O'Barr, Ph.D., DAC
Leonard R. Sanders, M.D., MAJ, MC, WBAMC
Annelle Shackelford, MT, DAC

(11) Key Words:
reactive hypoglycemia
glucose tolerance
counter-regulatory hormones

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/81 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 33

d. Total Number of Subjects Enrolled to Date: 345

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

The objectives of the hypoglycemic study is to continue to investigate in our large clinic population the glucose-insulin-glucagon and prolactin interrelationships and the response of counter-regulatory hormones to hypoglycemic stress. This project is a continuation of the previous project initiated in 1969 at the University of California Medical Center, Moffatt Hospital, (Cont'd)

(16) Technical Approach:

The clinical research protocol involves evaluation of control subjects and hypoglycemic patients to assess the interrelationships of beta cell and alpha cell responsiveness to oral and intravenous glucose administration. Based upon findings in controls and patients with disease states, a classification system has been proposed. The data have allowed for an understanding of the basic (Cont'd)

(17) Progess:

The study continues to be an active endocrine protocol with recruitment of new patients for evaluation and study. Several publications elucidating the unusual features of this disorder have resulted from the study. The patients studied in this program are currently being evaluated by a data management system developed by the Department of Automation using a Ciber Computer for data (Cont'd)

(15) Continued.

San Francisco, California.

(16) Continued.

pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine, Endocrine Clinic, with the assistance of an assigned GS-5 Medical Technician to perform blood sampling and assist during the testing. During the glucose tolerance test, the patient has an indwelling catheter for frequent sampling of blood glucose, and is continually monitored by a cardiac monitor system and blood glucoses are assessed by the Ames Reflectance Meter immediately after sampling. After glucose administration, blood insulins, glucagons, growth hormones, prolactins and cortisols are sampled and values are determined by a sensitive radioimmunoassay. The procedure is designed to provide a minimum of patient inconvenience in the performance of these well standardized procedures. Many normal individuals experience a low blood sugar state sometime after glucose administration, the clinical significance of a low blood glucose state is observed by recording appropriate adrenergic symptoms at the nadir of the glucose and determining if there is a counter hormonal responsiveness to defend the stress of a low blood glucose state. This approach allows strict definition of bona fide reactive hypoglycemia, and clearly distinguishes it from the benign low blood glucose states.

(17) Continued.

retrieval and use of BMD PNS P55 for statistical analysis. The Department of Clinical Investigation staff is currently in the process of developing a gastric inhibitory polypeptide assay to determine if alterations in this gastrointestinal factor may be implicated in reactive hypoglycemia.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 74/110

SERVICE Endocrine/Metabolic DEPARTMENT Medicine

(1) Abrams, R., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, P.: Late Reactive Hypoglycemia in Hypothyroidism. (Accepted for publication in American Journal of the Medical Sciences.)

(2) Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggings, J.T., and Elchner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients with Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia After Mixed Meals. Diabetes 30:465, 1981.

(3) Sanders, L.R., Hofeldt, F.D., Kirk, M., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072, 1982.

(4) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal 76:30, 1979.

(5) McCowen, K.D., Adler, R.A., O'Barr, T.P., and Hofeldt, F.D.: Clinical Implications of Flat Oral Glucose Tolerance Test. Military Medicine 144:177, 1979.

(6) Crapo, P.A., Scarlett, J.A., Kolterman, O., Sanders, L., Hofeldt, F.D., and Olefsky, J.: The Effects of Oral Fructose, Sucrose and Glucose in Subjects With Reactive Hypoglycemia. Diabetes Care 5:512, 1982.

PRESENTATIONS for FY 81 Annual Progress Report Proto No. 74/110

SERVICE Endocrine/Metabolic DEPARTMENT Medicine

(1) Hofeldt, F.D.: Reactive Hypoglycemia: Update 1980. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 16 January 1980.

(2) Sanders, L.R.: Reactive Hypoglycemia. Presented: Grand Rounds, University of Colorado Medical Center, Denver, CO, 13 March 1979.

(3) Sanders, L.R.: Reactive Hypoglycemia. Presented: Medical Grand Rounds, Denver General Hospital, Denver, CO, 15 March 1979.

(4) Sanders, L.R.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Medical Center, Denver, CO, 11 April 1979.

(5) Hofeldt, F.D.: Hypoglycemia. Grand Rounds, Delgado Amphitheater, Tuland Medical School Charity Hospital, New Orleans, LA, 28 April 1982.

(6) Hofeldt, F.D. and Scarlett, J.A.: Reactive Hypoglycemia. Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, March 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 76/102 (3) Status: Ongoing

(4) Title:

Anti-neoplastic Therapy with Methyl CCNU (NSC95441)/1-(2-Chloroethyl)-3-(4-Methyl Cyclohexyl) - 1-Nitrosourea

(5) Start Date: 1976	(6) Est Compl Date: 1983
(7) Principal Investigator: N.J. DiBella, MD,COL,MC	(8) Facility: FAMC
(9) Dept/Svc: HEM/ONC	(10) Assoc Investigators:
(11) Key Words: Chemotherapy, CA of colon	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Oct/82 b. Review Results: To continue

c. Number of Subjects Enrolled During Reporting Period: 4

d. Total Number of Subjects Enrolled to Date: See previous report

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To test the efficacy of methyl CCNU in metastatic or recurrent CA of the colon.

(16) Technical Approach:

Clinical study.

(17) Progess:

Four patients have been treated with this agent in combination with 5-FU. There have been no untoward effects and no responses to the chemotherapy but these were all patients who had been heavily pretreated.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 76/116 (3) Status: Terminated

(4) Title:

The Effect of Dexamethasone on Gonadotropins in Post-menopausal Women

(5) Start Date: 1976

(6) Est Compl Date: 1982

(7) Principal Investigator:

Michael Bornemann, M.D., LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine Service

(10) Assoc Investigators:

William J. Georgitis, M.D., MAJ, MC
Gary L. Treece, M.D., LTC, MC
Fred D. Hofeldt, M.D., COL, MC

(11) Key Words:

women
post-menopausal
Dexamethasone
gonadotropins

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objectives:

To clarify the mechanism whereby glucocorticoids may interfere with gonadotropin secretion or release in post-menopausal women. This is of interest because of the high frequency of gonadal dysfunction in both male and female patients with endogenous as well as exogenous Cushing's syndrome.

(16) Technical Approach:

Patient population to be studied are healthy, post-menopausal women on no medication. A post-menopausal woman will be defined as any woman with elevated plasma gonadotropin levels as a result of physiological ovarian failure or prior surgical extirpation of the ovaries. A baseline 0800 plasma FSH, LH, cortisol and prolactin level will be drawn on two consecutive days. The A.M. FSH, LH, (Cont'd)

(17) Progess:

Results of this research project has shown that patients in the postmenopausal state have a paradoxical increase in prolactin following GnRH stimulation and a response not previously heretofore reported in postmenopausal females. The paper in its completed form reporting the results of the study has been accepted for publication in Clinical Endocrinology. Because of lack of (Cont'd)

(16) Continued.

cortisol and prolactin levels will be obtained daily during the Dexamethasone treatment. In order to define the site of the anticipated Dexamethasone suppression of the gonadotropins a GnRH infusion test will be performed by giving a single IV bolus of 100 ug of GnRH on the day prior to, and on the third day of Dexamethasone treatment. Blood for FSH, LH, cortisol and prolactin will be drawn at -15, 0, 15, 30, 45, 60, 90 and 120 minutes after GnRH injection.

(17) Continued.

continued interest in the GnRH protocol, and the reassignment of the primary investigators, the protocol is terminated. The GnRH pharmaceutical has been returned to the Ayerst Co.

PUBLICATIONS:

(1) Treece, G., Dodson, L.E., and Hofeldt, F.D.: Effect of GnRH on Postmenopausal Gonadotropins and Prolactin Levels: Influence of Short-Term Glucocorticoid Administration. Program and Abstracts, 61st Annual Meeting of the Endocrine Society, Anaheim, CA 1979.

(2) Georgitis, W.J., Treece, G.L., and Hofeldt, F.D.: Gonadotropin Releasing Hormone Provokes Prolactin Release in Postmenopausal Women: A Response Not Altered by Dexamethasone. (Accepted for publication in Clinical Endocrinology.)

PRESENTATIONS:

(1) Treece, G., Dodson, L.E., and Hofeldt, F.D.: Effect of GnRH on Postmenopausal Gonadotropins and Prolactin Levels: Influence of Short-Term Glucocorticoid Administration. Presented: 61st Annual Meeting of the Endocrine Society, Anaheim, CA, 1979.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/102 (3) Status: on-going

(4) Title: The Development of Specific and Cross Sensitivity in the Tracheal Tissue of Guinea Pigs treated with Isoproterenol and Aminophylline.

(5) Start Date: 1978 (6) Est Compl Date: 1983

(7) Principal Investigator:
William Ronald Tipton, MD, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Allergy-Imm

(10) Assoc Investigators:
William P. Andrade, MD,LTC,MC
Linkus Goldberg, MD,CPT,MC
Edward Squire, MD,MAJ,MC

(11) Key Words:
subsensitivity
beta agonist
guinea pig trachea

(12) Accumulative MEDCASES:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest IRC Review: APR 82 b. Review Results: continued
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-granted IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
This study is designed to measure the development of the subsensitivity to two drugs, Isoproterenol and theophylline, by examining both their dilator response in histamine contracted tracheal tissue and ability to increase levels of cyclic-AMP in tracheal tissue and parenchymal lung tissue.

(16) Technical Approach: Guinea pig tracheal and peripheral lung strips will be analyzed for cyclic-AMP levels, metabolites of arachodonic acid and other tissue responses to various mediators employing a continuous flow tissue bath system. The equipment for this study is presently available at the Tripler Army Medical Center.

(17) Progress: A major portion of this particular protocol was completed in June 1982, including the pre-treatment of the animals followed by removal of trachea and lung tissue studies. Portions of the tracheas were frozen at [illegible] examined during November and December 1982. The data from the tissue studies is currently being [illegible] It is planned that a presentation of this material will take place in early 1983.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 78/102

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

(1) Tipton WR, Nelson HS, Souhrada JF, Morris HG, Jacobson KW: Dynamics of Isoproterenol Subsensitivity in Guinea Pig Airway Smooth Muscle. Lung 159:199;1981.

PRESENTATIONS:

(1) Tipton WR, Jacobson R, Nelson HS, Morris H, Souhrada J: Dynamics and Mechanism of Guinea Pig Trachea Subsensitivity to Isoproterenol, presented at 31st Annual Pulmonary Disease Symposium, Fitzsimons Army Medical Center, Aurora, Colorado, September 1978.

(2) Tipton WR, Jacobson K, Nelson HS, Morris H, Souhrada J: Dynamics and Mechanism of Guinea Pig Traches Subsensitivity to Isoproterenol, presented at the American Thoracic Society, Las Vegas, Nevada, May 1979.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/113 (3) Status: Terminated

(4) Title:
Effects of Salicylic Acid on Fatty Acid Oxidation in Rat Skeletal Muscle Mitochondria

(5) Start Date: 4 January 1979

(6) Est Compl Date: June 1982

(7) Principal Investigator:
Robert E. Jones, M.D., MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine Service

(10) Assoc Investigators:
Gerald S. Kidd, M.D., LTC, MC
David T. Zolock, MAJ, MS
Fred D. Hofeldt, M.D., COL, MC

(11) Key Words:
salicylic acid
mitochondrial fatty acid
long chain fatty acid:CoASH ligase (AMP)

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 10/81 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: N/A
d. Total Number of Subjects Enrolled to Date: N/A
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
The principal objective of this protocol is to determine the mechanism of salicylate-induced stimulation of fatty acid oxidation by studying the effects of salicylic acid and other compounds on the activation step of fatty acid oxidation, fatty acid: CoASH ligase (AMP)(E.C.6.2.1.3).

(16) Technical Approach:
Rat skeletal muscle mitochondria are isolated from the quadriceps femoris muscle group. Ligase activity is determined using a radio-ligand millipore filter procedure. Salicylic acid, phosphate and NaF are co-incubated with substrates for the ligase reaction. Statistical analysis is performed with a paired t-test on individual data points or an unpaired t-test on the slopes (Con't)

(17) Progess:
This study has been completed and has resulted in a publication of the methodology and observations in regards to perturbation of fatty acid oxidation and skeletal fat mitochondria with salicylic acid. The reassignment of the principal investigator, and the lack of interest by the remaining endocrine/metabolic staff, has led to the termination of this protocol.

(16) Continued.

of the lines generated by double-reciprocal plots.

PUBLICATIONS:

(1) Jones, R.E., Askew, E.W., Hecker, A.L., and Hofeldt, F.D.: Salicylic Acid Stimulation of Palmitic Acid Oxidation by Rat Skeletal Muscle Mitochondria. Biochimica et Biophysical Acta 666:120, 1981.

(2) Jones, R.E., and Hofeldt, F.D.: Stimulation of Mitochondrial Long Chain Fatty Acid: CoASH Ligase (AMP) by Salicylic Acid. (Abstr.) Program Fifty-Seventh Annual Meeting, Southwestern and Rocky Mountain Division American Association for the Advancement of Science, Colorado-Wyoming Academy of Science, 22-25 April 1981.

PRESENTATIONS:

(1) Jones, R.E.: Salicylic Acid Stimulation of Palmitic Acid Oxidation by Rat Skeletal Muscle Mitochondria. Presented: Hugh Mahon Lectureship Awards, FAMC, June 1980.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/114 (3) Status: Completed

(4) Title: The Use of Minoxidil in Treating Progressive Systemic Sclerosis

(5) Start Date: Jun 79	(6) Est Compl Date: Sep 82
(7) Principal Investigator: Steven R. Bailey, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Cardiology, DOM	(10) Assoc Investigators: Robert Claypool, COL, MC
(11) Key Words: Systemic Scleroderma/Minoxidil	

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

(14) a. Date, Latest HUC Review: 10/82 b. Review Results: Completed.
c. Number of Subjects Enrolled During Reporting Period: 2
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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: Minoxidil, a potent vasoactive medication, was being administered systemically to assess its potential in the therapy of systemic scleroderma and associated Raynaud's phenomena.

(16) Technical Approach: Consenting patients with systemic scleroderma were entered into this double-blind cross-over study, using Minoxidil at increasing dosage increments. The patients were followed at bi-weekly and monthly intervals with hospital admission upon entrance, at cross-over and at the end of the study for detailed physical examination and laboratory evaluation.

(17) Progess: The first patient was entered in June 1979. All nine patients entered have either completed the protocol or were dropped from the protocol but continued on Minoxidil with the consent of the FDA. One patient died; however indepth evaluation at the University of Kansas Medical Center and that of the FDA indicated that this was not related to Minoxidil. All patients have had subjective improvement on Minoxidil and there has been objective improvement as assessed by range of motion and improvement in the cutaneous manifestations in four patients. Results are being evaluated and a manuscript is being compiled for submission for publication in spring of 1983.

Publications and Paresentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/116 (3) Status: Completed

(4) Title:

The Effect of Positive and Negative Air Ions on Pulmonary Functions in Patients with Bronchial Asthma

(5) Start Date: 1978	(6) Est Compl Date: Completed
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: Brian Dantzler, MD, MAJ, MC Bruce Martin, MD, CPT, MC, USAF
(11) Key Words: small air ions	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: OCT81 b. Review Results: Continue

c. Number of Subjects Enrolled During Reporting Period: 0

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To evaluate the short-term response of patients with bronchial asthma to an increase in the ambient concentration of positive or negative air ions.

(16) Technical Approach:

Patients with bronchial asthma whose clinical condition was stable will be exposed on two consecutive days for periods of six hours to either an increased concentration of positive or negative small air ions. The response will be monitored by pulmonary function studies.

(17) Progess:

Nine patients were studied. The material has been presented and is presently ready for submission for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 78/116

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

NONE

PRESENTATIONS:

1. Dantzler, B.S.: The Effect of Positive and Negative Air Ions on Bronchial Asthma. Presented: 33rd Annual Pulmonary Symposium, Fitzsimons Army Medical Center, Aurora, CO, January 1981.

2. Dantzler, B.S., Martin, B., Nelson, H.S.: The Effect of Positive and Negative Air Ions on Bronchial Asthma. Presented: 37th Annual Meeting of American Academy of Allergy, San Francisco, CA, March 1981.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/117 (3) Status: On-going

(4) Title:

The Effect of Parasitic Infestation on Immediate Skin Test Reactions

(5) Start Date: 1980	(6) Est Compl Date: 1984
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: L.E. Mansfield, MD, LTC Praphan Phanupahak, MD, PhD
(11) Key Words: IgE parasites	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: OCT81 b. Review Results: Continue
c. Number of Subjects Enrolled During Reporting Period: Unknown
d. Total Number of Subjects Enrolled to Date: Unknown
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine whether antiparasite antibodies of the IgE class present in high concentrations in patients with infestations are able to saturate receptors in the mast cells and in so doing block mast cell sensitization by IgE antibody directed toward inhaled allergen.

(16) Technical Approach:

Evidence for mast cell IgE receptor saturation will be sought by comparing the direct immediate wheal and flare skin test to circulating levels of IgE specific for the same allergen. The clinical portion of this study will be performed in Thailand by Dr. Phanuphak. The laboratory portion will be performed at Fitzsimons.

(17) Progess:

The clinical portion of this study is currently being performed in Thailand. No reports have been received from Doctor Phanuphak for approximately one and one-half years. Current status is unknown.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/118 (3) Status: Ongoing

(4) Title: A Precision Measurement of Anatomic Deadspace Using Multiple Inert Gas Analysis, Comparison with Fowler's Technique and Application

(5) Start Date: September 1978	(6) Est Compl Date: 1984
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, PhD
(11) Key Words: Deadspace Steady State Diffusion	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 10/81 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To experimentally confirm a proposed new procedure for anatomic deadspace measurements which has important advantages over conventional techniques.

(16) Technical Approach: Deadspace measurements are first performed using the technique of Fowler, with careful attention to insure a constant inspiratory volume and expiratory air flow. This is followed by the multiple inert gas technique whereby two breaths of specific mixtures of argon, neon, and nitrogen are inhaled in a two breath sequence and the exhaled gas from each sequence analyzed on a gas chromatograph. From changes in concentration of

(17) Progess: The next phase of the study using the patients with obstructive lung disease is planned for the future as priorities permit.

(16) the inert gases deadspace is deduced.

PUBLICATIONS for FY 82 Annual Progress Report:

1.) Kindig, N.B., Perry, M.E., Filley, G.F., "Gas-Mixing Dead Space Measurement with Paired Tracers, Progress in Respiration Research, Volume 16, PP 31-32, 1981.

2.) Kindig, N.B., Perry, M.E., Filley, G.F.: Gas Mixing Deadspace: Measurement with Tracer Gases (Abstract) Unbound, Max Planck Institute for Experimental Medicine, July 1980.

PRESENTATIONS:

1.) Kindig, N. B., Perry, M.E., Filley, G.F.: Gas-Mixing Deadspace: Measurement with Tracer Gases; presented at the Symposium on Gas Exchange Function of Normal and Diseased Lungs, Max Planck Institute for Experimental Medicine, Goettingen, Germany, July 9-11, 1980.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/119 (3) Status: Completed

(4) Title:

The Effect of Aspirin on Platelet Aggregation in Aspirin Sensitive Asthmatics

(5) Start Date: 1978	(6) Est Compl Date: Completed
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: R.A. Gillham, MD, LTC, MC, USAF R.E. Danziger, MD, CDR, USN P.T. O'Barr, PhD, DAC
(11) Key Words: aspirin sensitivity platelet aggregation	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: OCT81 b. Review Results: CONTINUE

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine whether the intolerance to aspirin and other related substances manifested by some patients with bronchial asthma could be diagnosed by an in vitro test.

(16) Technical Approach:

The plan is to utilize the platelet aggregation assay and the thromboxane assay to compare the response of platelets from patients with aspirin sensitivity and control patients.

(17) Progess:

The study has been completed. The data has been analized and presented.

Publications: none

PRESENTATIONS for FY 82 Annual Progress Report Proto No. 78/119

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

1. Danziger RE, Effects of Aspirin on Platelet Aggregation and Arachidonic Metabolism in Aspirin Sensitivit Asthmatics, 33rd Annual Pulmonary Disease Symposium, Fitzsimons Army Medical Center, Aurora, CO, January, 1981.

2. Danziger RE, Gillham R, O'Barr PT, Nelson HS, The Effects of Aspirin on Platelet Aggregation and Arachidonic Acid Metabolism in Aspirin Sensitive Asthmatics, 37th Annual Congress American College of Allergists, Washington, DC, 6 Apr 81.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/121 (3) Status: Completed
(4) Title:

The Determination of Cross Allergenicity between Western Grass Pollens and Common Northern Grass Pollens

(5) Start Date: 1978	(6) Est Compl Date: Completed
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators:
(11) Key Words: grass pollen and cross allergenicity	B.G. Martin, MD, MAJ, MC, USAF
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: DEC81 b. Review Results: Continue
c. Number of Subjects Enrolled During Reporting Period: Not Applicable
d. Total Number of Subjects Enrolled to Date: Not Applicable
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: Not Applicable

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To study the cross allergenicity of extracts of common western prairie grasses and to compare them to the already well-studied northern pasture grasses and Bermuda grass.

(16) Technical Approach:

The approach is to employ a pooled allergic serum and RAST inhibitions with allergen disks manufactured in the allergy research laboratory at Fitzsimons and a variety of commercial allergy extracts.

(17) Progess:
Laboratory studies have been completed, the data has been evaluated and is in the final stages of preparation for submission for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 78/121

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

1. Martin BG, Manfield LE, Nelson HS: Patterns of Cross Allergenicity among Grasses (abstr) Journal Allergy-Clinical Immunology 65:229;1980.

PRESENTATIONS for FY 81 Annual Progress Report

1. Martin BG: Patterns of Cross Allergenicity among Grasses, presented at the annual meeting of the American Academy of Allergy, Atlanta, Georgia, 20 Feb 1980.

2. Martin BG, Nelson HS, Cross Allergenicity of Bahia Grass, presented at the 37th Annual Congress, American College of Allergists, Washington, DC, 6 Apr 81.

3. Martin, B.: Cross Allergenicity Among the Grasses. Presented: The Carl W. Temple Symposium, Fitzsimons Army Medical Center, Aurora, Colorado, 25-27 January 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/123 (3) Status: Ongoing

(4) Title: A Comparison of the Zimmerer and Dubois Techniques of Airway Resistance Measurements by Body Plethysmography

(5) Start Date: January 1979	(6) Est Compl Date: December 1984
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Robert W. Zimmerer, PhD Robert J. Browning, BS
(11) Key Words: Alveolar pressure Airway resistance Body Plethysmography	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 1/82 b. Review Results: Ongoing
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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To compare a clinically untried measurement of airway resistance with a standard technique.

(16) Technical Approach: Forced expiratory manuevers are performed with the subject seated in a constant volume body plethysmograph, while plethysmograph pressure and airflow are monitored and recorded with a DEC PDP11/10 computer. With this information and the previously determined FRC of the patient, alveolar pressure is calculated throughout the expiratory manuever. Pressure flow relationships are then related to the patient's maximal expiratory flow volume loop.

(17) Progess: Since the last report, an additional publication has arisen from this protocol. Before further work on this protocol occurs certain technical changes will be made utilizing a Steadwell's spirometer instead of a Numatac. Until this is implemented further work on this protocol will not continue.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 78/123

SERVICE Pulmonary Disease Service DEPARTMENT of Medicine

1.) Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerzied Plethysmography (Abstrast) Symposium on Computers in Critical Care in Pulmonary Medicine, Page 47, June 1980.

2.) Perry, M.E., Zimmerer, R.W., Nelson, R.A., Browning, R.J., Non-Invasive Determination of Alveolar Pressure-Flow Relationship (Abstract) American Review of Respiratory Disease, Volume 121, Page 389, April 1980.

3.) Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography (Abstract) AAMI 15th Annual Meeting, Page 246, April 1980.

4.) Perry, M.E., Zimmerer, R.W., Browning, R.J., "Non-Invasive Alveolar Pressure/Flow Pattern Determinations by Computerized Plethysmography", Computers in Critical Care and Pulmonary Medicine, Volume 2, PP 75-77, Plenum Press, 1982.

PRESENTATIONS:

1.) Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography, presented at the annual Computers in Critical Care and Pulmonary Medicine, Lund, Sweden, June 3-6, 1980.

2.) Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography, presented at the AAMI 15th Annual Meeting San Francisco, April 13-17, 1980.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/124 (3) Status: Ongoing

(4) Title:

A Self Consistent Method of Single Breath DLCO Measurement

(5) Start Date: September 1978	(6) Est Compl Date: December 1983
(7) Principal Investigator: Michael E. Perry, LTC,MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Neal B. Kindig, PhD Robert J. Browning, BS
(11) Key Words: Single Breath Diffusion Alveolar Gas Breathing Patterns	

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

(14) a. Date, Latest HUC Review: 1/82 b. Review Results: Ongoing
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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To experimentally confirm a proposed new method of DLCO measurement.

(16) Technical Approach: Data will be sampled during the single breath DLCO determination at various breath holding times and at various exhaled lung volumes. Data will be analyzed online by computer which will correct for volume averaging and effective breath holding time. If the theoretical approach as outlined in the original protocol is selfconsistent, the calculated diffusion capacity should remain constant regardless of breathing pattern or gas collection timing.

(17) Progess: The instrument is now fully operational and has been since Jan 1982 in full support of the hospital patient care mission. Two papers have been published this current fiscal year as well as four presentations. The study is ongoing because of further developments in the theoretical portion of this protocol which have come to light during the past 6 months.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 78/124

SERVICE Pulmonary Disease Service DEPARTMENT of Medicine

1.) Kindig, N.B., Hazlett, D .R., Filley, G.F.: "Timing and Volume Averaging in Single Breath DLCO Measurement". The Physiologist, 21:64, 1978.

2.) Browning, R.J., Kindig, N.B., Perry, M.E., "Computer Control Aspects of a Single Breath DLCO Station." Biomedical Sciences Instrumentation, Volume 18, April, 1982.

3.) Kindig, M.B., Perry, M.E., Browning, R.J., "Single Breath DLCO: Inspiratory Timing and Volume Averaging (ABS) Federation Proceedings, Volume 41, Mar, 1982.

PRESENTATIONS:

1.) Zimmerer, R.W.: Simulated Diffusion Testing. Presented: 32nd Annual Pulmonary Symposium, FAMC, Aurora, CO, September 1979.

2.) Browning, R.J., Kindig, N.B., Perry, M.E., "Computer Control Aspects of a Single Breath DLCO Station." Presented at the Nineteenth International Instrument Society of America Biomedical Sciences Instrumentation Symposium, Denver, CO, April, 1982.

3.) Kindig, N.B., Perry, M.E., Browning, R.J., "Single Breath DLCO: Inspiratory Timing and Volume Averaging". Presented at the Annual FASEB Meeting, New Orleans, April, 1982.

4.) Kindig, N.B., "Single Breath DLCO: Improved Time and Volume Measurement". Presented at the Annual Carl W. Tempel Pulmonary Symposium, Denver, CO, Jan, 1982.

5.) Perry, M.E., "Mechanism of Carbon Monoxide Effect on Oxyhemoglobin Dissociation". Presented at the Annual Carl W. Tempel Pulmonary Symposium, Denver, CO, Jan, 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/103 (3) Status: Completed

(4) Title: An Evaluation of Combined H1 and H2 Receptor Blocking Agents in the Treatment of Seasonal Allergic Rhinitis

(5) Start Date: 1979	(6) Est Compl Date: Completed
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: GB Carpenter, MD, MAJ, MC A Bunker-Soler, MD, MAJ, MC
(11) Key Words: histamine receptor blocking agents	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: COMPLETE
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: Unchanged
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine whether the addition of a blocker of the H2 receptor would provide greater symptomatic relief in patients with allergic rhinitis than was provided by an H1 blocking agent alone.

(16) Technical Approach:

A double-blind, crossover study was performed during the weed season of 1979. In this study patients continuously received an H1 blocker (Chlorpheniramine) and alternately for two week periods received either a placebo or Cimetidine, an H2 blocker. Patients recorded symptoms twice daily throughout the weed season.

(17) Progess:

The clinical study was performed during the weed season of 1979. The data is still in preparation for final publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 79/103

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

(1) Carpenter, G.B., Bunker, A.L., and Nelson, H.S.: An Evaluation of Combined H1 and H2 Antagonists in the Treatment of Seasonal Allergic Rhinitis. (Abst) Journal of Allergy and Clinical Immunology 65:187, 1980.

PRESENTATIONS:

(1) Carpenter, G.B.: An Evaluation of Combined H1 and H2 Antagonists in the Treatment of Seasonal Allergic Rhinitis. Presented: Annual Meeting of the American Academy of Allergy, Atlanta, Georgia, 18 February 1980.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/105 (3) Status: Ongoing

(4) Title: Breathing Pattern Effects on Steady State DLCO Measurement.

(5) Start Date: November 1979	(6) Est Compl Date: December 1984
(7) Principal Investigator: Michael E. Perry, LTC,MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, PhD
(11) Key Words: Disease Steady State DLCO Breathing Pattern	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 10/81 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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To experimentally confirm theoretically determined corrections for breathing patterns during steady state diffusion studies.

(16) Technical Approach: Breathing patterns - various breathing patterns including inspiratory and expiratory breath holds will be performed while the subject performs during the standard steady state diffusion measurement. If our approach is correct, mathematical corrections for breathing pattern will result in a constant value for diffusion capacity.

(17) Progess: The computer program for sampling and analyzing the breathing pattern has been written and is at this point ready for use. This protocol will be completed in concert with protocol No. 78/124 (A Self Consistent Method of Sincle Breath DLCO Measurement), and an attempt will be made to show the essential equivalence of these two different methods.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 79/105

SERVICE Pulmonary Disease Service DEPARTMENT of Medicine

1.) Perry, M.E., Browning, R.J., Kindig, N.B., "The Abbreviated Alveolar Air Equation Revisited, Chest, Volume 80, PP 763-764, December, 1981.

PRESENTATIONS:

1.) Kindig, N.B.: D_LCO_{ss} correction using PaCO back pressure predicted from venous blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, Colorado, January, 1981.

2.) Perry, M.E.: Simplified room air (A-a)O_2 D calculation. Presented: Carl E. Tempel Pulmonary Symposium, Denver, Colorado, January, 1981.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/106 (3) Status: Ongoing

(4) Title: Measurement of Lung Compliance Utilizing Pulmonary Capillary Wedge Pressures.

(5) Start Date: January, 1979	(6) Est Compl Date: December 1984
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators:
(11) Key Words: Wedge Pressure	Robert Zimmerer, PhD

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

(14) a. Date, Latest HUC Review: 10/81 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: none
d. Total Number of Subjects Enrolled to Date: none
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.:

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
Validation of lung compliance measurement using pulmonary capillary wedge pressure by simultaneous comparison with esophageal pressure.

(16) Technical Approach: Simultaneous measurements of intrathoracic pressure via Swan Ganz intraesophageal balloon, inhaled lung volumes, and airway pressures will be monitored with a specially designed computerized recording instrument and correlations between these measurements sought.

(17) Progess: The special instrument required for this protocol is under construction, although largely completed. The project will not begin until this instrument is completed.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/107 (3) Status: Ongoing

(4) Title:

The Effects of Fructose on Reactive Hypoglycemia

(5) Start Date: 1979	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Fred D. Hofeldt, M.D., COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Endocrine Service	(10) Assoc Investigators: Jerrold Olefsky, M.D., UCHSC Phyllis Crapo, UCHSC John Scarlett, M.D., UCHSC
(11) Key Words: fructose reactive hypoglycemia	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: ongoing

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

The objective of this study is to determine whether patients with reactive hypoglycemia will experience alterations in their glucose, insulin and counter-regulatory hormones following testing of glucose, fructose solutions and fructose meals. Patients with bonafide reactive hypoglycemia previously identified as having this disorder at Fitzsimons Army Medical Center (Cont'd)

(16) Technical Approach:

Patients with standard dietary intake will undergo the glucose tolerance test with measurements of insulin, glucagon and counter-regulatory hormones in response to either glucose, sucrose or fructose as a test solution or meal. Glucose clamp study to determine insulin sensitivity will be performed in an adipose tissue biopsy for measurement of in vitro insulin sensitivity (Cont'd)

(17) Progess:

Seven patients have been entered in protocol as noted in previous report of 30 September 1980. No new patients have been studied because of personnel shortages in the Endocrine/Metabolic Service. The results of this study in regards to dietary manipulation has recently been published in Diabetes Care. It is anticipated that a larger group of patients need to be studied because studies with the glucose clamp have shown two distinct populations. (Cont'd)

(15) Continued.

will be further studied under Clinical Research Unit.

(16) Continued.

in insolated adipose sites. It will be performed on each subject.

(17) Continued.

The vast majority of patients with reactive hypoglycemia have normal amounts of insulin receptors and sensitivity to glucose on the glucose clamp experiment. The affinity of glucose for the receptor has reduced the overall group of patients studied. A small subgroup of patients exist who are extremely sensitive to infused insulin and the mechanism of their reactive hypoglycemia may very well be an end organ hypersensitivity state. Additional patients are required to complete this study when personnel constraints, availability of space on the general clinical research unit occurs.

PUBLICATIONS:

(1) Crapo, P.A., Scarlett, J.A., Kolterman, O.G., Sanders, L.R., Hofeldt, F.D., and Olefsky, J.M.: The Effects of Oral Fructose, Sucrose and Glucose in Subjects With Reactive Hypoglycemia. Diabetes Care 5:512, 1982.

PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/108 (3) Status: Completed

(4) Title:

The Effect of Beta Adrenergic Bronchodilators on Serum Immunoglobulin-G Levels

(5) Start Date: 1981	(6) Est Compl Date: Completed
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: William Vinson, MD, COL, MC Paul Rabinowitz, MD, CPT, MC
(11) Key Words: immunoglobulin bronchodilators bronchial asthma	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JAN82 b. Review Results: Continue

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine whether chronic administration of beta adrenergic agonists depressed serum levels of immunoglobulin-G.

(16) Technical Approach:

To study the immunoglobulin-G levels of patients with bronchial asthma prior to their beginning therapy with beta agonists and periodically while they continue on the drugs.

(17) Progess:

Study of patients under this protocol was completed. The data has been analyzed but not yet presented or published.

Publications and Presentations: *none*

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/109 (3) Status: Ongoing

(4) Title: Control of Nausea and Vomiting with Delta-9-tetrahydro-cannabinol (THC) Combined with Standard Antiemetics (A Phase II Study)

(5) Start Date: June 1980	(6) Est Compl Date: June 1983
(7) Principal Investigator: Nicholas J. DiBella, MD,COL,MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Richard A. Artim, MD,MAJ,USAF,MC
(11) Key Words: Chemotherapy, nausea and vomiting control	

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

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 11
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: See block 17

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

1) To determine if THC has a useful antiemetic effect when added to standard antiemetic regimen.
2) To determine if the antiemetic effect is additive or potentiating.
3) To determine if THC reduces nausea and vomiting in those patients who do not respond to standard antiemetics.

(16) Technical Approach:
Clinical study

(17) Progess:
Fifty (50) patients have been entered on this protocol, approximately 22 have been double blinded. Our goal is to obtain 30 double blinded patients. A total of 4 patients have been removed from the study due to side effects,generally mental status changes. This represents less than 10% of the total patients with good to excellent control of nausea and vomiting, in approximately 88% of the patients treated.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/110 (3) Status: On-going

(4) Title:

Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Local Anesthetic

(5) Start Date: 1979	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: multiple
(11) Key Words: local anesthetic adverse drug reaction	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JAN82 b. Review Results: Continue
c. Number of Subjects Enrolled During Reporting Period: Unknown
d. Total Number of Subjects Enrolled to Date: Approximately 30-40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To confirm the safety and usefulness of the progressive challenge in a large number of patients with histories of previous suspected adverse reactions to local anesthetics.

(16) Technical Approach:
Patients with a history of an adverse reaction to local anesthetics will undergo progressive challenge with these drugs as has been practiced over the last eight years in the Fitzsimons Allergy Clinic. The historical data and results of challenge will be accumulated for future correlations.

(17) Progess:
Patients are being studied under this protocol at several installations.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/111 (3) Status: Ongoing

(4) Title:

A Comparison of the Development of Sensitivity to Penicillin in Normal and Atopic Individuals

(5) Start Date: 1980	(6) Est Compl Date: 1985
(7) Principal Investigator: Harold S. Nelson, MD, COL, MD	(8) Facility: FAMC
(9) Dept/Svc: MC/Allergy Immunology	(10) Assoc Investigators:
(11) Key Words: penicillin allergy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: FEB82 b. Review Results: CONTINUE

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.: Not Applicable

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the frequency with which normal and atopic individuals develop positive immediat wheal and flare skin test to penicillin following a course of therapy with the drug.

(16) Technical Approach: Children scheduled to receive a course of penicillin therapy will be skin tested prior to receiving the course of therapy to both penicillin and several pollen allergens. They will return for follow-up skin testing several weeks after completing the course of therapy. (Continued)

(17) Progess:

It has not been possible thus far to effectively recruit patients for this protocol at Fitzsimons Army Medical Center. It is possible the protocol will be reactivated at a later time.

(16) Data will be analyzed in terms of the frequency with which patients have unexpected positive skin test to Penicillin that they develop positive skin test following a course of therapy and the relation of this to the evidence of allergy as demonstrated by positive skin test to inhalant allergens.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/112 (3) Status: Ongoing

(4) Title: Use of Sodium Salt of Allopurinol to Control Hyperuricemia in Patients with No Therapeutic Alternative. A Pilot Study.

(5) Start Date: March 1980	(6) Est Compl Date: 1983
(7) Principal Investigator: N.J. DiBella, M.D., COL, MC	(8) Facility: FAMC FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Kenneth Beougher, CPT, MSC
(11) Key Words: Hyperuricemia, Allopurinol	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: March 82 b. Review Results: continued

c. Number of Subjects Enrolled During Reporting Period: One

d. Total Number of Subjects Enrolled to Date: Three

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the effect of a parenteral form of allopurinol to control hyperuricemia when the patient is unable to take the tablet form (commercially available).

(16) Technical Approach:

Clinical study.

(17) Progess:

A third patient has been treated successfully with I.V. Allopurinol with no ill-effects and with control of hyperuricemia.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/102 (3) Status: Terminated

(4) Title:
Study of Coagulation Parameters Prior To and Following Intravenous Injection of Radiographic Contrast Media.

(5) Start Date: 20 Mar 79	(6) Est Compl Date: N/A
(7) Principal Investigator: Stephen G. Oswald, DO,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc: Hematology-Oncology	(10) Assoc Investigators: Davor A Luketic, CPT, MC Judy Barber (A.S.C.P.) Patricia Rush (A.S.C.P.)
(11) Key Words: Radiographic contrast media, Hypercoagulation	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine if coagulation parameters which have been associated with hypercoagulable states are altered by injection of contrast media.

(16) Technical Approach:
Prior to the administration of radiographic contrast media, baseline coagulation parameters are drawn. Twenty-four (24) hours following contrast injection repeat studies are drawn and compared with the baseline results, i.e., each patient serves as his own control.

(17) Progess:
At present more than 20 patients have been studied. Thus far there have been no significant coagulation abnormalities from the baseline studies.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/103 (3) Status: Ongoing

(4) Title:
Etoposide (VP-16-213) Single Agent Chemotherapy in Small Cell Lung Cancer Patients Refractory to First Line Chemotherapy

(5) Start Date: June 1980	(6) Est Compl Date: 1982
(7) Principal Investigator: N.J. DiBella, M.D.,COL,MC	(8) Facility: FAMC
(9) Dept/Svc: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Chemotherapy protocol, small cell lung cancer	

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

(14) a. Date, Latest HUC Review: Jun 82 b. Review Results: To continue
c. Number of Subjects Enrolled During Reporting Period: 1
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To test the efficacy of VP-16-213 in patients with recurrent or metastatic small cell CA of the lung.

(16) Technical Approach:

Clinical study.

(17) Progess:
One additional patient has been placed on this drug during the last year. He failed to respond and was taken off the drug because of progressive disease. No serious toxicities were observed.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/104 (3) Status: Ongoing

(4) Title:
Etoposide, (VP-16-213) Combined with Cyclophosphamide plus Vincristine Compared to both Doxorubicin plus Cyclophosphamide plus Vincristine and Cyclophosphamide plus Vincristine of Small Cell Lung Cancer.

(5) Start Date: Jun/80	(6) Est Compl Date: 1983
(7) Principal Investigator: N.J. DiBella, MD,COL,MC	(8) Facility: FAMC
(9) Dept/Svc: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Small cell CA, chemotherapy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Jun 82 b. Review Results: To continue
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To compare the response, duration of response and survival of small cell lung cancer patients initially treated with either (a) Etoposide (VP-16-213) plus Vincristine plus Cyclophosphamide of (b) Doxorubicin plus Cyclophosphamide or (c) Cyclophosphamide plus Vincristine.
To compare the qualitative and quantitative toxicities of the above 3 regimens.

(16) Technical Approach:
Clinical study.

(17) Progess:

One patient was placed on one of the 3-drug arms (Cyclophosphamide, Doxorubicin, and Vincristine) and has obtained a minor response to date. There have been no unusual side effects.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/107 (3) Status: COMPLETE

(4) Title:

Cross Allergenicity among Grasses Determined by Tissue Threshold Changes

(5) Start Date: 1980	(6) Est Compl Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: B.G. Martin, MD, CPT, MC, USAF R. Renard, MD, CPT, MC D. Leavengood, MD, CPT, MC, USAF
(11) Key Words: immunotherapy cross allergenicity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: CONTINUE

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine if the cross allergenicity of the western grasses demonstrated by RAST inhibition can be confirmed in vivo using the tissue threshold technique.

(16) Technical Approach: Patient with broad reactivity to gresses who are beginning immunotherapy will have titrated sensitivity to the various grasses determined. Separate groups will then receive immunotherapy either with all the grasses to thich they are sensitive or only Timothy or Burmuda. It will be determined whether therapy with only Timothy and Bermuda suppresses cutaneous sensitivity to the entire group of grasses as well as does immunotherapy with all of the individual grass allergens.

(17) Progress: All patients completed the study in October 1981. The data was analyzed and is under preparation for submission for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 80/107

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

None

PRESENTATIONS:

1. Leavengood, Douglas: Cross Allergenicity among Grasses Determined by Tissue Threshold Changes. Presented: Annual Meeting of the American College of Allergists (Post Presentation), Miami Beach, Florida, 16-20 January 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/108 (3) Status: Ongoing

(4) Title:
Topical Cocaine for the Relief of Stomatitis in Patients with Malignancies: A Double-Blind Study.

(5) Start Date: Oct/80	(6) Est Compl Date: 1983
(7) Principal Investigator: N.J. DiBella, M.D.,COL.,MC	(8) Facility: FAMC
(9) Dept/Svc: Hem/Onc	(10) Assoc Investigators: Richard A. Artim, M.D.,MAJ,USAF,MC
(11) Key Words: Chemotherapy, Cocaine, Stomatitis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 1
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.: See block 17

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

a. To determine whether topical cocaine is better than Viscous Xylocaine in the treatment of stomatitis.
b. To determine which concentration of cocaine affords optimal relief and the fewest side effects in the treatment of stomatitis.

(16) Technical Approach:

Clinical study - Three different concentrations of cocaine combined with Viscous Xylocaine will be tested against Viscous Xylocaine alone in the relief of pain due to stomatitis.

(17) Progess:

Seven patients have been entered into this study. Transient benefit was noted in three patients. No significant toxicity was observed.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80-109 (3) Status: Terminated

(4) Title:
Insulin Post-Receptor Physiology

(5) Start Date: September 1980	(6) Est Compl Date: September 1982
(7) Principal Investigator: Robert E. Jones, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Endocrine Service	(10) Assoc Investigators:
(11) Key Words: insulin receptor post receptor defect insulin action	Gerald S. Kidd, M.D., LTC, MC Fred D. Hofeldt, M.D., COL, MC David T. Zolock, MAJ, MS

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

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: Terminated
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
The medical objective of this study is to study the receptor physiology and biochemistry to define membrane and/or intracellular mechanisms of insulin resistance.

(16) Technical Approach:
Establish the methodology for measuring glucose uptake in target tissue. The erythrocyte is the tissue that has been chosen for the experimental assessment of insulin post-receptor action. Previous work has been conducted in the erythrocyte to show changes in membrane receptors in relationship to physiologic insulin concentrations. In this study, H3-2-dioxyglucose, a non- (con't)

(17) Progess:
Due to reassignment of the Principal Investigator, all efforts in regards to developing this assay have been terminated. The existing personnel on the Endocrine Staff, either through lack of interest or personnel shortage, have elected not to continue the study.

(16) Continued.

metabolizable glucose analog, which is transported and trapped in a fashion similar to glucose will be used as a marker of glucose uptake in the red cell. Various ambient fatty acid concentrations in the incubation mixture will be used to determine the influence of fatty acids on receptor glucose transport.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/112 (3) Status: Completed

(4) Title:

The Effect of Troleandomycin and Methylprednisolone Along and in Combination on Bronchial Sensitivity to Methacholine

(5) Start Date: 1981	(6) Est Compl Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/Allergy Immunology	(10) Assoc Investigators: R.L. Renard, MD, CPT, MC W.P. Andrade, MD, LTC, MC
(11) Key Words: troleandomycin methacholine sensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: Completed

c. Number of Subjects Enrolled During Reporting Period: 1

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To attempt to demonstrate under carefully controlled conditions that Troleandomycin either by itself or in conjunction with Methylprednisolone decreases the hypersensitivity to inhaled Methacholine present in patients with allergic rhinitis and mild asthma.

(16) Technical Approach:

Patients with demonstrated Methacholine sensitivity but not requiring chronic bronchodilator administration will be studied in a double-blind manner with Methacholine sensitivity measured following placebo, methylprednisolone alone, troleandomycin alone or the combination of troleandomycin and methylprednisolone.

(17) Progess:

Nine patients were studies under this protocol. The results were analyzed and have been prepared for submission for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 80/112

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

NONE

PRESENTATIONS:

(1) Nelson, HS: Relation Between Positive Small Air Ions, Weather Fronts, and Pulmonary Function in Patients with Bronchial Asthma. Presented: Annual Meeting American College of Allergists, Miami Beach, Florida, 16-20 January 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/113 (3) Status: Completed

(4) Title:

The Effect of Spontaneous Variation in Ambient Small Ion Concentrations on Pulmonary Function in Patients with Bronchial Asthma

(5) Start Date: 1980	(6) Est Compl Date: Completed
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/Allergy Immunology	(10) Assoc Investigators: R. Danziger, MD, CDR, MC, USN C. Wagner, MD, LCDR, MC, USN
(11) Key Words: small air ions	

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

(14) a. Date, Latest HUC Review: SEP82 b. Review Results: Continue
c. Number of Subjects Enrolled During Reporting Period: 13
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.: Not Applicable

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To monitor pulmonary function in a group of patients with bronchial asthma in order to determine whether there is a deleterious effect of changes in concentration of small air ions which occurs spontaneously preceding the arrival of weather fronts.

(16) Technical Approach:

Ambient concentrations of small air ions are to be monitored three times daily and at approximately the same three times a group of patients with bronchial asthma will record their pulmonary function employing a Mini-Wright Peak Flow Meter. Weather information will be obtained from public sources.

(17) Progess:

The study was completed in November 1981. The data has been analyzed and is in preparation for submission for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 80/113

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

NONE

PRESENTATIONS:

Wagner, Charles: Relation Between Positive Small Air Ions, Weather Fronts, and Pulmonary Function in Patients with Bronchial Asthma. Presented: Annual Meeting of the American College of Allergists, Miami Beach, Florida, 16-20 January 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/115 (3) Status: Ongoing

(4) Title: Evaluation of Amiodarone for the Therapy of Cardiac Arrhythmias

(5) Start Date: 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Richard C. Davis, Jr., MD, LTC,MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Cardiology	(10) Assoc Investigators: None
(11) Key Words: Amiodarone, Cardiac arrhythmias	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: ongoing

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 studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To control symptomatic cardiac arrhythmias which have not been responsive to the conventional and accepted forms of treatment or whose control is dependent upon the use of a drug which has been shown to be harmful to or in other ways not tolerated by the individual.

(16) Technical Approach: After patient selection, baseline laboratory results as outlined in the protocol will be obtained. After initiation of therapy, the patient will be followed regularly by the principal investigator with frequent Holter monitors to assess the efficacy of the drug and other laboratory tests and examination to warn of potential toxicity.

(17) Progess: At this point, only the original patient is on protocol. No other candidates have been entered into the protocol. The patient continues without ventricular ectopy or further episodes of "sudden death". Her maintenance dose of amiodarone is 400 mg p.o. daily and her corneal deposits are stable without change in visual acuity.

Publications and Presentations: None.

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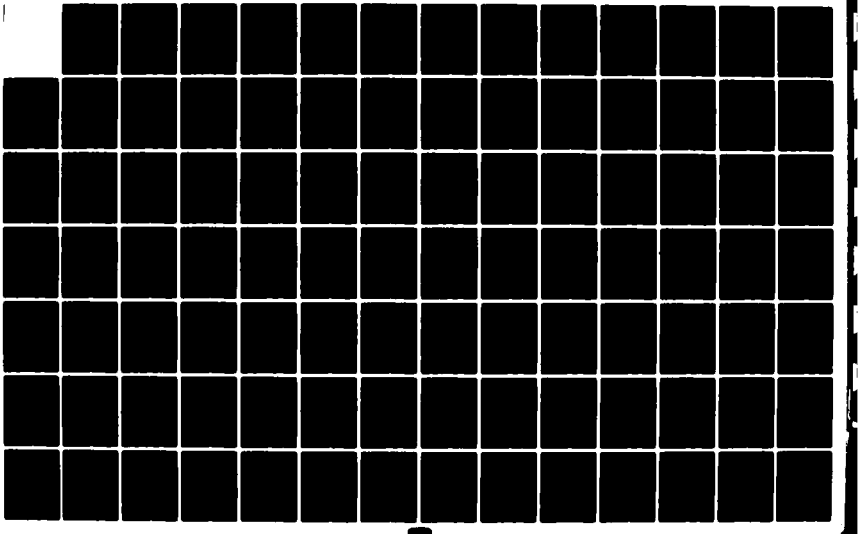

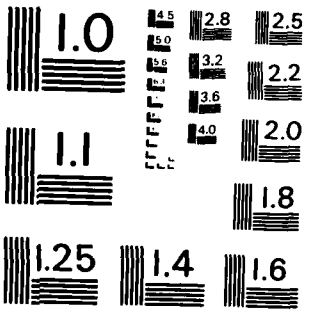

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FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/117 (3) Status: on-going

(4) Title: Correlation of Clinical Signs and Symptoms with Assays of Circulating Immune Complexes (CIC)

(5) Start Date: Oct 1980	(6) Est Compl Date: January 1983
(7) Principal Investigator: William R. Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/Allergy-Imm	(10) Assoc Investigators: R. Stephen Whiteaker, PhD,CPT,MSC Vasundhara Iyengar, MD, MAJ, MC Jeneen Nelson, MS
(11) Key Words: immune complexes C1Q laboratory assays	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NOV 81 b. Review Results: continued
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: The purpose of this study is to determine the relative time sensitivity of several laboratory assays for immune complexes in patients with suspected immune complex disorders.

(16) Technical Approach: Patients in whom serum is submitted for antinuclear antibodies will have a standard clinical evaluation and their serum will be examined by a standardized battery of four assays for circulating immune complexes. Correlations will then be made to determine which of the assays best reflects clinical disease.

(17) Progess: Currently the specimens are being assayed for a solid phase C1Q In addition, Doctor Iyengar has made a clinical evaluation on these patients to determine whether she would suspect circulating immune complexes. It is hoped that in early 1983 we will be able to correlate these two determinations and tenatively a presentation of this data is planned for next summer.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/118 (3) Status: Ongoing

(4) Title:
5-Azacytidine in the Treatment of Acute Nonlymphocytic Leukemia

(5) Start Date: Nov/1980	(6) Est Compl Date: Unknown
(7) Principal Investigator: Arlene J. Zaloznik, MD,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc: Hematology/Oncology	(10) Assoc Investigators: Nicholas J. DiBella, MD,COL,MC
(11) Key Words: 5-Azacytidine, Acute leukemia	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 3
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.: No adverse reactions

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine the efficacy of 5-Azacytidine in patients with acute non-lymphocytic leukemia who have relapsed after conventional chemotherapy.

(16) Technical Approach:
Patients who have proved to refractory to standard forms of acute leukemia are given 5-Azacytidine in an attempt to induce remission.

(17) Progess:
At the present time all patients enrolled had refractory leukemia. There have been no responses to the 5-Azacytidine.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/119 (3) Status: Completed

(4) Title:

Assessment of the Development of Alpha Adrenergic Subsensitivity with Chronic Ingestion of Oral Decongestant Agents

(5) Start Date: 1981	(6) Est Compl Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: Pinkus Goldberg, MD, CPT, MC Paul Rabinowitz, MD, CPT, MC
(11) Key Words: alpha adrenergic subsensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: DEC81 b. Review Results: CONTINUE

c. Number of Subjects Enrolled During Reporting Period: 3

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine whether chronic administration of oral nasal decongestants which are alpha adrenergic agonists induce a state of alpha adrenergic subsensitivity.

(16) Technical Approach: Response to nasal decongestants will be assessed by their ability to modulate the nasal airway resistance increase with instillation of histamine. Alpha adrenergic reactivity will be measured by the ability of neosinephrine to prolong the zeon washout time from the skin and the response in the cold pressor test. These responses will be studied before and after two weeks of chronic administration of the nasal decongestant medication.

(17) Progess:

A total of nine patients were studied, the data has been analyzed and submitted for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 80/119

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

(1) Nelson, HS: Assessment of the Afficacy and Development of Alpha Adrenergic Subsensitivity with Pseudoephrine.

submitted to the Journal of Allergy and Clinical Immunology

PRESENTATIONS:

(1) Goldberg, Pinkus: Assessment of the Afficacy and Development of Alpha Adrenergic Subsensitivity with Pseudoephrine. Presented: Annual Meeting of the American Academy of Allergy, Montreal, Canada, 6-10 March 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 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: April 1981	(6) Est Compl Date: April 1984
(7) Principal Investigator: Gerald S. Kidd, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrinology	(10) Assoc Investigators: T. P. O'Barr, Ph.D. Fred D. Hofeldt, MD, COL, MC
(11) Key Words: carbohydrate intolerance thyrotoxicosis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 3
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.: N/A

(Continue on a separate sheet and designate this continuation 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 tests. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring (Continued)

(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) Progess: All assays have been improved and now have a good insulin, free fatty acid and glucagon assay. Three patients have been studied without problems.

(15) Continued:

glucose, insulin, glucagon and free fatty acids, basally and after oral or intravenous glucose and by measuring the responses to exogenous insulin.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80-121 (3) Status: Ongoing

(4) Title: An Evaluation of Pituitary and Thyroid Hormonal Responses to a 4-Hour Continuous and a Bolus Intravenous Infusion of TRH as a Useful Test of Thyroidal Functional Reserve

(5) Start Date: March 1981	(6) Est Compl Date: July 1983
(7) Principal Investigator: Michael Bornemann, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Endocrine Service	(10) Assoc Investigators: Gerald S. Kidd, MD, LTC, MC Fred D. Hofeldt, MD, COL, MC William J. Georgitis, MD, MAJ, MC
(11) Key Words: thyroid functional reserve pituitary thyroid axis TRH infusion	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 28
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
The objective of this study is to determine if the diagnosis of mild or subclinical hypothyroidism can be more clearly established by some integrated parameter reflecting both the pituitary and thyroidal reserve responses to intravenous thyrotropin releasing hormone.

(16) Technical Approach:
Three groups of subjects will be evaluated in this protocol. Group 1 will consist of normal control patients; Group 2 will consist of patients with mild hypothyroidism diagnosed by an elevated TSH level but normal thyroid hormone levels; Group 3 will consist of patients with the Thyroid Clinic with high-normal TSH values and normal thyroid function tests, but who are clinical

(17) Progess:
Additional patients continue to be added to the study. Data analysis is starting; study should be completed by July 1983.

(15) Continued:

suspects of having mild hypothyroidism. The patients will undergo two TRH infusion tests in a random manner consisting of conventional bolus administration of 500 ug of TRH solution and the constant infusion of TRH over a 4-hour period with 500 ug of TRH diluted in normal saline and diffused at a rate of 2 ug per minute over the 4 hours using a Harvard infusion pump. The TSH values in the various groups of patients will be determined and statistically analyzed for differences between the groups.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/100 (3) Status: Ongoing

(4) Title:

EVALUATION OF THIAZIDE USE AND CHOLELITHIASIS

(5) Start Date: 3 March 1982	(6) Est Compl Date: 3 March 1983
(7) Principal Investigator: Steve H. Parker, M.D. Gregory J. DeWerd, M.D. Stanley F. Smazal, M.D.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Cardiology	(10) Assoc Investigators: Bob Kazenoff, M.D. Thomas Brewer, M.D. Nasser Ghaed, M.D.
(11) Key Words: Cholelithiasis Thiazides	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 93

d. Total Number of Subjects Enrolled to Date: 175

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

A. To objectively evaluate the reported association between thiazide use and gallbladder disease. B. To evaluate the dose-response relation of the duration of thiazide usage to cholelithiasis. C. To evaluate a possible relationship between other antihypertensives and gallbladder disease.

(16) Technical Approach:

Approximately 300 total patients (divided into three groups of 100 each) will be evaluated. One group is designated the control group, a second is designated the hypertensive control group, and the third group is comprised of hypertensive patients on thiazides. All patients in the above three groups are evaluated by ultrasound for the detection of cholelithiasis

(17) Progess: To date, 175 patients have been included in the study with 90 pat falling into the thiazide group, 60 into the control group, and 25 into the hypertensive control group. In order to prevent investigator bias, prospective data has not yet been tabulated and will not be tabulated until each group contains enough patients for valid statistical analysis. Preliminary tabulations reveal that there has been a significant correlation between thiazide use and cholelithiasis.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-101 (3) Status: Ongoing

(4) Title: Development and evaluation of rapid immunologic procedures for the diagnosis of giardiasis.

(5) Start Date: 5 May 1981	(6) Est Compl Date: May 1984
(7) Principal Investigator: Thomas G. Brewer, et al.	(8) Facility: FAMC
(9) Dept/Svc: Gastroent./DCI	(10) Assoc Investigators:
(11) Key Words: Diarrhea, giardiasis, Giardia lamblia	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 5/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To develop immunodiagnostic procedures for rapid detection of Giardia lamblia antigen in fecal and doudenal aspirate specimens and the detection of anti-Giardia antibodies in the serum of giardiasis patients. To evaluate the efficacy of these tests for rapid diagnosis of giardiasis in a select patient population.

(16) Technical Approach: We have not deviated from the technical approach described in detail in the protocol.

(17) Progess: Two seperate strains of G. lamblia have been cultivated as part of Phase I. Three groups of rabbist have been utilized to produce anti-Giardia sera as part of Phase II. Phase III (which is ongoing) has included development and/or improvement of IFA, ELISA, CIE, and co-agglutination procedures. Seventy-eight sera and 133 fecal specimens have been collected for evaluation during Phase IV, and 57 of the sera have been shipped to CDC for IFA testing. Cyst purification procedures are being developed and/or evaluated.

PUBLICATIONS AND PRESENTATIONS: NONE

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-102 (3) Status: Ongoing

(4) Title: Treatment of herpes zoster with high does versus low dose systemic steroids.

(5) Start Date: 1 July 1981	(6) Est Compl Date: 1 July 1985
(7) Principal Investigator: James E. Fitzpatrick, M.D. Major, MC	(8) Facility: FAMC
(9) Dept/Svc: Dermatology/ D. O. M.	(10) Assoc Investigators: Dennis L. May, MD., LTC, MC
(11) Key Words: Herpes zoster Steroids	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: April 8 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 2

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: The primary objective is to determine if high dose prednisone (80 mg per day) is more effective than moderate dose oral prednisone (40 mg per day) in the prevention of post-herpetic neuralgia secondary to herpes zoster.

(16) Technical Approach: A double blind study compares high versus medium dose oral prednisone in the prevention of post-herpetic neuralgia. Subjective testing and objective evaluation of nerve damage using pinprick and histamine flare skin test is utilized. Patients are followed on days 3, 7, 14, 21, and 60.

(17) Progess: Seven patients have started the protocol and six have completed the protocol. All patients have had resolution of their herpetic pain thus far. Two problems have prevented accumulation of large numbers of patients. First of all, the prinicipal investagators have changed during this reporting period resulting in a large lag period. Secondly, there has been some reluctance of patients to enter the protocol because of the very ominous wording of the side effects listed for prednisone. We plan in the very near future to propose a new consent form which will place the side effects in a more proper prospective. (fiscal year for this report 10ct 1981 to 30 Sept 1982)

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/102

SERVICE Dermatology DEPARTMENT Medicine

none

PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/104 (3) Status: on-going

(4) Title: The Incidence of Host Defense Deficiency in Patients Presenting with frequent or Prolonged Infections

(5) Start Date: To be determined by the Imm Ser, Clin Inves Service	(6) Est Compl Date: 4-5 years
(7) Principal Investigator William R. Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC Allergy Immunology	(10) Assoc Investigators: Harold S. Nelson, MD, COL, MC R. Stephen Whitaeker, CPT, MSC Joseph Lima, BAC Fellows, Allergy-Immunology Service
(11) Key Words: immunodeficiency infection laboratory tests	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: July 82 b. Review Results: Continue
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine the cost effectiveness of performing various laboratory evaluations of immune responsiveness in patients presenting with frequent or prolonged infections.

(16) Technical Approach: Patients who are referred for this protocol will have a standarized clinical evaluation by the Fellows in the Allergy-Immunology Service and then will have a standard battery of tests performed to evaluate their immune status and phagocytic function. On the basis of the clinical history certain laboratory tests will be determined to have been clinically indicated, subsequently the yield from the routine battery of tests will be compared to (Continued)

(17) Progess: In spite of the unavailability of the killing assay being perfected by the laboratory, it is now elected to go ahead and implement this protocol as much as possible. (Continued on attachment)

(16) to the yield from those tests which were thought to have been clinically indicated.

(17) Forms have been completed and the Department of Medicine and the Department of Pediatrics contacted to make them aware of the availability of this evaluation. It must be appreciated that there will not be a large number of such patients, and that indeed, this is a long termn study over four to five years to determine the caused effectiveness of our approach to patients with suspected immunodeficiency.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/105 (3) Status: On-going

(4) Title:

Measurement of the Effects of Specific IgG on the Levels of Specific IgE as Measured by the Radioallergosorbent Test

(5) Start Date: JULY 1981	(6) Est Compl Date: MARCH 1983
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: TP O'Barr, PhD, DAC R Ledoux
(11) Key Words: RAST Blocking antibody	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: CONTINUE

c. Number of Subjects Enrolled During Reporting Period: Not Applicable

d. Total Number of Subjects Enrolled to Date: Not Applicable

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: Not Applicable.

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine whether IgG blocking antibodies generated by allergy immunotherapy significantly interfere with the determination of specific IgE by the radio-allergosorbent test.

(16) Technical Approach:

Sera with and without levels of blocking antibody will be studied before and after adsorption with Staphylococcus protein A. The parameters measured will be total IgG and IgE and antigen specific RAST and blocking antibody.

(17) Progess:

Laboratory work on this protocol is completed, the data is being analyzed.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/105

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

NONE

PRESENTATIONS:

Ledoux, Robert: Measurement of the Effects of Specific IgG on the Levels of Specific IgE as Measured by the Radioallergosorbent Test. Presented: Annual Meeting American Academy of Allergy, Montreal, Canada, 6-10 March 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/106 (3) Status: On-going
(4) Title:

Clinical Effectiveness and Development of Subsensitivity with Chronic Administration of Atropine Methonitrate

(5) Start Date: 1981	(6) Est Compl Date: 1983
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: Allergy-Immunology Service Fellows, DOM
(11) Key Words: atropine subsensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: Continue
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the effect of chronic administration on the bronchodilator response to atropine.

(16) Technical Approach:

The efficacy will be determined by a double-blind placebo atropine comparison, each of one week's duration monitored by home measurement of pulmonary function. In addition, the acute response to atropine inhalation will be monitored prior to and following the week of chronic atropine administration.

(17) Progess:

No studies have been undertaken under this protocol.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/107 (3) Status: On-going

(4) Title:

Relation of Distance and Direction on the Effect of One Immediate Wheal and Flare Skin Test Upon Another

(5) Start Date: 1981	(6) Est Compl Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: WR Tipton, MD, COL, MC C. Ross Westley, MD, MC D. McBride, MD, MAJ, MC
(11) Key Words: false positive skin tests	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: Continue

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.: Not Applicable

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the extent to which a positive immediate wheal and flare skin test can influence the response to a nearby skin test.

(16) Technical Approach:

A skin test giving a large positive prick test reaction will be repeated on the back surrounded in varying directions and at varying distances by prick tests to an antigen which previously gave a negative response. The occurrence of false positive skin tests will be monitored.

(17) Progess:

A preliminary study was done with six patients and the results were presented by Poster at the Annual Meeting of the American College of Allergists, Miami Beach, Florida, 16-20 January 1982. Based upon these results, it is intended to enroll 20 additional patients for a more definitive study.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/107

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

NONE

PRESENTATIONS:

(1) Vinson, William: Relation of Distance and Direction on the Effect of One Immediate Wheal and Flare Skin Test Upon Antoher. Presented: Annual Meeting of the American College of Allergists, Miami Beach, Florida, 16-20 January 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/108 (3) Status: On-going
(4) Title:

Development and Class Specificity of Tolerance to Antihistamine Drugs

(5) Start Date: 1981	(6) Est Compl Date: 1983
(7) Principal Investigator: Harold S. Nelson, MC, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: Richard Taylor, MD, MAJ, MC William Long, MD, MAJ, MC
(11) Key Words: antihistamine subsensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: Continue
c. Number of Subjects Enrolled During Reporting Period: 16
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.: Not Applicable

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To re-examine the development of subsensitivity to the anti-H1 effects of commonly employed antihistamine preparations and to determine whether the tolerance is related to the chemical structure of the H1 antagonist or applies equally to all H1 antagonists regardless of chemical structure.

(16) Technical Approach:

The ability of antihistamines to suppress the skin test to histamine and either morphine or an allergen will be measured prior to and during the course of prolonged antihistamine therapy.

(17) Progess:

Active enrollment and study of patients under this protocol is presently taking place.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/109 (3) Status: Ongoing

(4) Title:

Southwestern Oncology Group Collaborative Studies

(5) Start Date:	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas J. DiBella, MD,COL,MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc 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 HUC Review: 2/82 b. Review Results: to continue
c. Number of Subjects Enrolled During Reporting Period: 7
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: Variable according to protocols involved. FAMC currently participating in 29 protocols.

(16) Technical Approach: Clinical approach.

(17) Progess: Seven patients have been entered onto SWOG protocols this year. Four patients have been entered on protocol 8027 which involves no therapy but primarily a study of the natural history of stage I estrogen receptor positive breast cancer. Two patients were placed on protocol 7727, for the management of metastatic malignant melenoma with chemotherapy. No unusual problems have been encountered. One patient has been placed on protocol 7927 for the treatment of multiple myeloma. He has encountered no unusual toxicities but appears to be having progression of his disease and may need to be taken off of protocol.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/110 (3) Status: Completed

(4) Title:

Lability of Blocking Antibody during Allergy Immunotherapy.

(5) Start Date: 1981	(6) Est Compl Date: Not Applicable
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: TP O'Barr, PhD, DAC C Wagner, MD, LCDR, MC, USN
(11) Key Words: blocking antibody lability	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: JUL82 b. Review Results: Continue

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: no change

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To follow a group of patients through a course of allergy immunotherapy with the objective of determined the duration of the rise in specific IgG following an injection of allergy extract at different intervals following the commencement of treatment.

(16) Technical Approach:

The response over a one month period of time will be measured to a single injection of allergy extract in patients just reaching maintenance doses and in patients who have been on maintenance injections for several years.

(17) Progess:

The study was completed in the fall of 1981.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/110

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

Lability of blocking antibody during allergy immunotherapy.CJ Wagner, RJ Taylor, HS Nelson. Submitted the to Annals of Allergy.

PRESENTATIONS:

Wagner, Charles: Lability of Blocking Antibody during Allergy Immunotherapy. Presented: Annual Meeting American Academy of Allergists, Montreal, Canada, 6-10 March 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/111 (3) Status: on-going

(4) Title: Comparative Effect of Major Corticosteroids on Lymphocyte Blastogenesis and Assessment of the Corticosteroid Sparing Effect of Troleandomycin

(5) Start Date: July 1981	(6) Est Compl Date:
(7) Principal Investigator: James S. Brown, MD, MAJ, MD	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: William R. Tipton, MD, COL, MC R. Stephen Whiteaker, CPT, MSC
(11) Key Words: corticosteroids lymphocyte blastogenesis doseage of steroids	

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

(14) a. Date, Latest HUC Review: JULY 82 b. Review Results: Continued
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine if various classes of corticosteroids differ in the magnitude of suppression of lymphocyte blastogenesis and to ascertain the effect of Troleandomycin in combination with these corticosteroids on lymphocyte blastogenesis.

(16) Technical Approach: This is an in vitro study using normal lymphocyte populations for blastogenesis as triggered by mitogens and measured by incorporation of tritiated thymidine.

(17) Progess: This protocol thus far has shown some very interesting results with the ratio of dosage equivalence between various corticosteroids. A repeat, however, while internally consistent, showed quite different results, which perhaps was a dilutional error. Because of the marked changes found, pure drug with dexamethasone is being obtained from Merck Sharp and Dohme and additional runs will be made to either substantiate or refute the original determination. It is anticipated that this will be accomplished during October and November 1982 and it is planned for this material to be presented in January 1983.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/111

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

NONE

PRESENTATIONS: NONE

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/112 (3) Status: Complete

(4) Title:

Prediction of Clinical Response to Allergy Immunotherapy, Role of the RAST, Serum and Nasal Blocking Antibody, Titrated Skin Test and Nasal Challenge

(5) Start Date: September 1981	(6) Est Compl Date: September 1982
(7) Principal Investigator: H. S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/Allergy Immunology	(10) Assoc Investigators: D. McBride, MD, MAJ, MC E. Squire, Jr., MD, MAJ, MC T.P. O'Barr, Ph.D., DAC Robert LeDoux, B.S., DAC
(11) Key Words: allergy immunotherapy prediction of response	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: due Sept 83

c. Number of Subjects Enrolled During Reporting Period: 33

d. Total Number of Subjects Enrolled to Date: 33

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To measure the response to allergy immunotherapy and determine which perimeter best reflects the clinical improvement.

(16) Technical Approach:

Performance of skin tests and antibodies studies prior to beginning immunotherapy and again just prior to the pollen season with measurement of symptom scores by the patient during the pollen season.

(17) Progess:

Thirty-three patients either received immunotherapy with grass alum-precipitated extract or were on treated controls. Laboratory studies are being completed on the specimens which were collected during the study. Following this, the results will be prepared for submission for presentation and publication.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/113 B72#03 (3) Status: Ongoing

(4) Title:
Aminocarproic acid for the control or prevention of hemorrhage in thrombocytic patients

(5) Start Date: May/81

(6) Est Compl Date: Unknown

(7) Principal Investigator:
Arlene J. Zaloznik, MD,MAJ,MC
Hematology-Oncology Svc

(8) Facility: FAMC

(9) Dept/Svc: Hematology-Oncology

(10) Assoc Investigators:
Nicholas J. DiBella, MD,COL,MC

(11) Key Words:
AMICAR, thrombocytopenia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 1
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.: No adverse drug reactions noted.
(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine the efficacy of AMICAR in thrombocytopenic patients in the control of bleeding. This is a forearm study whereby AMICAR is either given prophylactically or therapeutically in patients with thrombocytopenia (less than 20,000 platelet count). It is hoped that by administering AMICAR the number of platelet transfusions can be decrease

(16) Technical Approach:

(17) Progess:

Patient accrual has been slow. The majority of the thrombocytopenic patients have had an acute leukemia and for various reasons AMICAR was not considered as a part of their therapeutic regimen.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/114 (3) Status: Ongoing

(4) Title:
Adjuvant chemotherapy in Localized Non-Oat Cell Cancer of the Lung

(5) Start Date: Sep/1981

(6) Est Compl Date: Unknown

(7) Principal Investigator:
Arlene J. Zaloznik, MD,MAJ,MC

(8) Facility: FAMC

(9) Dept/Svc: Hematology/Oncology

(10) Assoc Investigators:
Nicholas J. DiBella, MD, COL, MC

(11) Key Words:

Chemotherapy,
Non-Oat Cell Cancer

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 8 Oct 82 b. Review Results: Ongoing

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.: No adverse reactions have been noted.

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

A) To determine whether postoperative combination chemotherapy with Cytoxan, CCNU, Vincristine, Adriamycin, and Cis-platinum will improve either disease free interval or survival in resected non-oat cell lung cancer with positive nodes.

B) To determine whether such combination chemotherapy when given prior to

(16) Technical Approach:
Patients receive the chemotherapy after they have received definitive surgery for their lung cancer.

(17) Progess:
This study is ongoing and in corporation with the Denver VA Hospital and at the present time there is no data to report.

15. Study Objective cont'd:

radiation will improve disease free survival or survival in localized bone resectable non-oat cell lung cancer.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-115 (3) Status: Ongoing

(4) Title: Comparison of Modalities for Treatment of SLE Nephritis

(5) Start Date: 1982

(6) Est Compl Date: 1984

(7) Principal Investigator:
Sterling G West MD, C, Rheumatology Svc, MAJ, MC; Peter A. Andersen, MD AsstC, Rheumatology Svc, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Dept of Med/Rheumatology

(10) Assoc Investigators:
Rogert G Claypool MD, C, Dept of Med, COL, MC; Jorge L Herrera MD, Internal Medicine, CPT, MC; Mark Nelson MD, MAJ, MC; Richard C Welton MD, MAJ, MC

(11) Key Words: SLE, nephritis, steroids, Chlorambucil

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: two

d. Total Number of Subjects Enrolled to Date: four

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: a. To evaluate the efficacy and side effects of single daily dose corticosteroids versus split dose steroid therapy. b. Provide an alternative form of therapy in patients with SLE nephritis that have not responded to conventional steroids and to evaluate the patient's clinical and serologic response to therapy.

(16) Technical Approach: Patients with lupus nephritis are randomly assigned after informed consent to one of two modes of therapy--either split dose or single dose steroids. A variety of serologic parameters are monitored indicating a response to these medications. Patients who do not respond to this therapy are randomized to either receiving high-dose pulse steroids or Chlorambucil again based on a random method. Again, serologic parameters are followed (cont'd)

(17) Progess: Although SLE is a relatively uncommon disease, we have been able to incorporate two additional patients into our protocol over the past year. Our requirements for admission into this protocol are fairly rigid and, thus, we are pleased that we were able to gain this many patients. Other Army institutions will be incorporated into this protocol and we should expect to see further gains over the next two to three years to come.

(16) to indicate response to this therapy.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/116 (3) Status: Ongoing

(4) Title:
Hypertransfusion in Acute Leukemia

(5) Start Date: Oct/81

(6) Est Compl Date: Unknown

(7) Principal Investigator:
Arlene J. Zaloznik, MD,MAJ,MC

(8) Facility: FAMC

(9) Dept/Svc:Hematology/Oncology

(10) Assoc Investigators:
Nicholas J. DiBella, MD,COL,MC

(11) Key Words:
Hypertransfusion,
acute leukemia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 6

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.: No adverse reactions

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine the advantage of maintaining an elevated hematocrit during induction chemotherapy for acute leukemia vs. the maintenance of an adequate hematocrit.

(16) Technical Approach:
Patients undergoing induction chemotherapy for acute leukemia are randomized into receiving packed red blood cells to maintain a hematocrit greater than 45% during induction vs. those who receive packed red blood cells only as clinically indicated.

(17) Progess:
To date there has been a trend in the hypertransfused group of the platelet count not dropping as low as in the non transfused group. The numbers in each arm are very small and no conclusion can be reached at this time.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-117 (3) Status: Ongoing

(4) Title:

The Role of Calcitonin in Osteoporosis

(5) Start Date: November 1982

(6) Est Compl Date: July 1984

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

(8) Facility: FAMC

(9) Dept/Svc: Endocrine Service

(10) Assoc Investigators:
Fred D. Hofeldt, M.D., COL, MC
Gerald S. Kidd, M.D., LTC, MC
Peter Blue, M.D., LTC, MC
Nasser Ghaed, M.D., COL, MC

(11) Key Words:
osteoporosis
calcitonin deficiency
bone density

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 40

d. Total Number of Subjects Enrolled to Date: 40

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

The objectives of this study are to further investigate the role of calcitonin, or its deficiency, in the development of osteoporosis and to determine if thyroidectomized patients, who are calcitonin deficient, are at increased risk of developing osteoporosis.

(16) Technical Approach:

Four groups of individuals are studied with bone densitometry using the Norland apparatus. A control group of normals and a thyroid suppressed group of patients compared with a group of thyroidectomized patients who are therefore calcitonin deficient.

(17) Progess:

Review should be accomplished by Dr. McDermott. Ensuing fiscal year will show progress.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81-117

SERVICE Endocrine/Metabolic DEPARTMENT Medicine

(1) McDermott, M.T., Kidd, G.S., Blue, P., Ghaed, V., and Hofeldt, F.D.: Reduced Bone Mineral Content in Totally Thyroidectomized Patients: Possible Effect of Calcitonin Deficiency. (In press - Journal of Clinical Endocrinology.)

PRESENTATIONS:

(1) McDermott, M.T.: Bone Mineral Content in Totally Thyroidectomized Patients. Presented: Uniformed Services Society of Endocrinology, San Francisco, CA, June 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-118 (3) Status: Ongoing

(4) Title:

Hypothalamic Pitultary Gonadal Function in Hypothyroidism

(5) Start Date: 3 September 1981

(6) Est Compl Date: Indefinite

(7) Principal Investigator:

Michael T. McDermott, M.D., MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine Service

(10) Assoc Investigators:

Gerald S. Kidd, M.D., LTC, MC
Fred D. Hofeldt, M.D., COL, MC

(11) Key Words:

hypothyroidism
HPG axis
gonadal function

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

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.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(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 a GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progess:

Review should be accomplished by Dr. McDermott. Ensuing fiscal year will show progress.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-119 (3) Status: Ongoing

(4) Title:

The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion

(5) Start Date: March 1983

(6) Est Compl Date: March 1984

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

(8) Facility: FAMC

(9) Dept/Svc: Endocrine Service

(10) Assoc Investigators:
Gerald S. Kidd, M.D., LTC, MC
Fred D. Hofeldt, M.D., COL, MC

(11) Key Words:
gonadotropin releasing hormone
thyrotropin releasing hormone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

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.: None. Awaiting FDA approval of GnRH.

(Continue on a separate sheet and designate this continuation as (14)e.)

(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:

Ten 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 hormones to determine interaction between two releasing hormones.

(17) Progess:

Review should be accomplished by Dr. McDermott. Ensuing fiscal year will show progress.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-121-N (3) Status: Ongoing

(4) Title: (79-2)

IgA Nephropathy: A Prospective Evaluation

(5) Start Date: Dec. 81	(6) Est Compl Date: Dec. 83
(7) Principal Investigator: JOHN B. COPLEY, M.D. LTC, M.C.	(8) Facility: FAMC
(9) Dept/Svc: Medicine, Nephrology	(10) Assoc Investigators: LINDA S. BARTRAM, M.D. MAJ, M.C.
(11) Key Words: IgA nephropathy, prospective evaluation	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Dec. 81 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.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine pathologic and clinical-pathologic criteria for the diagnosis of IgA nephropathy, the prognosis of patients with such a diagnosis and their suitability for continued military service, the extent of evaluation and degree of follow up required for such patients, and the sensitivity and specificity of various noninvasive diagnostic techniques which potentially could obviate the necessity for renal biopsy.

(16) Technical Approach: Patients who meet patients' selection criteria established in the protocol are enrolled and subjected to the following: skin biopsy, serum IgA levels, IgA coated peripheral lymphocyte analysis, and HLA typing. In addition, their kidney biopsy is closely scrutinized and the patient examined reference symptoms accompanying their disease, and other associated symptomatology. Follow up is conducted indefinitely at six month intervals and if the patient develops a

(17) Progess: Six patients have been enrolled in this study at Fitzsimons AMC and the study is a collaborative study being conducted at Walter Reed AMC, Dwight D. Eisenhowe AMC, and recently at William Beaumont AMC. Thus far approximately 30 patients have been enrolled totally in the study amongst all centers and the study is well on its way to fruition. Data analysis thus far has shown that serum IgA levels and ski biopsies are not predictive of IgA nephropathy. In addition, analysis has not shown

16. Technical Approach: (Cont.)

decrease in renal function, kidney biopsy is repeated. Repeat skin biopsy is accomplished only for episodes of gross hematuria.

17. Progress: (Cont.)

any difference in renal biopsy light microscopy or electron microscopy when one attempts to differentiate this entity from primary renal hematuria and only that immunofluorescence is definitive. Pending studies on patients are IgA coated lymphocytes and HLA typing, and it is hoped that a relationship between IgA nephropathy and primary renal hematuria will develop from comparison of these groups and that perhaps HLA typing and IgA coated lymphocytes will be predictive of IgA disease. It is anticipated that several papers over the next year will ensue from this protocol. Follow up of individuals in the protocol will be indefinite.

Publications and Presentations: none

JOHN B. COPLEY, M.D.
LTC, M.C.
Chief, Nephrology Service

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-122-N (81-3) (3) Status: Ongoing

(4) Title:
Utility of Furosemide in Early Oliguric or Non-oliguric Renal Failure

(5) Start Date: Feb. 82

(6) Est Compl Date: Feb. 84

(7) Principal Investigator:
JOHN B. COPLEY, M.D. LTC, M.C.
DIRK CRAFT, DO CPT, M.C.
LINDA S. BARTRAM, M.D. MAJ, M.C.

(8) Facility: FAMC

(9) Dept/Svc: Medicine, Nephrology

(10) Assoc Investigators:
JACK MOORE, JR., MAJ, M.C.
Asst. Chief, Nephrology Service, WRAMC
ROBERT W. SCHRIER, M.D.
Chief, Department of Medicine
Univ. of Colo. Health Sciences Center

(11) Key Words: Furosemide, oliguric non-oliguric, renal failure

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
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.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To prospectively determine if Furosemide is capable of producing diuresis and thereby of attentuating the severity of acute renal failure when administered early in the course of oliguria. An additional purpose is to determine if non-oliguric acute renal failure patients would benefit from Furosemide therapy; to determine if their need for dialysis could be decreased.

(16) Technical Approach: Patients accepted for the protocol per parameters listed therein are randomized into two therapeutic trial groups, Furosemide or Saline. Patients are then given specific doses by weight of Furosemide or specific amounts of Saline and their response to same is monitored immediately and over ensuing days.

(17) Progess: This study represents a collaborative study between the Renal Division, University of Colorado Health Sciences Center and Departments of Nephrology, Walter Reed AMC, William Beaumont AMC, and Fitzsimons AMC. Fitzsimons has provided four patients for this study group since approval of the protocol in February 1982. It is too early in the protocol to comment on the utility of Furosemide but the stu is extremely important because of the fact that Furosemide in very high doses is a widespread clinical use in the treatment of oliguric renal failure when its efficacy and toxicity have not been critically evaluated. Thus far there has been no identified drug reaction to the use of Furosemide and further data is expected to be

17 Progress: (Cont.)

forthcoming as more patients are enrolled in the study.

Publications and Presentations: none

JOHN B. COPLEY, M.D.
LTC, M.C.
Chief, Nephrology Service

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/123-N (3) Status: Ongoing
(4) Title: (81-4)

Primary Renal Hematuria: A Prospective Evaluation

(5) Start Date: Feb. 82	(6) Est Compl Date: Feb. 85
(7) Principal Investigator: JOHN B. COPLEY, M.D. LTC, M.C.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Nephrology	(10) Assoc Investigators: LINDA S. BARTRAM, M.D. MAJ, M.C. JOHN MANI, M.D. RESIDENT, UROLOGY
(11) Key Words: Primary renal hematuria, prospective, evaluation	

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

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: ongoing
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine the etiology and significance of hematuria, microscopic and macroscopic, as well as prognosis in patients who have neither personal or family history of renal disease, nor evidence of systemic disease or extra renal causes of hematuria.

(16) Technical Approach: Patients who meet established criteria contained within the protocol are evaluated with skin biopsy, serum IgA levels, and IgA coated peripheral lymphocytes. Most patients, then, undergo renal biopsy and/or renal arteriography. HLA typing is accomplished on all patients and patients are followed every six months for an indefinite period regardless of renal biopsy findings to determine the course of their disease.

(17) Progess: This study represents a collaborative study with Walter Reed AMC, Dwight D. Eisenhower AMC, William Beaumont AMC, and Fitzsimons AMC. and it is hoped that over a three year period at least 50 individuals will be enrolled in this study for long term follow up of primary renal hematuria. Fitzsimons has thus far contributed four patients and it is anticipated that amongst all participating c er

17. Progress (Cont.)

that the goal of 50 patients easily will be reached over a three year period. All patients enrolled in the study thus far have had abnormalities on kidney biopsies sufficient to explain their hematuria and one patient is developing a decrease in his renal function which may necessitate a repeat kidney biopsy in the future, but which will be most informative concerning prognosis of the specific entity.

JOHN B. COPLEY, M.D.
LTC, M.C.
Chief, Nephrology Service

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/123-N (81-4)

SERVICE Nephrology DEPARTMENT Medicine

1. Zierdt, C.H.; Hasbargen, J.H.; Copley, J.B.: Failure to Recover Alpha Streptococci or "Malignancy Associated" Microorganisms From Patients With Kidney Disease And Normal Humans. J. Clin. Micro. In Press

Presentations: none

JOHN B. COPLEY, M.D.
LTC, M.C.
Chief, Nephrology Service

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/124 (3) Status: Ongoing

(4) Title: Intra-Coronary Strptokinase in Evolving Myocardial Infarction

(5) Start Date: Dec 1981	(6) Est Compl Date: Dec 1983
(7) Principal Investigator: Kenneth L. Trnka, MD, MAJ, MC JAMES H. WILKIN, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Cardiology	(10) Assoc Investigators: TROY H. WILLIAMS, MD, COL, MC RICHARD C. DAVIS JR, MD, LTC, MC CARLOS A. MENDOZA, MD, MAJ, MC
(11) Key Words: Acute MI Intra-coronary streptokinase	

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

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 17
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.: None.

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To assess the efficiency and safety of intra-coronary streptokinase infusions in patients with acute myocardial infarction.

(16) Technical Approach: Patients selected for study are hospitalized and taken to the Cardiac Catheterization Laboratory after a complete history and physical exam. Prior to catheterization, CBC, SMA-18, PT, PTT, thrombin time, fibrinogen level, urinalysis, EKG and chest x-ray are done. In the Catheterization Lab, hemodynamic parameters are measured with left heart ventriculogram and selective coronary angiography. (continued)

(17) Progess: Following the start of the protocol, 17 patients have been enrolled in the study. Reperfusion of an obstructed coronary artery has been successful in 30% of the patients. No complications have arisen and only one death occurred 12 hours after an attempt at reperfusion from an acute anterior MI. Comparison of left ventricular ejection fraction pre- vs. post-streptokinase shows a trend toward improvement. A select subgroup has consented to repeat cath at two weeks. In this group (continued)

PUBLICATIONS AND PRESENTATIONS: None.

(16) Technical approach continued:

Following this, intracoronary streptokinase 10,000 IU bolus followed by 2500 units/min. x 60 minutes is infused in the obstructed coronary artery. Prior to streptokinase, 50 mg IV Benadryl is given as well as 300 mg of intracoronary nitroglycerin. The patient is then taken to the Coronary Care Unit for monitoring and routine CCU care.

(17) Progress continued:

33% have had 100% occlusion of arteries that had been reperfused. Left ventricular ejection fraction has again shown a trend toward improvement. This is in agreement with that reported in the medical literature.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-125 (3) Status: active

(4) Title:
Flexible Fiberoptic Esophageal Vein Sclerosis--A Multi-Center Prospective Study.

(5) Start Date: Sept 1981	(6) Est Compl Date: Mar 1984
(7) Principal Investigator: at FAMC: Thomas G. Brewer M.D.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Gastro	(10) Assoc Investigators: at FAMC: Michael Keegan M.D.
(11) Key Words: esophageal varices fiberoptic vein sclerosis	

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

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: four
d. Total Number of Subjects Enrolled to Date: twenty-five
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine the therapeutic efficacy and safety of flexible fiberoptic vein sclerosis in preventing recurrent bleeding in patients with recent hemorrhage from esophageal varices.

(16) Technical Approach: We have not deviated from the technical approach to sclerosing technique outlined in the protocol.

(17) Progess: Of the 25 total patients with variceal hemorrhage entered from all three participating centers, we have entered 4 patients--all of whom have been randomized to the sclerosis group. Endoscopic esophageal vein sclerosis has been carried out in each patient's case with complete ablation of varices and without occurance of any major complications. Transient

(17) con't
substernal chest pain and dysphagia lasting 24-48 hrs have been noted by all patients and have resolved in every case. All patients are currenty alive and maintaining clinical follow-up in the FAMC GI Clinic.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/100-N (82-1) (3) Status: Ongoing

(4) Title:
Combined Prednisone and Cyclophosphamide Therapy Coupled with Plasmapheresis in the Treatment of Antiglomerular Basement Membrane (anti-GBM) Antibody Induced Disease.

(5) Start Date: Mar. 82 (6) Est Compl Date: Mar. 85

(7) Principal Investigator:
JOHN B. COPLEY, M.D., LTC, M.C.
LINDA S. BARTRAM, M.D., MAJ, M.C.

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Nephrology

(10) Assoc Investigators:
None

(11) Key Words: Prednisone, Cyclophosphamide, plasmapheresis, anti-GBM antibody induced disease

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

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine whether Prednisone and cyclophosphamide alone or in combination with plasmapheresis are efficacious in lowering circulating anti GBM antibody levels and thereby affecting the clinical course of anti-GBM induced nephritis. In addition, it is desirable to learn if treatment with Prednisone and cytotoxin with or without plasmapheresis has a role in the prevention of, or is therapeutic for, the pulmonary manifestations of anti-GBM induced disease.

(16) Technical Approach: Patients with anti-GBM antibody disease are randomized into one of two treatment groups consisting of Prednisone and cyclophosphamide alone or prednisone, cyclophosphamide and plasmapheresis. Patients are monitored with history and physical examination as well as hematologic and chemistry monitor to include renal function parameters as well as anti-GBM antibody titers. Criteri for withdrawal from the study as well as analysis of the study are as indicated wit

(17) Progess: Anti-GBM mediated pulmonary and renal disease is a rare entity which accounts for this study being a collaborative study between FAMC, WRAMC, the Natio Navy Medical Center, and the National Institutes of Health. Thus far, since inception of the protocol, FAMC has not had any patients who meet criteria for ent into the protocol. However, during the course of the next several years it is anticipated that FAMC will contribute one to two patients per year to the protocol but that analysis of patients from all medical centers will be necessary to draw meaningful conclusions from acquired data.

16. Cont.
the protocol.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82(83-4)101-N (3) Status: ~~Ongoing~~

(4) Title:

Steroid And Immunosuppressive Drug Therapy In Idiopathic Crescentic Glomerulonephritis.

(5) Start Date: April 1982	(6) Est Compl Date: April 1985
(7) Principal Investigator: John B. Copley, M.D. LTC, M.C. Linda S. Bartram, M.D. MAJ, M.C.	(8) Facility: FAMC
(9) Dept/Svc: ~~Medicine/Nephrology~~	(10) Assoc Investigators: James E. Balow, M.D. National Institutes of Health Howard A. Austin, M.D. National Institutes of Health
(11) Key Words: Steroid, immunosuppressive Drug, idiopathic crescentic glomerulonephritis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

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

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 1 at FAMC

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To compare the efficacy of intravenous methylprednisolone, vs. intravenous cyclophosphamide in the treatment of idiopathic crescentic glomerulonephritis. Comparison will be made of the number of favorable outcomes of renal function and renal pathology as well as drug related toxicities manifested by each treatment group at the end of the sixth study month.

(16) Technical Approach: Patients with idiopathic crescentic glomerulonephritis are randomized into one of two study groups to receive either monthly intravenous pulse methylprednisolone for six months or monthly intravenous pulse cyclophosphamid for six months. All patients are treated with oral prednisolone in addition. Effe of therapy are monitored with frequent histories and physical examinations as well as hematologic, urinalysis and renal function monitoring. At the end of six months

(17) Progess: Idiopathic crescentic glomerulonephritis is a rare disease, and it is for this reason that this protocol represents a collaborative effort between the Nephrology Service, FAMC, Nephrology Service, WRAMC, and the Nephrology Section of NIADD of the National Institutes of Health. Since the inception of the protocol one patient at Fitzsimons has been enrolled and was randomized to the pulse methylprednisolone treatment group. He now is in his fifth month of treatment and his renal function has improved by approximately 50% such that he has not required hemodialysis. Despite what appear to be impressive results with pulse methyl-prednisolone in this patient, it is much too early to draw conclusions from this

17. Cont.
a second renal biopsy is accomplished to determine the effects of the above mentioned therapy. Criteria for withdrawal from the study, retreatment of patients who exacerbat their course of glomerulonephritis, and analysis of the study are as indicated in the study protocol.

18. Cont.
study. The patient will receive a repeat renal biopsy in the next two month period. Because of the rarity of this disease, completion date for this study amongst all centers is anticipated to take at least three years. No publications have emanated from this protocol.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 32/102 (3) Status: Ongoing

(4) Title:

Laboratory Evidence of Hypercoagulability as an Indicator for Early Graft Closure

(5) Start Date: Indefinite	(6) Est Compl Date: Indefinite
(7) Principal Investigator: RICHARD C. DAVIS JR MD LTC MC TROY H. WILLIAMS, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Cardiology	(10) Assoc Investigators: None
(11) Key Words: Hypercoagulability Coronary artery bypass graft Graft closure	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/82 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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine if there is a group of patients with laboratory evidence of hypercoagulability that have an increased risk for early closure of coronary artery bypass grafts. Also, to assess whether long term treatment with oral anticoagulants prevents graft closure in this group of patients.

(16) Technical Approach: Laboratory assessment of hypercoagulability prior to coronary artery bypass graft, randomization of patients with decreased AT III levels to treatment with coumadin vs. no anticoagulation and evaluation of graft patency by CAT scan and cardiac catheterization.

(17) Progess: None to date, awaiting purchase of flow probe by Thoracic Surgery through CIS.

Publications and presentations: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/103 (3) Status: Ongoing

(4) Title:
A Survey of Lymphocyte Subpopulations in Patients with Malignancies

(5) Start Date: 15 Nov 82	(6) Est Compl Date: 30 Sep 84
(7) Principal Investigator: N.J. DiBella, M.D., COL, MC	(8) Facility: FAMC FAMC
(9) Dept/Svc: Hem/Onc, Dept of Med	(10) Assoc Investigators: R. Stephen Whiteaker, Ph.D., CPT, MSC Jeneen K. Nelson, GS-9, DAC
(11) Key Words: Lymphocytes, cancer	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: due in May/83
c. Number of Subjects Enrolled During Reporting Period: None yet
d. Total Number of Subjects Enrolled to Date: None yet
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine if there are abnormalities of peripheral blood lymphocyte subpopulations in patients with malignancies.

(16) Technical Approach:
Blood samples from cancer patients will be surveyed to determine the composition of lymphocytes.

(17) Progess:
Study has not been initiated yet pending acquisition of necessary reagents.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82-104 (3) Status: Ongoing

(4) Title:
The Effect of Tamoxifen on Gynecomastia

(5) Start Date: March 1983	(6) Est Compl Date: March 1985
(7) Principal Investigator: Michael T. McDermott, M.D., MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Endocrine Service	(10) Assoc Investigators: Fred D. Hofeldt, M.D., COL, MC Gerald S. Kidd, M.D., LTC, MC
(11) Key Words: Tamoxifen gynecomastia therapy	

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

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

The objective of this protocol is to evaluate, in a double-blind placebo controlled prospective trial, the effect of Tamoxifen on males with gynecomastia and to characterize any co-existent hormonal changes.

(16) Technical Approach:

A randomized, double blind, placebo controlled study of the effects of Tamoxifen therapy on idiopathic gynecomastia will be performed. Breast size will be assessed by photographs, palpation and measurement of tissue.

(17) Progess:

Review should be accomplished by Dr. McDermott. Ensuing fiscal year will show progress.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/106(85-13) Status: Ongoing

(4) Title:

Clinical Usage of High Frequency Jet Ventilation

(5) Start Date: June, 1981	(6) Est Compl Date: June 84
(7) Principal Investigator: Gary R. Ripple, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Pulmonary Clinic/Lab	(10) Assoc Investigators: Michael E. Perry, LTC,MC Jim Gilbert, MAJ, MC Mike Schlachter, CPT, MC William Strampel, MAJ, MC
(11) Key Words: High Frequency Jet Ventilation Airway Pressure Arterial Blood Gases	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: High frequency jet ventilation (HFJV) will be used on certain patients as outlined in the protocol who have not responded to conventional ventilation. The investigators will moniter airway pressure and arterial blood gases to determine HFJV usefulness and clinical applicability.

(16) Technical Approach: Utilizing a standard ventilator as a "back-up" means of ventilation, the HFJV jet is insorted into the endotrachial tube adaptor and the rate and 1:E ratio of the HFJV generator is adjusted to determine adequacy of ventilation. The investigators by monitoring air flow, airway pressure and clinical response may then determine optimal HFJV settings and modification which are to date unpublished.

(17) Progess: Of the two patients who have undergone jet ventilation, both were in end-stage respiratory failure and both died of respiratory failure. Documentation of HFJV efficiency is indeterminable on just two cases, but in each case the use of elevated airway pressure caused a marked increase in CO_2 retention. Whether this is a function of our individual machine or a function or increased pressure is currently under investigation.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(85-4)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/107 (3) Status: Ongoing

(4) Title: Interstitial Lung Disease Protocol

(5) Start Date: June 1981	(6) Est Compl Date: June 1984
(7) Principal Investigator: Gary R. Ripple, CPT, MC	(8) Facility: FAMC National Jewish Hospital VA Medical Center UofC Health Science Center
(9) Dept/Svc: Pulmonary	(10) Assoc Investigators:
(11) Key Words: Interstitial Lung Dis. Gallium Seitigraphy Bronchoalveolar lavage Open Lung Biopsy Corticosteroid	Michael E. Perry, LTC, MC Jimmy Gilbert, MAJ, MC William Strampel, MAJ, MC Michael Schlachter, CPT, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing
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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: Through the correllation of Gallium Scitigraphy, bronchoalveolar lavage, open lung biopsy and pulmonary function testing the investigators are striving to determine the role of immune complexes and neutrophils in the pathogenesis and treatment (with corticosteroids) of interstitial lung disease.

(16) Technical Approach: Consenting patients with interstitial lung disease (ILD) are evaluated initially by Gallium scitigraphy, bronchoalveolar lavage, pulmonary function studies and open lung biopsy. Those patients having ILD of undetermined etiology on biopsy are re-evaluated by gallium scanning, bronchoalveolar lavage, and pulmonary function studies 6 weeks after biopsy (before steroids) and after 6 weeks of steroids. The purpose is to

(17) Progess: For the fiscal year of 1981, of the four patients enrolled in the study only one was found to have Idiopathic Interstitial Lung Disease, (usual interstitial pneumonitis) and he was removed from the study protocol when the severity of his illness required treatment other than that outlined by the protocol. The other three patients had a variety of illnesses other than Idiopathic ILD (i.e. sarcoidosis, malrodantin lung, and allergic alveolitis vs bronchiectasis). Thus, to date none of our patients are included in the multicontor study statistics.

(16) corrollate disease activity with diagnostic procedures.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/108 (3) Status: Completed

(4) Title:

An Evaluation of the Efficacy of Cromolyn Sodium 2% Ophthalmic Solution in the Treatment of Seasonal Allergic Rhinitis

(5) Start Date: August 1982	(6) Est Compl Date: September 1982
(7) Principal Investigator: W. R. Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: H.S. Nelson, MD, COL, MC Kenneth Kray, MD, MAJ, MC Edward Squire, Jr., MD, MAJ, MC
(11) Key Words: allergic conjunctivitis cromolyn	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: due Aug 1983

c. Number of Subjects Enrolled During Reporting Period: 43

d. Total Number of Subjects Enrolled to Date: 43

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the effectiveness of a 2% Cromoyln solution placed in the eyes, six times per day in blocking symptoms of allergic conjunctivitis.

(16) Technical Approach:

Patients were matched by pre-seasonal sensitivity as measured by the RAST. Equal numbers of each degree of sensitivity were treated with either placebo or Cromolym Eye Drops while controlling their nasal symptoms with atopical steroid preparation. Effectiveness was measured by symptom score cards completed daily.

(17) Progess:

Forty-three patients participated during the peak of the weed season in 1982. The data is currently awaiting analysis prior to submission for presentation and publication.

Publications and Presentations: none

SURGERY

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 71-202 (3) Status: ongoing

(4) Title:
Evaluation of Peripheral Nerve Injuries at FAMC

(5) Start Date: 1971	(6) Est Compl Date: indef.
(7) Principal Investigator: COL William W. Eversmann, Jr, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic Service	(10) Assoc Investigators: LTC Stephen J. Frushour, MC
(11) Key Words: Neurorrhaphy, peripheral nerve	

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

(14) a. Date, Latest HUC Review: 7/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: Data maintained in Surgic
d. Total Number of Subjects Enrolled to Date: 400 estimate Researc
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To establish a pattern of peripheral nerve repair and recovery following injuries to peripheral nerves greater than the usually accepted two year time period. Within the course of this study interesting findings of late recovery of nerve function have already been gleaned.

(16) Technical Approach: Detailed questionnaire follow-up of patients with peripheral nerve injuries who have undergone repair are followed by detailed outpatient physical examination and evaluation supplemented by the questionnaires. The questionnaires are divided into specific detailed questions and customized for the level and type of nerve injury.

(17) Progess: During FY 1982 we have continued the ongoing clinical data and have continued to follow specific patients with detailed examination of the recovery of their nerve. It has been ascertained that certain patients with high nerve injuries continue to experience recovery of those nerve injuries some 6, 7 or even 8 years after suture of the nerve which is contrary to the literature and indeed almost unheard of. Small groups of specific nerve injuries have been reviewed in detail.

Publications and Presentations: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 73/219 (3) Status: Ongoing

(4) Title:
Treatment of Urinary Tract Trauma in the Laboratory Animal

(5) Start Date: May 1973	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Major John H. Mani, M.D., MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Urology	(10) Assoc Investigators: LCDR William Shipton, MSN, MC Cpt John Wolthuis, MC LTC Michael Morris, MC Col Edward Buck, MC Col Howard Fauver, MC
(11) Key Words: Trauma Renal transplantation Inosine	

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

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: Investigation of, and comparison of various modes of treatment of urological trauma with emphasis on newer surgical techniques to include renal vascular repair, bench surgery, autotransplantation and pre- and intraoperative chemical intervention, e.g., use of inosine

(16) Technical Approach: Various techniques of vascular reanastomosis and autotransplantation will be performed. Function preservation in the face of these surgeries, and in face of temporary suspension of renal blood flow will be evaluated using inosine as a preservative. Excretory urograms and/or renal scans may be used at intervals to ascertain success or failure.

(17) Progess: Personnel shortages - Temporary loss to the Urology Service of one resident for one year - have curtailed the protocol. Progress is expected to be resumed on receipt of test substances and return of the resident at the start of the next academic year.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 23/219

SERVICE Urology DEPARTMENT Surgery

(1) Levisay, G.L.: Renal Autotransplantation in the Dog. Proc of the Kimbrough Urolo Sem, January 1974.

(2) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Proc of the South Central Sect, AUA, Denver, CO 15-19 September 1974.

(3) Page, M.E.: Renal Autotransplantation with Venal Caval Occlusion. Proc of the Kimbrough Urolo Sem, Seattle, WA, 5 October 1975.

PRESENTATIONS:

(1) Levisay, G.L.: Renal Autotransplantation in the Dog. Presented: Kimbrough Urological Seminar, Washington, D. C., January 1974.

(2) Levisay, G.L.: Renal Autotransplantation in the Dog. Presented: South Central Section Meeting of the AUA, Denver, CO, September 1974.

(3) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: South Central Section of the AUA, Denver, CO, 15-19 September 1974.

(4) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: Kimbrough Urological Seminar, San Antonio, TX, 14-19 November 1974.

(5) Page, M.E.: Renal Autotransplantation with Vena Caval Occlusion. Seattle, Washington, October 1975.

(6) Page, M.E. and Weigel, J.W.: Exhibit-renal transplantation with Proximal Vena Caval. Presented: South Central Section Meeting in Urology, September 1975.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 76/203 (3) Status: Completed

(4) Title:
Screening Program for Military Children at High Risk for Hearing Loss

(5) Start Date: 17 Oct 76 | (6) Est Compl Date: 3 March 82

(7) Principal Investigator:
Susan T. Slibeck, M.S., DAC | (8) Facility: FAMC

(9) Dept/Svc: Surgery/Otolaryngology/Audiology | (10) Assoc Investigators:
None

(11) Key Words:
Parent Interview
Chart Review
High Risk Registry

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

(14) a. Date, Latest HUC Review: 1/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 80
d. Total Number of Subjects Enrolled to Date: 1670
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To screen infants and children for information indicating high risk for hearing loss so that early identification and treatment can be enhanced.

(16) Technical Approach: Trained Red Cross volunteers screened the medical and family histories of all newborns, pediatric ward patients (0-6) years of age), and one year old Well Baby Clinic patients through parent interviews and medical chart reviews. The investigator reviewed the gathered data for indications of high risk for hearing loss and designated children as AT RISK or NOT AT RISK. Parents of AT RISK children were notified suggesting that they arrange an audiology evaluation for their child. Tested AT RISK children will be followed and treated appropriately.

(17) Progess:

Of all the AT RISK children followed with this protocol, 12% were found to have some degree of hearing impairment. All of these losses were identified before the children were 3½ years of age. The disposition of the FAMC Clinical Investigati- Institutional Review Committee was to judge this study as completed and this pr tocol as having successful clinical application. The technical approach, as described above, has been incorporated as a standard operating procedure for the Audiology Section.

PUBLICATIONS for FY 82 Annual Progress Report Proto No._____

SERVICE Otolaryngology Svc DEPARTMENT Audiology Section/Dept of Surgery

None.

PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 77/204 (3) Status: Terminated

(4) Title:
The Anatomical and Physiological Development of the Flexor Tendon Sheaths in the Human Fetus.

(5) Start Date: Sep 79	(6) Est Compl Date: indef.
(7) Principal Investigator: William W. Eversmann, Jr., COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic Svc	(10) Assoc Investigators:
(11) Key Words: Flexor Anatomical Development Flexor Tendon	none

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

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: Terminated
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: The objective of this study is to detail the anatomical development embryologically of the flexor tendon sheaths of the human fectus to 20 weeks of age and to correlate this development with biochemical changes within the flexor muscle mass which are indicative of developing contractility.

(16) Technical Approach: Collection of human fetal specimens to 20 weeks of ages gestation and combined anatomical and correlative biochemical studies of the flexor muscle mass.

(17) Progess: Because of the lack of available specimens following a congressional mandate in 1980 to not support voluntary interruption of pregnancy at military hospitals this study by necessity had to be discontinued.

Publications and Presentations: None

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/200 (3) Status: Ongoing

(4) Title:
Anastomosis of the Dog Vas Deferens Using Microsurgical Technique

(5) Start Date: April 1978	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Col Howard E. Fauver, M.D.,MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Urology	(10) Assoc Investigators: Col Edward Buck, MC LTC Michael Norris, MC Maj John Mani, MC LCDR William Shipton, MC (USN) Cpt John Wolthuis, MC
(11) Key Words: Microsurgery-vasovasostomy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To master the microsurgical anastomosis of the vas deferens.

(16) Technical Approach:Standard bilateral vasectomy performed on mongrel male dogs. Three weeks later a two layer microsurgical anastomosis using 10-0 nylon is completed. Three weeks later the dog is sacrificed and bilateral vasograms completed.

(17) Progess: Personnel shortages have curtailed the protocol. With return of the junior resident next academic year, active use is anticipated. This protocol continues to be an invaluable and irreplaceable tool for teaching of residents and staff in the techniques of microsurgery.

Continuing experimentation with various sutures and microsurgical technique is being performed. Since it is felt that a minimum of thirty hours of microscope time is essential before this procedure can be performed in human subjects, this current protocol represents the only practical way in which experience can be gained.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 78/200

SERVICE Surgery/Urology DEPARTMENT Surgery

Vaccaro, J.A.: Microscopic Vasovasostomy: The Fitzsimons Experience. Kimbrough Urological Proceedings, Vol. 14, 1980.

PRESENTATIONS:

Vaccaro, J.A.: Microscopic Vasovasostomy: The Fitzsimons Experience. Presented: Kimbrough Urological Seminar, November 1980, San Diego, CA.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/201 (3) Status: Ongoing
(4) Title:

Clinical Study for Intraocular Lenses

(5) Start Date: September 1976	(6) Est Compl Date: Unknown
(7) Principal Investigator: Andrew J. Cottingham, Jr.,M.D.	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Calvin E. Mein, M.D., Major, MC Douglas A. Freeley, M.D., LTC, MC Thomas H. Mader, M.D., Major, MC William R. Wilson, M.D., CPT, MC (cont'd)
(11) Key Words: Cataract Intraocular Lens Pseudophakos	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Apr 82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 25 implants
d. Total Number of Subjects Enrolled to Date: 500 Intraocular lenses
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
1). To determine postoperative visual acuity of patients receiving an 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.
2). To describe the occurrence and time course of postoperative ocular complications and adverse reactions both for intraocular lens implant (cont)

(16) Technical Approach:
After didactic courses, observations, laboratory practice and assistance with an experienced implant surgeon, a surgeon who can perform an accomplished cataract extraction, is then allowed to perform intraocular lens surgery under proper tutorage. Postoperative examinations include: pachyometry, keratometry, and specular microscopy. Contraindications to surgery include: patients with (cont)

(17) Progess:
Due to the initial 25 implants between September 1976 and February 1978 the implantation of intraocular lenses at FAMC was expanded. We now have implanted over 500 intraocular lenses.
As a result of the past six years experience, we have evolved better guidelines for patient selection, better surgical techniques and improved guidance for postoperative care. Our study includes tabulation of operative (cont)

(10) William G. Carey, M.D. CPT, MC
Ronald R. Holweger, M.D., Major, MC
John A. McCubbin, M.D., CPT MC

(15)
(2). subjects and for control subjects.
(3). To compare the occurrence of adverse reactions and ocular complications in the implant group and in the control group, in order to delineate any significant difference.
(4). To describe the occurrence of postoperative lens complications for the implant group, and their relationship to ocular complications.
(5). To identify subgroups within the implant study population that are at "high risk" of particular complications as compared to the control group.

(16)
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, and a history of previous retinal detachments or uveitis.

(17)
complications, postoperative complications, visual results, endothelial cell loss, corneal thickness changes, changes in corneal astigmatism, and residual refractive error.

The results of every ophthalmologist implanting intraocular lenses in the United States additionally compiled by computer in Washington, D.C. by the FDA, our results are a small part of this overall study. Final data from this massive study is to be completed in the future. As a result of this study many intraocular lenses have been taken off the protocol due to their proven safety. These devices that have been taken off the protocol study need only be registered when implanted at this time.

PUBLICATIONS for FY 82 Annual Progress Report: none

PRESENTATIONS for FY 81 Annual Progress Report Proto No. 78/201

SERVICE Ophthalmology DEPARTMENT Dept of Surgery

(1) Cottingham, Jr., A.J.: Keratoplasty. Presented: Optometry Meeting, FAMC, October 1978.

(2) Cottingham, Jr., A.J.: Endophthalmitis - Cause and Treatment. Presented: University of Colorado Health Sciences Center, January 1979.

(3) Cottingham, Jr., A.J.: Corneal Keratomycoses. Presented: University of Colorado Health Sciences Center, January 1979.

(4) Cottingham, Jr., A.J.: Bacterial Corneal Ulcers. Presented: University of Colorado Health Sciences Center, January 1979.

(5) Cottingham, Jr., A.J.: The Use of Vitrectomy Instrumentation in Anterior Segment Reconstruction. Presented: Scheie Institute Trauma Symposia, Philadelphia, Pennsylvania, September 1979.

(6) Cottingham, Jr., A.J.: An Analysis of the Initial Twenty-Five Intraocular Lens Implantations in an Ophthalmology Residency Training Program. Presented: 7th Biennial, Walter Reed Ophthalmology Post Graduate Course and Alumni Meeting, April 1978.

(7) Cottingham, Jr., A.J.: An Analysis of the Initial Twenty-Five Intraocular Lens Implantation in an Ophthalmology Training Program. Presented: Bascom Palmer Eye Insititute Annual Resident Alumni Meeting, June 1978.

(8) Cottingham, Jr., A.J.: Residual Astigmatism - Postoperative Keratoplasty. Presented: American Academy of Ophthalmology, Chicago, Illinois, 7 November 1980.

(9) Cottingham, Jr., A.J.: Endophthalmitis - Diagnosis and Treatment. Presented: 9th Biennial Walter Reed Ophthalmology Post Graduate Course and Alumni Meeting, April 1982.

(10) Cottingham, Jr., A.J.: Posterior Chamber Implantation of Intraocular Lenses. Presented: Letterman Army Medical Center, April 1982.

(11) Cottingham, Jr., A.J.: Ocular Trauma for the Non-ophthalmologist. Presented: Garey Wratten Surgical Symposium, San Antonio, Texas, March 1982.

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **79/201** (3) Status: **Ongoing**

(4) Title: **Platelet Function in Disease States**

(5) Start Date: **7 Aug 79**

(6) Est Compl Date: **Indefinite**

(7) Principal Investigator:
Jeffrey Clark, MD, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: **Surgery/Gen Surg Svc**

(10) Assoc Investigators:
T.P. O'Barr, Ph.D., DAC
Donald G. Corby, MD, COL, MC
J. Bryan Smith, Ph.D.
Ellen Swanson, DAC

(11) Key Words:
prostaglandins, thromboxane, arachidonic acid, prostacyclin, platelets

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **10/81** b. Review Results: **Ongoing**
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.: **NA**

(Continue on a separate sheet and designate this continuation as (14a).)

(15) Study Objective:

a. To develop and assess methods of measuring in vitro platelet function.

b. To investigate the importance of arachidonic acid (AA) metabolism in platelet function.

c. To use the TxB_2 radioimmunoassay to measure platelet survival.

d. To use the above described tests of platelet function to screen patients with various clinical illnesses for disturbed platelet function.

e. To investigate in vivo platelet function using an animal model and the above described platelet function tests.

f. To propose and test new clinical therapeutic modalities to treat disease of altered platelet function. These modalities will be based on the results obtained from pursuing objectives a,b,c,d, and e.

(16) Technical Approach: To use tests of platelet function to screen surgical patients for platelet related abnormalities.

(17) Progress: The effect of aspirin (ASA) on perioperative blood loss was studied in 52 patients undergoing unplanned operation. Twenty-two of 52 (48%) patients were found to have taken ASA prior to operation. Five other patients were suspected to have taken ASA or some aspirin-like drug prior to operation.

(17) Progress: (cont'd)

All patients who remembered taking ASA preoperatively had significantly decreased platelet thromboxane B_2 (TxB_2) levels. Only eight of 22 patients who took ASA had abnormal template bleeding times.

There was no significant increased perioperative blood loss in patients who had taken ASA. Neither the ASA-induced decrease in TxB_2 levels nor the increase in template bleeding times was associated with increased perioperative blood loss.

We conclude that ASA is commonly used prior to unplanned operations, but that preoperative ASA usage does not result in increased perioperative blood loss in patients with normal coagulation parameters and normal platelet counts. There is no need to delay operation in this group of patients because of recent ASA ingestion.

The original Principal Investigation, Dr. Victor Ferraris, will be beginning cardiovascular residency at Letterman Army Medical Center. This protocol will be initiated at Letterman at that time. TxB_2 assays will continue to be performed at FAMC under the direction of the new P.I., Dr. Jeffrey Clark, until procedures can be developed at LAMC.

PUBLICATIONS:

1. Eiseman, B.: Prognosis of Surgical Disease. W. B. Saunders Company, 1980.
   The following chapters were contributed:

   Hirata, Richard M.: Carcinoma of the Oral Cavity
   Davies, Ross S.: Reflux Esophagitis
   Mologne, Lewis: Varicose Veins

2. Ferraris, V.A. and Sube, Janis: Retrospective study of the Surgical Management of Reflux Esophagitis Surgery. OB-GYN 152:17-21, January 1981.

PRESENTATIONS:

1. Ferraris, V.A., and Sube, Janis: Retrospective Study of the Surgical Management of Reflux Esophagitis. Presented: William Beaumont Army Medical Center, El Paso, Texas, March 1980.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/200 (3) Status: Ongoing

(4) Title:
Hearing Loss in Hypothyroidism

(5) Start Date: 1980	(6) Est Compl Date: June, 1984
(7) Principal Investigator: Marc Sachs, CPT. MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Otolaryngology	(10) Assoc Investigators: COL John Kolmer COL Fred Hofeldt
(11) Key Words: hypothyroidism hearing loss	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: 10/81 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 13
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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: The objectives are to determine if there is a relationship of hearing loss to hypothyroidism, the locus of this effect, and the potential reversability of this effect.

(16) Technical Approach: Newly diagnosed hypothyroid patients are given a routine hearing evaluation, tympanograms, and a BSER. They are then restudied four weeks after beginning therapy, and again at least twelve weeks later.

(17) Progess: Thirteen patients are currently being studied. The percentage of these patients having hearing loss is about 40% (from all causes). Two patients actually presented with hearing loss to the ENT Clinic and were later diagnosed as being hypothyroid. Only one new patient has been added since the last review. This is partially due to the small number of hypothyroid patients being available, and partially due to my being away from FAMC on TDY and not being in the ENT Clinic last year. At present, not enough data are present to comment on the reversability.

CONTINUATION SHEET, FY 82 ANNUAL PROGRESS REPORT Proto No.:_____

PUBLICATIONS and PRESENTATIONS: none.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80-201 (3) Status: Ongoing

(4) Title: Comparison of Cardiac Output and Left Ventricular Stroke Work Before and After Standard Anesthesia Induction of Patients Undergoing Surgical Correction of Combined Mitral Valve Disease and Coronary Artery Disease

(5) Start Date: 1 Oct 80	(6) Est Compl Date: 30 Sep 85
(7) Principal Investigator: LTC William J. Reynolds, MD	(8) Facility: FAMC
(9) Dept/Svc: Anes & Op Svc, D/Surg	(10) Assoc Investigators: Refer to Continuation Sheet
(11) Key Words: Fantanyl, Cardiovascular Anesthesia, Coronary Artery Disease, Mitral Valvular Disease, Open Heart Surgery	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 10/81 b. Review Results: Ongoing
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine the presence or absence of significant statistical difference of left ventricular work as affected by conventional cardiac anesthesia techniques.

(16) Technical Approach: Real-time data is obtained from pulmonary artery and radial artery catheters using transistor-generated analog data. Portable digital microprocessor provides all second generation data analysis. Cardiac anesthesia uses routine technique.

(17) Progess: Two additional patients have entered the study during the reporting period. This represents approximately eight percent of the minimum experimental population.

CONTINUATION SHEET, FY 81 ANNUAL PROGRESS REPORT Proto No.: 80-201

(10) ASSOCIATE INVESTIGATORS:

MAJ Jonathan H. Chang, MC, Anes and Oper Svc
COL Konstantine Kalandros, ANC, CRNA
LTC Raymond Golden, ANC, CRNA
LTC Richard Lenig, ANC, CRNA
MAJ David Bohner, ANC, CRNA
MAJ Donald Newton, ANC, CRNA
CPT Yvonne Boles, ANC, CRNA
CPT Brenda Galeas, ANC, CRNA
CPT Frederick Masters, ANC, CRNA
MS Rosemarie Perillo, CRNA, DAC
MS Vivian Lucas, CRNA, DAC
MR Eugene Pennington, CRNA, DAC

Deleted Investigators - due to military reassignment or resignation

LTC Francis Moriarty, ANC, CRNA
MAJ Thomas W. Muller, MC, Anes and Oper Svc
MR Ronald Rabe, CRNA, DAC
MS Sharon Heiss, CRNA, DAC

New Investigators -

CPT Marshall L. Fay, MC, Anes and Oper Svc
CPT John K. Williford, MC, Anes and Oper Svc

PUBLICATIONS AND PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/200 (3) Status: ongoing

(4) Title: Biomechanical and Anatomical Characterization of Unstable Burst Fractures of the Thoracolumbar Spine and an Evaluation of Surgical Approaches for Stabilization and Decompression.

(5) Start Date: Apr 81	(6) Est Compl Date: Nov 82
(7) Principal Investigator: LTC George G. Richardson, Jr, MC	(8) Facility: FAMC
(9) Dept/Svc: Ortho	(10) Assoc Investigators: COL Ghaed Dr. Lowe Mr. Jatko
(11) Key Words: Spine Fractures	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To create bursting injuries in the thoracolumbar spine in cadaver material and thereafter describe the biomechanics and anatomy of these burst fractures involving gross anterior bursting with involvement of the posterior complex resulting in characteristic fracture fragments which impinge on the spinal canal. These will be characterized by axial tomography and radiographic examination as well as anatomic dissection.

(16) Technical Approach: To develop a model through a study of several phases which will arrive at a final phase to develop surgical approaches for stabilization and decompression. Hopefully the data obtained will provide clearer indication for one-stage anterior and posterior approaches.

(17) Progess: Having attained the necessary engineering material to accomplish the study, the availability of spine material for this study has been elusive. Ideally fresh cadaver material should be obtained. Attempts continue to obtain this material and in the meantime the engineering model for compression will be adapted to a study of distal radius and wrist injuries which will be submitted under a separate protocol.

Publications andPresentations: None

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **81/202** (3) Status: **Ongoing**

(4) Title: **Treatment of Recurrent Otitis Media: Chemoprophylaxis vs Tympanostomy Tubes**

(5) Start Date: **January 1982**	(6) Est Compl Date: **June 1983**
(7) Principal Investigator: **Carlos Gonzalez, CPT, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Surgery/ENT**	(10) Assoc Investigators: **James Arnold, MD, CPT, MC** **John W. Kolmer, MD, COL, MC** **Thomas Kueser, MD, CPT, MC** **Edward A. Woody, MD, CPT, MC**
(11) Key Words: **recurrent otitis media** **tympanostomy tubes** **chemoprophylaxis**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **10/82** b. Review Results: **Ongoing**
c. Number of Subjects Enrolled During Reporting Period: **56**
d. Total Number of Subjects Enrolled to Date: **56**
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **none**

(Continue on a separate sheet and designate this continuation as (14)f.)

(15) Study Objective: **To determine which modality of treatment for recurrent otitis media, chemoprophylaxis or P.E. tubes or both and if one or both offers better control of future otitis media episodes considering morbidity and complications.**

(16) Technical Approach: Patients who meet criteria of study will be randomly placed in three different groups. Patients will be followed on a monthly basis for six months. Episodes of recurrent otitis media will be reported and seen by us.

(17) Progress: To date, 56 patients are enrolled in this study. Approximately 50-60% have greater than a six month follow-up. It is projected to continue to enroll children until January 1983 or until 65 children are enrolled, whichever comes first. At that time, follow-up will continue for 6 months. The medication code will not be broken until at least 6 months of follow-up. To date, there have been no severe adverse reactions or complications reported. (Dr. Arnold, assoc. investigator, has been transferred to Madigan Army Medical Center where he is to start this protocol and results will be combined.) All progress reported is in FY82.

PUBLICATIONS and PRESENTATIONS: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **82/200** (3) Status: **Terminated**
(4) Title: **Use of the St. Jude Medical Prosthesis at Fitzsimons Army Medical Center**

(5) Start Date: **1982**	(6) Est Compl Date: **1982**
(7) Principal Investigator: **Fred Pauling, M.D.** **Colonel, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Surgery/Thoracic**	(10) Assoc Investigators: **Olyn M. Walker, M.D., COL, MC** **Roy L. Kingry, Jr., M.D., COL, MC**
(11) Key Words: **prosthesis** **cardiac valve**	

(12) Accumulative MEDCASE:
Refer to Last Summary Sheet of this report.
(13) Est Accum OMA Cost:

(14) a. Date Latest HUC Review: **NA** b. Review Results: **NA**
Number of Subjects Enrolled During Reporting Period: **NA**
Total Number of Subjects Enrolled to Date: **3**
Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA awarded IND.: **NA**

Continue on a separate sheet and be sure to include confirmation as (14)

(15) Study Objective: **To use the St. Jude Medical Prosthesis in selected patients until approval of the prosthesis by the FDA.**

(16) Technial Approach: **The St. Jude medical prosthesis will be used in selected patients with small annuli and/or with relative contraindication to use of coumadin.**

(17) Progress: **Three patients were entered in the protocol. There were no complications. The study has been terminated as the FDA approval was obtained.**

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/201 (3) Status: Ongoing

(4) Title: Prospective Double Blind Randomized Study of the Effects of Supplemental Dietary Calcium and Vitamin D on the Healing of Distal Radius Fractures in Adults

(5) Start Date: 1 Aug 82	(6) Est Compl Date: 1 Aug 84
(7) Principal Investigator: Timothy S. Loth, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic/Surgery	(10) Assoc Investigators: William W. Eversmann, Jr., M.D. Petter Blue, M.D. Nasser Ghaed, M.D.
(11) Key Words: Bone density distal radius fractures, bone healing.	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine whether supplemental dietary calcium and Vitamin D accelerate distal radius fracture healing in humans older than 20 years of age.

(16) Technical Approach: In individuals 20 years and older with closed distal radius fractures will be asked to participate in this study assessing the effects of calcium and vitamin D dietary supplementation on the rate of distal radius fractur healing. Patients will be assessed using bone densitometry as well as clinical and conventional radiographic evaluation. Evaluations will be performed within 1 week, at 3, 6, 12 & 24 weeks following injury. The injured wrist will be compared to the opposite normal control.

(17) Progess:
We are currently awaiting suitable candidates for enrollment in this study.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RC MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU# 82/202-N (3) Status: Ongoing

(4) Title:

Lateral electrical stimulation for the treatment of scoliosis.

(5) Start Date: March 1982	(6) Est Compl Date: March 1986
(7) Principal Investigator: Stephen J. Frushour, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopaedic/ Surgery	(10) Assoc Investigators:
(11) Key Words: Scoliosis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 3

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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To demonstrate that nocturnal transcutaneous electrical stimulation of paraspinal muscles is as effective as the use of a full-time spinal orthosis (brace) in the treatment of idiopathic scoliosis occuring in skeletally immature adolescents.

(16) Technical Approach:

The scoliosis patients who qualify for the study will be fit with electrical stimulation unit and instructed in its use. They will then have a two week trial period at home to insure that they can conform to the protocol. They are then followed closely at regular intervals to ascertain the outcome.

(17) Progess:

To date there are three patients in the program at FAMC. All have done well without problems. There have been no complications. At this time all of the curves in the scoliosis in these patients have either stayed the same or have become better (less of a Cobb angle).

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/203-N (84-4) (3) Status: Ongoing

(4) Title:
Effectiveness of EMG Biofeedback in Maintaining Fluency Obtained in an Intensive Stuttering Treatment Program

(5) Start Date: 1982

(6) Est Compl Date: 30 months after start

(7) Principal Investigator:
Jon M. Hasbrouck, Ph.D.

(8) Facility: FAMC

(9) Dept/Svc: Surg/Oto/Speech

(10) Assoc Investigators:
Fran Lowry-Romero, M.S.

(11) Key Words:
Stuttering
Biofeedback

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: None

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: Compare effects of extensive EMG biofeedback training and practice to EMG monitoring with no biofeedback and to no EMG monitoring and no biofeedback, to determine how EMG biofeedback relates to the acquisition and maintenance of fluency as one aspect of an intensive adult stuttering treatment program.

(16) Technical Approach: SS in 3 groups will be pretested, receive 3 concurrent treatment procedures (airflow, relaxation, biofeedback) followed by a fourth treatment (discriminative stimulus control) and be post-tested. Group 1 will receive extensive EMG biofeedback monitoring, training, and practice. Group 2 will receive the same treatment as Group 1 but will receive no auditory or visula feedback of performance. Group 3 will receive no EMG biofeedback training or monitoring but will receive the same amount of time in activities similar to Group 1 and 2.

(17) Progess:

Still acquiring equipment, no progress to date.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/204-N (3) Status: Ongoing

(4) Title:

Evaluation of Treatment Methods for Extravasation of Chemotherapeutic Agents

(5) Start Date: 9 Aug 82	(6) Est Compl Date: 14 Nov 82
(7) Principal Investigator: CPT Timothy Loth, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic/Surgery	(10) Assoc Investigators: COL William W. Eversmann, Jr., MC
(11) Key Words: Chemotherapeutic, Extravasation, Necrosis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To compare the efficacy of incision and debridement with standard methods of treatment for extravasation of chemotherapeutic agents.

(16) Technical Approach: A rat model will be used to evaluate the comparative effectiveness of various modalities of intervention for the treatment of chemotherapeutic agent extravasations. Intradermal injections using various vesicant agents will be performed and treated in several ways. Several groups will undergoe surgery at different intervals, while groups will be treated using injectable and topical antidotes.

(17) Progess: This study currently is in its final stages. The paper is currently being prepared for publication.

Publications and Presentations: none

CLINICAL INVESTIGATION

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **72-302** (3) Status: **Ongoing**

(4) Title: **Comparison of Metabolic and Functional Changes in Defects of Platelet Function**

(5) Start Date: **1972**	(6) Est Compl Date: **1984**
(7) Principal Investigator: **Donald G. Corby, M.D. Colonel, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Clinical Investigation**	(10) Assoc Investigators: **Thomas P. O'Barr, Ph.D., DAC**
(11) Key Words: **platelet function newborn**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **11/81** b. Review Results: **Ongoing**
c. Number of Subjects Enrolled During Reporting Period: **NA**
d. Total Number of Subjects Enrolled to Date: **NA**
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **To correlate biochemical and functional parameters to gain a better understanding of the pathophysiology of the disorders of platelet function.**

(16) Technical Approach:

Subjects: In most part, this study will deal with the further investigation of the platelet "defect" found in the normal newborn infant. However, since the techniques of studying the biochemical aspects of platelet function developed in previous studies permit the thorough evaluation of qualitative platelet disorders in older children and adults, the protocol is also intended to cover the diagnostic evaluation of patients with functional platelet syndromes associated with the "hemorrhagic state".

Platelet Function Studies: When indicated clinically, platelet counts, bleeding times, platelet adhesion, and whole blood and PRP aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation.

(16) Technical Approach (cont'd):

Biochemical Studies: Assessment of the content and release of the content of the platelet's subcellular storage organelles (alpha and dense granules) and evaluation of the Platelet membrane will include, but not be limited to the following:

a. Electron microscopy and mepacrine staining of dense granules.
b. Content of platelet factor 4 and B-thromboglobulin activity in the alpha granules.
c. Production of platelet-derived growth factor by ^{3}H-thyamide incorporation in 3T3 mouse fibroblasts by platelet lysates.
d. Measurement of secretable acid hydrolases (B-glucuronidase, B-galactosidase, and membrane P-nitrophenyl phosphatase) activities.
e. Membrane glycoprotein and phospholipid content.
f. Release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase.
g. Mobilization of Ca++.
h. Other studies as they become available.

(17) Progress: During the past fiscal year, work on this protocol has centered on the evaluation of membrane glycoproteins in newborn platelets. Results are summarized in the following abstract:

As part of our continuing evaluation of newborn platelet dysfunction, washed platelets from neonates and normal adults were prepared for electrophoresis by solubilization and incubation in 2% sodium dodecyl sulfate containing 2% (v/v) mercaptoethanol. Proteins were separated on vertical 7.5% polyacrylamide gel slabs using the buffer system of Laemmli. Analysis of periodic acid=Schiff and Coomasie Blue stained gels revealed statistically significant decreases in 2 protein bands in the newborn platelets: a slow-migrating band with an apparent molecular weight (M_r) of ~ 68000 identified as albumin by immunofixation, and a fast band ($M_r \sim 185000$) identified as thrombospondin based upon its secretion from the platelets by human alpha-thrombin in EDTA-containing buffer and its retention within the alpha-thrombin stimulated platelets in the presence of Ca^{+2} and Mg^{+2}. Since thrombospondin and albumin are components of the alpha-granule, these results suggest the presence of a deficiency of alpha-granule proteins in the newborn platelet. Whether this is an isolated deficiency of these proteins or represents a generalized deficiency of all alpha-granule proteins, i.e., FVIII/VW factor, platelet factor 4, B-thromboglobulin, Fibrinogen, and Fibronectin, remains to be determined during FY 1983.

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). (Abst.) Clin. Res. 21:304, 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst., P. 107), III Congress, International Society on Thrombosis Hemostasis (Vienna, Austria), June 1973.

(3) Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.

(4) Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration on the Function of Human Platelets. Proceedings of the Society for Experimental Biology and Medicine, 146:96-98, 1974.

(5) Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.

(6) Corby, D.G., and Zuck, T.F.: Newborn Platelet Dysfunction: A Storage Pool and Release Defect. Thrombosis and Haemostasis, 36:200-207, 1976.

(7) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn, Thrombosis and Haemostasis (Stuttgart), 38:35, 1977 (Abstract).

(8) Corby, D.G., O'Barr, T.P.: Decrease in -Adrenergic Binding Sites in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Blood, 52:161, 1978.

(9) Corby, D.G.: Aspirin in Pregnancy: Maternal and Fetal Effects. Pediatrics, 62:930, 1978.

(10) Corby, D.G., O'Barr, T.P.: Decreased Alpha-Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine. Dev Pharmacol & Ther, 2:215-225, 1981.

(11) Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. Haemostasis, 10(4):177-232, 1981.

Publications for FY 82 Annual Progress Report (72/302) - continued

(12) Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book "Acquired Bleeding Disorders in Childhood". Masson Publ, pages 31-37, 1981.

(13) Corby, D.G., O'Barr, T.P., and Swanson, E.E.: Evidence for a Deficiency of Alpha-Granule Proteins in the Platelets of Newborn Infants. (Submitted for publication in Society for Pediatric Research)

Presentations:

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, California, February 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress, International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.

(3) Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infants, Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.

(4) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Presented: VIth International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.

(5) Corby, D.G. and O'Barr, T.P.: Decreased - Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VIIth Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **77/300** (3) Status: **Ongoing**

(4) Title: **Immunologic Disorders in Children and Adults: 1. Correlation of Immune Functions in the Immunodeficiency State. II. Correlation of Immune Functions of Leukemia and other Childhood Malignancies.**

(5) Start Date: **1 October 1977**	(6) Est Compl Date: **Open ended**
(7) Principal Investigator: **R. Stephen Whiteaker, CPT, MSC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/Immunology Sfc**	(10) Assoc Investigators: **Donald G. Corby, M.D., COL, MC**
(11) Key Words: **immunologic disorders**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **4/82** b. Review Results: **ongoing**

c. Number of Subjects Enrolled During Reporting Period: **153**

d. Total Number of Subjects Enrolled to Date: **577**

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **Existing specialized immuno-chemical procedures will be consolidated into a registered protocol for use, on a consultative basis, by the hospital staff.**

(16) Technical Approach: **A clinical laboratory immunology consultation service has been established. Main emphasis is performance and evaluation of specialized immuno-chemical tests, for training house-staff personnel and consultative support of hospital. The major areas of studies include humoral and cellular immunity and leukocyte function evaluation. Patients are selected on the basis of severity of recurrent infections, clinical immunodeficiency state, lack of response to medical management and availability of Department of Clinical Investigation for laboratory evaluations for patient care.**

(17) Progress: A total of 153 patients were evaluated on a consultative basis for immunologic disorders. During this period seven physician housestaff personnel were also trained in laboratory clinical immunology procedures. Patients Studied: 41 in the area of serum protein gammapathies, 50 in the area of cell-mediated function, and 62 in the area of combined humoral-cellular function. Subjects with indicated major findings were as follows: 1) Humoral immunologic disorders - serum protein profile evaluations: 11 cryoglobulinemias, 31 serum protein gammopathaies, 19 immunoglobulin disorders (heavy or light chain or benign spike), 4 hypogammaglobulinemias, 9 hypergammaglobulinemias, 3 complement abnormalities; 11) Cellular immunologic disorders - 97 lymphocyte transformations, of these 13,3, and 4 patients were recorded suppressed to PHA, PWM, and candida stimulations respectively, 104 T-lymphocyte enumerations with 7 patients recorded as low T-lymphocyte percentages, 58 B-lymphocyte enumerations with 0 patients recorded as abnormal, 23 NBT evaluations with 3 patients recorded as abnormal.

PUBLICATIONS: none

PRESENTATIONS:

1. Brown, George L. and Heggers, J.: Medical Mycology: Assessment of Bacteriologic and Seroligic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **78/303** (3) Status: **Terminate**

(4) Title: **Evaluation of Humic Substances as Potential Gastrointestinal Decontaminants in the Emergency Management of the Poisoned Patient.**

(5) Start Date: **1978**	(6) Est Compl Date: **1982**
(7) Principal Investigator: **Donald G. Corby, M.D.** **Colonel, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Clin. Investigation**	(10) Assoc Investigators: **T.P. O'Barr, Ph.D., DAC** **Walter J. Decker, Ph.D.** **Texas Medical Branch, Galveston** **R.L. Wershaw** **Ronald L. Malcolm**
(11) Key Words: **humic acid, gastrointestinal decontamination, poisons**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **12/81** b. Review Results: **Ongoing**
c. Number of Subjects Enrolled During Reporting Period: **NA**
d. Total Number of Subjects Enrolled to Date: **NA**
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **To prepare and evaluate in vitro the ability of humic substances to bind a large variety of potentially toxic drugs and household poisons.**

(16) Technical Approach: Humic acid will be extracted from highly organic soil from Florida through acid-base extractions and then lyophilized. After obtaining a low ash product in vitro studies will be performed to determine the relative complexing or adsorptive activities of these substances to amphetamine, primaquine, chlorpheniramine, colchicine, dephenylhydantoin, aspirin, probenecid, quinacrine, chlorpromazine, meprobamate, chloroquine, quinidine, quinine, ferrous sulfate, iodine phenal, methylsalilcylote, 2, 4-D(20%), malathion (50%), DDT, N-methyl carbamate, basic acid (3%), d-propoxyphene hydrochloride, mineral acids, sodium and potassium hydroxide, sodium metasilicate, and talbutanide.

CONTINUATION SHEET FOR FY 82 Annual Progress Report Proto No. 78/303

(17) Progress: Work on other higher priority protocols has precluded further work on this study during FY 1982. Although, the results thus far obtained do indicate that humic acid will bind Fe^{++} (600 ug Fe^{++}/mg Humic Acid). In vivo studies do not indiciate clinical effectivness. Recommend this study be terminated so that resources can be utilized in more promising gastrointestinal decontaminants.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **78/304** (3) Status: **Completed**

(4) Title: **Treatment of Iron-deficiency Anemia 1: Comparison of Hematologic Parameters following Treatment with Carbonyl Iron of Ferrous Sulfate in Wistar Rats.**

(5) Start Date: **1978**	(6) Est Compl Date: **1982**
(7) Principal Investigator: **Donald G. Corby, M.D. Colonel, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Clin. Investigation**	(10) Assoc Investigators: **Walter J. Decker, Ph.D. Texas Medical Branch, Galveston Lawrence E. Jones, DAC SFC Troy Engle**
(11) Key Words: **iron-deficiency anemia carbonyl iron, ferrous sulfate, hematocrit values**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To evaluate carbonyl iron in the treatment of experimentally induced iron deficiency in the rat.

(16) Technical Approach: This will be a comparative study of hematocrit values using an animal model. In addition, this study will evaluate CBC indices, serum iron, unsaturated iron-binding capacity, and stainable bone marrow iron. This experiment will be conducted in three phases in which the first two phases will be identical due to time, space, and personnel limitations to minimize temporal changes.

(17) Progress: Experimental phases of the study as outlined in the protocol have been completed. Despite several unexpected problems (inability to determine FEP and Ferritin), preliminary analysis of data indicates that carbonyl iron is absorbed from the GI tract and thus appears to be an effective hematinic agent at concentrations of 24 ppm Fe^{++}. Increases in

(17) Progress - continued

g% HgB/day were 0.090 and 0.081 (p=NS) for the $FeSO_4$ and carbonyl iron-treated rats. There was no evidence of either acute or chronic toxicity with carbonyl iron.

PUBLICATIONS and PRESENTATIONS: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 83u182)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/300 (3) Status: Ongoing

(4) Title: **A Study of the Hormone-dependent Growth of Human Mammary Tumors In Vitro**

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

(7) Principal Investigator:
John W. Harbell, Ph.D., CPT, MSC

(8) Facility: FAMC

(9) Dept/Svc: **DCI/SRL**

(10) Asso Investigators:
Donald B. Mercill, B.S., DAC
SP5 Norman R. Jones, B.S.

(11) Key Words:
breast tumors
organ culture

(12) Accumulative MEDCASE:*
*Refer to Unit Summary Sheet of this report.

(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA on patients in studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this section (14).)

(15) Study Objective: To examine the hormone requirements for the growth of human mammary tumors using explant organ culture.

(16) Technical Approach: Tissue samples are obtained from biopsy or mastectomy specimens. Each sample is cut into many small pieces and distributed, for culture, in a battery of hormone combinations. Replicate samples from each hormone combination are subjected to the appropriate radiolabelled precursor to determine DNA, RNA, and protein synthesis. Histology and macromolecular synthesis measure response.

(17) Progress: To date, over 50 samples of normal, hyperplastic and malignant human breast tissue have been studied. The interaction of insulin with ovarian and pituaitary hormones has been the major thrust thus far. As expected from rodent studies, normal human mammary epithelium required insulin to undergo maximum proliferation when stimulated by other mammatrophic hormones. However, even malignant epithelium which was apparently insensitive to the other mammatrophic hormones also showed a marked insulin dependence. Due to the small number of human carcinomas available, corollary experiments with rodent tissue were completed to characterize the biochemistry of this dependence. Normal, benign, and malignant murine mammary epithelia were studied.

(17) Progress: cont'd-

Each required insulin while only the normal and benign required ovarian and pituitary hormones. Assessment of DNA, RNA, and protein synthesis as well as glucose utilization demonstrated the DNA synthesis was the most sensitive to the insulin concentration with the other parameters markedly less so. Autoradiographs prepared from human tissue samples are being analyzed as work on other protocols permits.

PUBLICATIONS:

1. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Strain Mouse Mammary Tissues. In Vitro 16(3):247, 1980.

PRESENTATIONS:

1. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Mouse Mammary Tissues. Presented: 31st Annual Meeting, Tissue Culture Association, St. Louis, MO, June 4, 1980.

AD-A131 312 CLINICAL INVESTIGATION PROGRAM(U) FITZSIMONS ARMY MEDICAL CENTER AURORA CO D G CORBY 30 SEP 82 18

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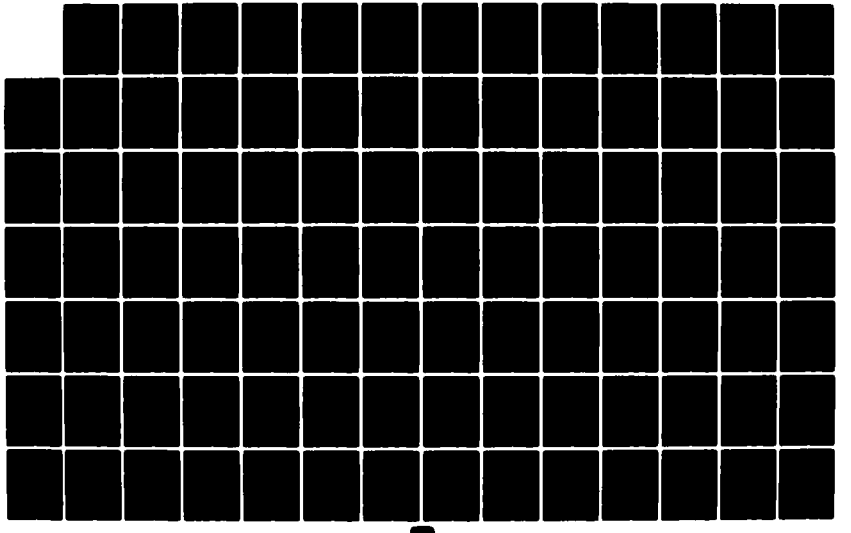

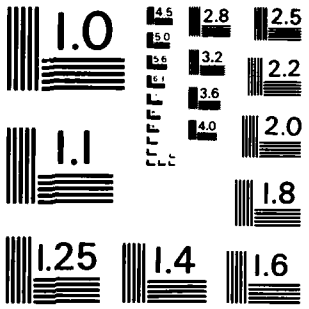

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(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/301 (3) Status: Ongoing

(4) Title: **Basic Studies to Hasten Recovery from or Help Prevent Bone Injury**

(5) Start Date: 1979	(6) Est Compl Date: October 1984
(7) Principal Investigator: **David T. Zolock, MAJ, MSC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/Biochemistry Svc**	(10) Assoc Investigators: **Daniel D. Bikle, M.D., Ph.D. Veterans Administration Med.Ctr. San Francisco, CA**
(11) Key Words: **vitamin D, calcium, bone, intestine, calcium binding protein**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To reduce the incidence of fracture wounds and to reduce the time involved to heal fracture wounds by increasing the absorption and retention of calcium and phosphorus through nutritional and medical therapeutic improvements.

(16) Technical Approach: Since bone mineralization is indirectly regulated by intestinal absorption, the bone as well as the intestinal responses to various therapeutic measure, will be studied. In general, the animal of choice will be chicks which will be fed a vitamin D deficient diet containing 0.43% phosphorus for approximately three weeks.

(17) Progress: Rachitic chickens (2 1/2 weeks old) were given various vitamin D metabolites in order to compare their mechanism of action on the transport of calcium across the intestine and on the uptake of calcium by the bone. Bone calcium uptakes for 1,24,25-trihydroxycholecalciferol (1,24,25-THCC) and 1,25,26-trihydroxycholecalciferol (1,25,26-THCC) were approximately 60% of the response by 1,25-dihydroxycholecalciferol (1,25-DHCC). Intestinal transports for the trihydroxymetabolites were approximately 50% of the response by 1,25-DHCC. The vitamin D dependent calcium binding protein (CaBP) synthesized by the

(17) Progress: cont'd

intestinal mucosa in response to 1,24,25-THCC and 1,25,26-THCC was less than 25% of the response with 1,25-DHCC. When these chicks were given cycloheximide, a protein synthesis inhibitor along with the different metabolites, the intestinal calcium transport was unaffected, but the bone calcium uptake was blocked. Since the stimulated intestinal calcium transport by the vitamin D metabolites does not require protein synthesis, the mechanism of action of the metabolites on the epithelial cell probably is a direct one. A possible mechanism would be the alteration of the membrane structure in the brush border directly by the vitamin D metabolite. Bone calcium uptake does depend on protein synthesis for all three of the vitamin D metabolites. When all the results are compared, 1,25-DHCC is the most active metabolite of the three tested in both the intestine and the bone. Although the results are not significant in all cases, 1,24,25-THCC appeared to be more active in the intestine than 1,25,26-THCC and 1,25,26-THCC appeared to be more active in the bone than 1,24,25-THCC. These results indicate a mechanism of action similar for all three vitamin D metabolites, a mechanism of action which is different for the intestine and the bone, and two different receptor mechanisms with different metabolite specificities for intestinal calcium transport and for CaBP synthesis.

In order to determine if 1,25-DHCC has an effect on the distribution and excretion of calcium in the body, a dose of ^{45}Ca was administered i.v. to rachitic chicks and rachitic chicks receiving a dose of 1,25-DHCC 24 hours before. Serum calcium for the rachitic and 1,25-DHCC treated chicks were 6 and 8 mg/dL, respectively. No significant difference was found between the two groups of chicken in serum ^{45}Ca or bone ^{45}Ca uptake. However, the 1,25-DHCC treated chicks had lower intestinal mucosal accumulation of ^{45}Ca and higher ^{45}Ca content in luminal fluid as compared to the rachitic chicks. These results suggest that 1,25-DHCC not only has an effect on the brush border membrane, but also on the basolateral membrane of the epithelial cell. These results also support our theory that CaBP is necessary for maintaining a low cellular concentration of calcium in the intestinal cell.

PUBLICATIONS:

1. Zolock, David T., Morrissey, Robert L., and Bikle, Daniel D.: Meaning of Non-parallel $1,25(OH)_2D_3$ Mediated Response Relationships in Intestine and Bone to Dose and Time in Vitamin D; Biochemical, Chemical and Clinical Aspects Related to Calcium Metabolism. Walter DeGruter, Inc., New York, 1979.

2. Bikle, Daniel D., Morrissey, Robert L., Zolock, David T. and Herman, R.H.: Stimulation of Chick Gut Alkaline Phosphatase Activity by Actinomycin D and 1,25-dihyroxyvitamin D_3: Evidence for Independent Mechanisms. J Lab Clin Med 94:88-94, 1979.

3. Bikle, Daniel D., Morrissey, Robert L., and Zolock, David T.: The Mechanism of Action of Vitamin D in the Intestine. Am J Clin Nutr 23:2322-2338, 1979.

4. Morrissey, Robert L., Zolock, David T., Mellick, P.W. and Bikle, Daniel D.: Influence of Cycloheximide and 1,24-dihydroxyvitamin D_3 on Mitochondrial and Vesicle Mineralization in the Intestine. Cell Calcium 1:69-79, 1980.

5. Bikle, Daniel D., Askew, E.W., Zolock, David T., Morrissey, Robert L. and Herman R.H.: Calcium Accumulation by Chick Intestinal Mitochondria: Regulation by Vitamin D_3 and 1,25-dihydroxyvitamin D_3. Biochem Pharmacol 89"63-142, 1981.

6. Bikle, Daniel D., Empson, R.N., Morrissey, Robert L., Zolock, David T., Bucci, T.J., Herman, R.H. and Pechet, M.M.: Effect of 1 alpha-hydroxyvitamin D_3 on the Rachitic Chick Intestines: A Comparison to the Effects of 1,12-dihyroxyvitamin D_3. Cal Tiss Int 32:9-17, 1980.

7. Bikle, Daniel D., Morrissey, Robert L., Zolock, David T. and Rasmussen, H.: The Intestinal Response to Vitamin D. Rev Physiol Biochem Pharmacol 89:63-142, 1981.

8. Bikle, Daniel D., Zolock, David T. and Morrissey, Robert L.: Action of Vitamin D on Intestinal Calcium Transport. Annals NY Academy of Sciences 372:481-501, 1981.

9. Charles, M.A., Tirunagura, P., Zolock, David T. and Morrissey, Robert L.: Duodenal Calcium Transport and Calcium Binding Protein Levels in Experimental Diabetes Mellitus. Mineral Electrolyte Metab 5:15-22,1981.

10. Bikle, Daniel D., Peck, C.C., Holford, N.H.S., Zolock, David T. and Morrissey, Robert L.: Pharmacokinetics and Pharmacodynamics of 1,25-dihyroxyvitamin D_3 in the Chick. Endocrin 111:939-946, 1982.

PRESENTATIONS:

1. Zolock, David T., Morrissey, Robert L. and Bikle, Daniel D.: Meaning of Non-parallel 1,25$(OH)_2$ D_3 Mediated Response Relationships in Intestine and Bone to Dose and Time. Presented: Proceedings of the Fourth Workshop on Vitamin D, Berlin (West) Germany, February 1979.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/302 (3) Status: Ongoing

(4) Title: **Rapid Detection of Bacterial Antigens in Patient Specimens Using Counterimmunoelectrophoresis (CIE)**

(5) Start Date: 1 January 1981	(6) Est Compl Date: 1 June 1983
(7) Principal Investigator: **Pari L. Morse, DAC**	(8) Facility: FAMC
(9) Dept/Svc: DCI/Microbiology Svc	(10) Assoc Investigators: **Donald D. Paine, DAC** **Paul G. Engelkirk, LTC, MSC**
(11) Key Words: **Bacterial antigens** **Counterimmunoelectrophoresis**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To develop laboratory procedures using CIE which will detect bacterial antigens in patients specimens within a few hours of receipt.

(16) Technical Approach: Using commerical antisera and published methodologies, we developed the capability of performing CIE procedures for the detection of bacterial antigens in clinical specimens. We then evaluated these procedures as a rapid adjunct to the bacteriological procedures currently being used by the FAMC clinical Microbiology Laboratory for the diagnosis of bacterial diseases.

(17) Progress: From 1 Sep 1981 to 1 Sep 1982, 191 specimens from 177 patients have been studied under this protocol. Twelve specimens from 12 patients have been positive for H. influenzae type b. We did not detect antigen to Group B Streptococcus or S. pneumoniae from any of these specimens. We did not experience any false positives during (cont'd)

(17) Progress: (cont'd)

this year's study specimens. CIE results are difficult to correlate with routine culture results from the FAMC clinical microbiology laboratory because dual specimens were rarely submitted. This year, performance of CIE results at FAMC has saved the Department of Pathology approximately $5600.00. DCI personnel are currently training Department of Pathology personnel in the CIE procedures. It is planned that Department of Pathology personnel will be able to assume the CIE testing in the near future. Several new studies utilizing CIE to detect antigen to various organisms (including L. pneumophilia, Mycoplasma and Giardia) are under consideration.

PUBLICATIONS and PRESENTATIONS: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **80/303** (3) Status: **Ongoing**

(4) Title: **Study of Sensitivity of Tumors to Chemotherapy**

(5) Start Date: **December 1980**	(6) Est Compl Date: **Indefinite**
(7) Principal Investigator: **John W. Harbell, Ph.D.,CPT,MSC** **Arlene J. Zaloznik, M.D.,MAJ,MC** **Nicholas J. DiBella, M.D.,COL,MC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/SRL**	(10) Assoc Investigators: **Donald B. Mercill, B.S., DAC** **SP5 Norman R. Jones**
(11) Key Words: **chemotherapy** **in vitro, in vivo** **tumor cell**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **1/82** b. Review Results: **Ongoing**

c. Number of Subjects Enrolled During Reporting Period: **NA**

d. Total Number of Subjects Enrolled to Date: **NA**

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **a) To perform in vitro chemotherapeutic sensitivity testing using tumor cell systems. b) To correlate in vitro chemotherapeutic sensitivity testing results with in vivo chemotherapeutic responses. c) To provide better patient care, i.e., better tumor cell kill, by using in vitro chemotherapeutic sensitivity testing.**

(16) Technical Approach: Human tumor cell lines are established in monolayer culture. After purification and cell type varification, replicate cultures are subjected to physiological concentrations of chemotherapeutic agents. Efficacy is determined through measurement of macromolecular snythesis labeling index and cell loss. Correlations between in vitro parameters and patient responses are then established.

(17) Progress: To date, 600 primary cultures from over 140 samples have been processed. Retrospective comparison of in vivo and in vitro responses have been encouraging though firm statistical correlation will require more samples from tumors which respond to chemotherapy. Over 600 cell lines have been produced. Adjunct subprojects using the cell lines and assay system have been completed and presented at national meetings.

PUBLICATIONS:

1. Moore, G.E., Harbell, J.W., Woods, L.K., Morgan, R.T., and Semple, T.U.: RPMI 8226, a Human Myeloma Cell Line: an Update. (Abst) Proceedings of the American Association for Cancer Research 23:33, 1982.

2. Harbell, J.W. and DiBella, N.J.: Studies on the Interaction of Tetrahydrocannabinol (THC) with Chemotherapeutic Agents Against Human Tumors In Vitro. (Abst) Proceedings of the American Association for Cancer Research 23:226, 1982.

3. Harbell, J.W., Mercill, D.B., Jones, N.R. and Woods, L.K.: Establishment of a Human Leiomyosarcoma Cell Line. (Abst) In Vitro 18(3):295, 1982.

PRESENTATIONS:

1. Mercill, D.B., Jones, N.R., and Harbell, J.W.: Distilled Water Lavage to Kill Human Tumor Cells: an In Vitro Evaluation of a Traditional Surgical Technique. Presented: Society of Armed Forces Medical Laboratory Scientists Tri-services Annual Meeting, Reno, Nevada, March 1982.

2. Harbell, J.W. and DiBella, N.J.: Studies of the Interaction of Tetrahydrocannabinol (THC) with Chemotherapeutic Agents Against Human Tumors In Vitro. Presented: American Association for Cancer Research, St. Louis, MO, May 1982.

3. Moore, G.E., Harbell, J.W., Woods, L.K., Morgan R.T., and Semple, T.U.: RPMI 8226, a Human Myeloma Cell Line: an Update. Presented: American Association for Cancer Research, St. Louis, MO, April 1982.

4. Harbell, J.W., Mercill, D.B., Jones, N.R., and Woods, L.K.: Establishment of a Human Leiomyosarcoma Cell Line. Presented: Tissue Culture Association, San Diego, CA, June 1982.

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/300 (3) Status: Terminated

(4) Title: **Rapid Detection of Clostridial Toxins Using Counterimmuno-electrophoresis (CIE).**

(5) Start Date: 1 March 1981	(6) Est Compl Date: March 1982
(7) Principal Investigator: **Pari L. Morse, DAC** **T.J. Fritz**	(8) Facility: FAMC
(9) Dept/Svc: DCI/Pathology	(10) Assoc Investigators: **Paul G. Engelkirk, LTC, MSC** **Dick J. Wuerz, DAC** **Donald D. Paine, DAC**
(11) Key Words: **Clostridial Toxins** **Counterimmunoelectrophoresis**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To develop laboratory procedures using CIE to detect the presence of toxins produced in growing cultures of clostridial organisms. This technique could later be developed to detect toxins in patient specimens, such as serum and feces, and in food items.

(16) Technical Approach: Procedures developed for detecting bacterial antigens using CIE were adapted for detecting clostridial toxins. It was found that changes in buffer molarity and pH and electrophoretic time were necessary. ATCC cultures of C. difficile, C. tetani and C. botulinum were grown, and cell-free culture filtrates containing toxin were purified for use as antigen. Commercially prepared anti-toxins were used as antibody.

(17) Progress: Three patient specimens were tested using the procedures developed last year for detecting clostridial toxins. One patient was positive for C. difficile toxin in the stool. This procedure has been eliminated, as it was found that the commerically purchased antisera to C. difficile toxin was not specific; it detected both antigens of the

(17) Progress: cont'd

organism and the toxin as well as C. sordelli antigens and toxin. It was recommended that physicians requiring detection of C. difficile toxin submit the patient specimens for cytotoxicity assay at another hospital. Due to nonavailability of patient specimens, this protocol has been terminated.

PUBLICATIONS AND PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
"ISPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-301 (3) Status: Terminated

(4) Title: Field trial of a transport medium for clinical specimens being sent to reference laboratories for processing for mycobacteria.

(5) Start Date: March 1981	(6) Est Compl Date: September 1982
(7) Principal Investigator: M.V. ROTHLAUF S. HAYNE M. CHO	(8) Facility: FAMC
(9) Dept/Svc: DCI/MICRO	(10) Assoc Investigators: P.G. Engelkirk J.K. McClatchy
(11) Key Words: Mycobacteria Transport medium Holding medium	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 3/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To develop and evaluate the use of a transport medium for clinical specimens being sent to reference laboratories for isolation of mycobacteria.

(16) Technical Approach: The initial phase of this investigation involved a controlled study of the holding medium using specimens from known positive patients (the specimens were kindly furnished by National Jewish Hospital-National Asthma Center). The second phase was a field trial of the holding medium involving specimens submitted to FAMC by Munson and Irwin Army Hospitals.

(17) Progess: Valid comparisons of contamination rates can be made on 172 of the specimens received from the cooperating facilities since the beginning of this project. Comparison of the holding medium portion of these specimens with the untreated portion revealed some difference between the results on 7H11 but no difference for S7H11. Since all the contamination rates are higher than those for FAMC specimens, it appears that addition of holding medium to the mailed specimens does not reduce contamination. This protocol has been terminated.

PUBLICATIONS AND PRE"NTATIONS: NONE

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/302 (3) Status: Ongoing

(4) Title: **Induction of Cerebellar Hypoplasia in Pups by Intra-uterine Inoculation of Canine Parvovirus.**

(5) Start Date: **15 Sep 82**	(6) Est Compl Date: **Sep 82**
(7) Principal Investigator: **Cheryl K. Smith, D.V.M.,CPT,VC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/SRLS**	(10) Assoc Investigators: **John W. Harbell, Ph.D.,CPT,MSC** **SP5 Leslie C. Kramer**
(11) Key Words: **canine parvovirus** **cerebellar hypoplasia**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **6/82** b. Review Results: **ongoing**

c. Number of Subjects Enrolled During Reporting Period: **NA**

d. Total Number of Subjects Enrolled to Date: **NA**

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **To determine if canine parvovirus will induce cerebellar hypoplasia in puppies as the feline parvovirus does in kittens.**

(16) Technical Approach: Puppies will be taken from the bitches at birth to prevent ingestion of colostrum and fed a commercially available puppy formula. The pups will be divided into four groups. One group of pups will be injected with 0.5 ml of virus preparation intraperitoneally and one group will be injected intracerebrally. Control pups will be inoculated with 0.5 ml of saline eithe. 1P or 1C. Pups will then be euthanized at three weeks of age with an overdose of halothane anesthesia. Tissues will be taken for histopathologic examination to a veterinary pathologist.

17. Progress: One litter of puppies were inoculated intracerebrally with virus preparation. Control pups were injected IC with saline. The pups were sacrificed at 4 weeks of age and their brains were examined histologically by a neuropathologist. Significant pathology was noted in the cerebellums of virus-infected pups and no changes were found in the controls. Experiments on a second group of puppies has been performed and results from the pathologist are forthcoming.

PUBLICATIONS and PRESENTATIONS: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/303 (3) Status: Ongoing

(4) Title: **Use of Urinary Counterimmunoelectrophoresis (CIE) to Detect Occult Bacteremia in Young Children.**

(5) Start Date: 1 November 1981	(6) Est Compl Date: December 1983
(7) Principal Investigator: **Pari L. Morse, DAC** **L. Graham**	(8) Facility: FAMC
(9) Dept/Svc: DCI/Pediatrics	(10) Assoc Investigators: **E.N. Squire** **Paul G. Engelkirk, LTC, MSC** **B.J. Anders** **D. Moffitt**
(11) Key Words: **Bacteremia** **Counterimmunoelectrophoresis**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To evaluate the sensitivity of CIE for early detection of bacteremia among young children with high fever but no obvious etiology or treatable focus of infection, so that patients needing antibiotics and closest attention may be rapidly identified.

(16) Technical Approach: To utilize previously reported and standardized CIE procedures.

(17) Progress: To date, 5 patients have been studied with two patients being positive for H. influenzae type b. One of the positive patients was identified by CIE 24 hours before normal culture results were available. Future testing of patients is planned. The small number of patients to date is due primarily to a change in principal investigator, necessitated by the fact that the original PI (Dr. Squire) initiated an Allergy Residency during the past year.

Publications and Presentations: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/304 (3) Status: Ongoing

(4) Title: Electron Microscopic Observations of the In Vitro Interacting Between Giardia lamblia Trophozoites and Peripheral and Peritoneal Cells of Rabbits.

(5) Start Date: 2 February 1982	(6) Est Compl Date: 2 February 1984
(7) Principal Investigator: Paul G. Engelkirk, LTC, MSC	(8) Facility: FAMC
(9) Dept/Svc: DCI/Microbiology Svc	(10) Assoc Investigators: Mary V. Rothlauf, DAC Donald D. Paine, DAC
(11) Key Words: Giardia lamblia in vitro	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: a) To determine the effects of anti-Giardia antibodies, complement, and sensitized host cells on the phagocytosis and destruction of Giardia lamblia trophozoites in vitro.

b) To determine the time frame in which rabbit phagocytic cells attach to and phagocytose live Giardia trophozoites in vitro.

c) To determine the host cell types that play a role in the phagocytosis of Giardia trophozoites in vitro.

(16) Technical Approach: Giardia lamblia trophozoites will be incubated with various combinations of host cells, anti-Giardia antibodies, and complement. Light microscopic, transmission electron microscopic, and scanning electron microscopic observations will be made to determine the type and extent of host cell/parasite interaction under the various experimental conditions.

(17) Progress: Three experiments have been conducted to date:

Expt #1 - Used rabbits from protocol #81/101; peritoneal cells v.s. trophozoites; TEM; observations awaiting EM technician availability.

Expt #2 - Used rabbits from protocol #81/101; peripheral leukocytes v.s. trophozoites; TEM observations awaiting EM technician availability.

Expt #3 - Used rats; peritoneal cells v.s. trophozoites; TEM and light microscopy observations in progress; SEM observations in progress at CDC.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **81/305** (3) Status: **Ongoing**

(4) Title: **Development of a Standardized Method for Minimum Inhibitory Concentration (MIC) Antibiotic Testing of Alpha-hemolytic Streptococci.**

(5) Start Date: **1 March 1982**	(6) Est Compl Date: **1 March 1983**
(7) Principal Investigator: **Pari L. Morse, DAC** **Clifford Butler, DAC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/Microbiology Svc**	(10) Assoc Investigators: **Paul G. Engelkirk, LTC, MSC** **Robert E. Holcomb, LTC, MSC**
(11) Key Words: **MIC** **alpha-hemolytic streptococci**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **NA** b. Review Results: **NA**

c. Number of Subjects Enrolled During Reporting Period: **NA**

d. Total Number of Subjects Enrolled to Date: **NA**

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **To develop a standardized, acceptable method for determining the MIC of alpha-hemolytic streptococci to antibiotics.**

(16) Technical Approach: This study was designed with 4 phases: 1) development of a modified MIC procedure for alpha-hemolytic streptococci, 2) testing of the modification on standard ATCC control organisms, 3) testing of 100+ alpha-hemolytic streptococci from routine cultures, and 4) further modification for "rough" forms of alpha-hemolytic streptococci.

(17) Progress: Phase 1 has been completed. Phases 2 and 3 are currently under study. Six sets of six ATCC control organisms have been tested with good reproducibility using both the modification and the standard MIC technique. Forty-six clinical isolates of alpha-hemolytic streptococci

(17) Progress: cont'd

have been tested with the modification. Twenty (43%) of the streptococci have failed to grow on the standard MIC technique, whereas only 4 (9%) failed to grow with the modification of the MIC technique.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **81/306** (3) Status: **Ongoing**

(4) Title: **Histopathologic and Electron Microscopic Observations of the In Vivo Interactions Between Giardia lamblia trophozoites and the Small Intestinal Mucosa of a Variety of Small Laboratory Animals.**

(5) Start Date: **2 February 1982**	(6) Est Compl Date: **2 February 1984**
(7) Principal Investigator: **Joseph P. Johns, CPT, MC** **Paul G. Engelkirk, LTC, MSC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI & Dept of Medicine**	(10) Assoc Investigators: **Cheryl K. Smith, CPT, VC** **Mary V. Rothaluf, DAC**
(11) Key Words: **Giardia lamblia** **in vivo interaction**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **NA** b. Review Results: **NA**

c. Number of Subjects Enrolled During Reporting Period: **NA**

d. Total Number of Subjects Enrolled to Date: **NA**

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: a. To determine whether the laboratory cultivated strain of Giardia lamblia being used in approved protocol #81/101 is capable of colonizing the small intestine of a variety of small laboratory animals (mice, rats, guinea pigs, perhaps kittens).

b. To determine which of the small laboratory animals would be suitable as an animal model for this laboratory cultivated strain of G. lamblia.

c. To determine the amount of time required for adherence of the Giardia trophozoites to the intestinal mucosa of these laboratory animals.

d. To make light and electron microscopic observations of the in vivo interactions between G. lamblia trophozoites and intestinal defensive cells; to determine the types of cells involved in these interactions and their chronological sequence of appearance.

e. To work out the methodology for future ligated intestinal loop experiments involving animals which have been artificially immunized with G. lamblia antigen or which have recovered from G. lamblia infection.

(16) Technical Approach: Giardia lamblia trophozoites will be inoculated into ligated small intestinal loops of live small laboratory animals. After varying periods of time, sections of small intestinal mucosa will be examined by light and transmission electron microscopy to determine the degree of trophozoite colonization, and the type and extent of host cell/parasite interaction.

(17) Progress: To date, four experiments have been conducted:

Expt #1 - 4 Jan 82 - one rat - ligated loops
Expt #2 - 21 Jan 82 - two rats - one had a Roux-en-Y; one had ligated loops
Expt #3 - 28 Jan 82 - two guinea pigs - one had a Roux-en-Y; one had ligated loops
Expt #4 - 1 Feb 82 - one rat and one guinea pig - each had a Roux-en-Y

Little interaction has occurred between the inoculated trophozoites and the small intestinal mucosa, which may reflect 1) the inability of our laboratory strain to colonize, 2) use of unsuitable animal models, 3) unsuitable in vivo conditions, or other factors.

This protocol may be terminated if a suitable replacement cannot be found for Dr. Johns, who has been reassigned to Germany.

PUBLICATIONS and PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/300 (3) Status: ongoing

(4) Title: Studies of Immunologically Mediated Thrombocytopenia

(5) Start Date: May 1982	(6) Est Compl Date: April 1984
(7) Principal Investigator: R. Stephen Whiteaker, Ph.D. CPT, MSC	(8) Facility: FAMC
(9) Dept/Svc: Clin Investi/Immunol	(10) Assoc Investigators: Donald G. Corby, M.D., COL, MC Chief, Dept of Clin Investigation Jean E. Howard, M.D., MAJ, MC FAMC
(11) Key Words: thrombocytopenia antiplatelet antibody, immune complexes	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: N/A

c. Number of Subjects Enrolled During Reporting Period: 17

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.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To develop an assay to differentiate anti-platelet thrombocytopenia from "innocent bystander" thrombocytopenia.

(16) Technical Approach:

Patient serum is mixed with pooled type O platelets and platelet adsorbable IgG is detected and quantitated using an anti-IgG ELISA procedure.

(17) Progess:

An enzyme-linked immunosorbent assay (ELISA) has been developed to detect platelet adsorbable IgG. This procedure will detect as little as 4 ug/ml of aggregated IgG in the absence of complement. Complement has been shown to significantly reduce the binding of aggregated IgG to platelets. Studies are presently underway to determine the amount of platelet bindable IgG in normal sera and the best method to differentiate anti-platelet antibody from platelet adsorbable immune complexes.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/301 (3) Status: ongoing

(4) Title:

The Antigenic Evaluation of Axenically-Cultivated Giardia lamblia.

(5) Start Date: 1 July 82	(6) Est Compl Date: 30 January 84
(7) Principal Investigator: Vic Feuerstein Mary Rothlauf	(8) Facility: FAMC
(9) Dept/Svc: DCI, Immunology Svc.	(10) Assoc Investigators: R.S. Whiteaker, Ph.D.,CPT, MSC. P.G. Engelkirk, Ph.D.,LTC, MSC. T.B. Brewer,M.D., MAJ, MC. J.E. Lima, Supervisor,Imm. Svc. D. Paine, Supervisor,Micro. Svc.
(11) Key Words: Immunology, Giardiasis, Antigenic, cyst, trophozoite.	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* $2564.84

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 1 July 82 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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To ellucidate and immunologically characterize the antigenic make-up of the trophozoites of axenically-cultivated Portland strain Giardia lamblia.

(16) Technical Approach:

To ellucidate and characterize the antigenic make-up of Giardia lamblia utilizing current and state of the art immunological techniques including: chromatographic chromatofocusing, immunodiffusion, isoelectric focusing, electrophoresis, immunoelectrophoresis, lymphocyte blastogensis and centrifugation.

(17) Progess:

Preliminary experiments utilizing chromatofocusing, centrifugation, lymphocyte blastogenesis, immunodiffusion, electrophoresis, immuno-electrophoresis and isoelectric focusing have been conducted and have established the basic parameters for continuing experiments.

PROGRESS REPORT RESEARCH PROTOCOL 82/301 1 June to 1 October 1982

Principal Investigator V. Feuerstein Immunology Svc, DCI.

Initial experiments designed to evaluate the antigenic make-up of Giardia lamblia have concentrated on three areas of research:

1) Separation by chromatographic procedures the proteins present in sonicated and non-ionic detergent lysed trophozoites of axenically cultured Portland strain organisms, based upon isoelectric potential point.

   Accomplishments 1 June to 1 October 1982:
   Chromatofocusing gels have been acquired, chromatographic columns established, basic parameters defined and utilized to evaluate sonicated preparations. No fewer than 14 proteins have been separated. Continuing efforts are being directed towards refinement of techniques and the accumulation of sufficient quantities to enable immunologic evaluation of individual proteins.

2) Isoelectric electrophoretic procedures designed to separate proteins present in sonicated trophozoite preparations of axenically cultured Portland strain organisms, based upon isoelectric potential point in polyacrylamide gels.

   Accomplishments 1 June to 1 October 1982:
   The parameters for wide-range isoelectric focusing of sonicate preparations have been identified and conducted. An excess of 20 individual proteins have been observed. In addition, more sensitive staining procedures are being pursued to ellucidate very dilute proteins.

3) Evaluation of lymphocytes in culture, initially recovered from rabbits vaccinated with sonicated trophozoite preparations and from humans to establish parameters for future evaluations.

   Accomplishments 1 June to 1 October 1982:
   Basic lymphocyte transformation parameters have been identified and initial runs conducted on rabbits vaccinated with trophozoite preparations demonstrate there may be a potential reaction taking place. Lymphocyte transformations conducted on human lymphocytes also show the potential for a reaction to sonicated trophozoite preparations. Continuing efforts are being made to refine techniques in preparation for potential future immunodiagnostic applications.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 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: 1 July 1982	(6) Est Compl Date: None
(7) Principal Investigator: **Pari L. Morse, DAC** **Clifford Butler, DAC**	(8) Facility: FAMC
(9) Dept/Svc: DCI/Dept of Pathology	(10) Assoc Investigators: **Robert E. Holcomb, LTC, MSC** **Paul G. Engelkirk, LTC, MSC** **J.T. Stocker, LTC, MC**
(11) Key Words: **Diagnostic microbiology** **Microbiological products**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **To evaluate recently introduced products which are of interest to the Microbiology Section, Department of Pathology, FAMC, but which cannot adequately be evaluated within that 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: Several new products are being considered for study, including the Dupont Isolator Blood Culture System and Wellcogen Strep B for rapid diagnosis of Group B Streptococcus on the newborn ward.

Publications and Presentations: none

DEPARTMENT OF CLINICAL INVESTIGATION

Surgical Research Laboratories Service

Training Support Summary

During the year, 130 students received training in suturing techniques. Eight-seven were students in the practical nurse (91C) course; twenty were FAMC Emergency Treatment Service personnel; eleven were third and fourth year medical students from the University of Colorado; four were Naval Reservists from Navy Reserve Surgical Team 218, Denver Federal Center; three were assigned to General Surgery Service, FAMC; three from the Aurora Public Schools Technical Center; and one each from Surgical Research Laboratories Service and the 328th Med Det (USAR). Training consisted of a slide seminar and movie, introduction to the operating room, including aseptic technique, scrub, gowning and gloving, and hands-on experience in the dry and wet labs. Training was conducted on 29 days, using 30 dogs, and required 354 hours of training support by Surgical Research Labs personnel.

The Department of Pedicatrics trained ten nurses and medical students in the placement of endotracheal and chest tubes, using five cats in two visits of approximately three hours duration each. Fifteen hours was required of Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring and maintenance.

Fifty sessions of microsurgical training were conducted, including twenty-four visits by Neurosurgery Service, using twelve rabbits, and training four surgeons; eighteen visits by Orthopedic Surgery Service, using nine rabbits, and training five surgeons; seven visits by Gynecology Service, using four rabbits, and training five surgeons; and one visit by Plastic Surgery Service, using one rabbit and training two surgeons. Anesthesia, surgical preps and maintenance required two hundred and fifty hours of support by personnel from Surgical Research Labs. Approximately one hundred seventy-five hours of training was received, in all.

General Surgery Service, Department of Surgery, used two dogs to train eleven surgeons in the use of staple guns. Thirty-three hours of training was received, requiring sixteen hours of support by Surgical Research Labs personnel for pre-operative anesthetic induction, surgical preps, anesthesia monitoring, circulating, and clean-up.

One feasibility study was conducted, using one dog, in an effort to develop an animal model for the study of reactive hypoglycemia, and involved four physicians from the Endocrinology Service, Department of Medicine. Two Surgical Research Labs personnel spent forty-two hours in pre-operative anesthetic induction, surgical prep, surgical assistance, and postoperative follow-up which included several glucose tolerance tests.

Cost of Training

Suturing Techniques:	$ 105/animal	x	30 animals	=	$3,150
Pediatrics:	20/animal	x	5 cats	=	100
Rabbit Microsurgery:	90/session	x	50 sessions	=	4,500
Staple Gun Exercises:	90/animal	x	2 animals	=	180
Hypoglycemia:	225/animal	x	1 animal	=	225
					$8,155

Under a Memorandum of Agreement, three high school seniors from Aurora Public Schools Technical Center received on-the-job vocational training, two as veterinary aides and one as a laboratory aide. A total of 515 hours of training was received, requiring 775 hours of instruction and supervision by personnel of Surgical Research Labs.

OB-GYN

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/350 (3) Status: ongoing

(4) Title: GOG protocol, a collective and collaborative study on the management of gynecological malignancies. (See attached list for corrections.)

(5) Start Date: August 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Francis J. Major, M.D.	(8) Facility: FAMC
(9) Dept/Svc: OB-GYN	(10) Assoc Investigators: George L. Phillips, JR, M.D., LTC, MC Jay M. Hill, M.D., COL, MC
(11) Key Words: Treatment study of gynecological malignancies	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: OCT 81 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: This clinical investigation is to participate in approved protocols of the GYN-Oncology Group in the study of gynecological malignancies. The studies which the group engages in are primarily Phase III studies comparing a proven method of primary or adjuvant treatment with a newer method of treatment in an attempt to improve response and survival in patients with gynecologic malignancies. Phase II studies are also conducted imploring experimental drugs. Entry of patients on Phase II study is permissible only when conventional methods of therapy or Phase III study treatments have failed to show an improvement in the patients condition.

(16) Technical Approach: It is proposed patients be entered on approved studies (see attached appendices) for which they are eligible, following the patients' signatures being obtained on a form consent. Each protocol permits the removal of the patient from the study should there be progression of the disease or should serious adverse effects occur. The study portion involves a combination of various approved drugs and/or adjuvant therapy with radiation or chemotherapy to standard surgical procedures. Any radiation therapy employed in these protocols is a standard accepted dose and field treatment and has received prior approval of the National Cancer Institute before incorporation in a study protocol. The data collection, patient counselling and chemotherapy instruction and administration is performed by Lynn Filip, RN, Oncology Nurse Specialist, credentialed at FAMC and supplied at no cost by the GOG Office. It is anticipated that between 30 and 40 patients per year will be entered from FAMC on these protocols. There will be no financial impact on FAMC as all experimental drugs will be furnished free of charge and maintained in the FAMC Pharmacy by the Oncology Pharmacist. Patients with gynecologic malignancies eligible for protocol will be receiving the newest, most advanced treatment which is currently available.

CONTINUATION SHEET, FY 82 ANNUAL PROGRESS REPORT PROTOCOL NO: 80/350

(17) *Progress:
The GOG has recently received approval for continuation of its clinical studies through 1984. This approval was granted by the National Cancer Advisory Board and it is planned to continue these studies as long as the GOG is functional. It should be noted that different protocols require different periods of time to complete and the completion date is based, not on the availability of patients at Fitzsimons Army Medical Center, but the availability of patients throughout the entire GOG which consists of 20 member institutions throughout the United States. As protocols are closed to study the Department of Clinical Investigation will be immediately notified of the termination of a study and as new protocols are activated they will be submitted in advance to the Department of Clinical Investigation for review by the Human Use Committee at FAMC. (Please review the attached collective listing of protocols as to the ones closed and the ones ongoing. It will be noted that Protocol Nos 24, 25, 42, 43 and 47 have been closed. Protocols activated this period are 26N, 52, 54, 56, 57, 58, 59 and 60. It should also be noted that the address for the control of the study in Colorado has been changed to: Colorado Foundation for Medical Care, Denver General Hospital, Box 0661, West 8th and Bannock, Denver, Colorado 80204.)

PUBLICATIONS and PRESENTATIONS: None.

Originally 16 GOG Studies (Simsen) OB-GYN

Dr. Frank Major, MD, UCMC, Consultant, OB-GYN, Colo Regional Cancer center, Inc, 234 Columbine St, Suite 200, Denver, CO 80206 TP (303) 320-5921; address since changed to Colorado Foundation for Medical Care, Denver General Hospital, Box 0661, West 8th and Bannock, Denver, Colorado 80204; phone (303) 592-1271. FAMC PI: Donald A. Simsen, COL, MC, OB-GYN, since trf to LAMC. New PI for FAMC: LTC George L. Phillips, JR, MD, MC (Jay M. Hill, MD, COL, MC, Chief, OB-GYN Dept).

First No. shown below is FAMC sub-series: B(C)64#5 - : followed by GOG Protocol No. All studies are shown in brief title only:

(1) 24 Treatment of Women With Cervical Cancer, Stage IIB, IIIB, IVA
(2) 25 A Randomized Comparison of Melphalan Alone (NSC #8806)
(3) 26 SECTION A: Master Protocol for Phase II Drug Studies
SECTION I: A Phase II Trial of AMSA (NSC 249,992)
SECTION C: A Phase II Trial of "CIS-PLATINUM" (NSC 119875)
SECTION L: A Phase II Trial of Tamoxifen (NSC #180973)
(4) 33 A Clinical-Pathologic Study of Stage I and II Carcinoma
(5) 34 A Randomized Study of Adriamycin as an Adjuvant
(6) 40 A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas
(7) 41 Surgical Staging of Ovarian Carcinoma
(8) 42 Treatment of Recurrent or Advanced Uterine Sarcoma
(9) 43 A Randomized Comparison of CIS-Platinum (NSC 119875)
(10) 44 Evaluation of Adjuvant Vincristine (NSC #76575)
(11) 45 Evaluation of Vinblastine (NSC #049842), Bleomycin (NSC #125066)
(12) 47 A Phase III Randomized Study of Adriamycin (NSC #123127)
(13) 48 A Study of Progestin Therapy and a Randomized Comparison
(14) 49 A Surgical-Pathologic Study of Women with Invasive Carcinoma
(15) 7601 Ovarian Cancer Study Group Protocol for Selected Stage I-A_1
(16) 7602 Ovarian Cancer Study Group Protocol for All Stage I-C and II
(17) 55 Hormonal Contraception and Trophoblastic Sequelae
(18) 26N Phase II Trial of DHAD
(19) 52 A Phase III Study of Cyclophosphamide
(20) 53 (NEVER ACTIVATED BY MCI) Double Blind Trials, Cholestyramine
(21) 54 Treatment of Women With Malignant Tumors of Ovarian Stroma
(22) 56 A Randomized Comparison of Hydroxyurea
(23) 57 A Randomized Comparison of Multiagent Chemotherapy
(24) 58 A Study of Cytoplasmic Progesterone
(25) 59 Extended Field Radiation Therapy
(26) 60 A Phase III Study of Doxorubicin

FOR COMPLETE TITLES TO THE ABOVE, CONSULT MASTER PROTOCOL FILE.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/350 FAMC(3) Status: on-going

(4) Title: Detection of postmenopausal women at risk for endometrial carcinoma by the progesterone challenge test

(5) Start Date: September 1981	(6) Est Compl Date: February 1983
(7) Principal Investigator: John Hanna, M.D. MAJ, MC, USA Resident, Dept of OB-GYN	(8) Facility: FAMC
(9) Dept/Svc: OB-GYN	(10) Assoc Investigators: NONE
(11) Key Words: Endometrial cancer Progesterone challenge test	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 28

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.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: to ascertain if a progesterone challenge test can identify postmenopausal women with pre-cancerous lesions of the endometrium.

(16) Technical Approach: Asymptomatic postmenopausal women undergo endometrial biopsy in the Clinic followed by an injection of progesterone. Positive or negative withdrawal bleeding is correlated with endometrial histology.

(17) Progess: To date, 28 women have been sampled. Five women had a withdrawal period. Of the 23 that showed no withdrawal bleeding, all had inactive or atrophic endometrium, or no pathologic diagnosis. Of, of the five that did withdraw, 4 had abnormal pathology including two with adenomatous hyperplasia. Though not significant, this suggests that the progesterone challenge test may predict women at risk for endometrial carcinoma.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/351-N (3) Status: ongoing
(4) Title: Serum levels of 13, 14 dihydro-15 keto prostaglandin F_2 in term and preterm labor.

(5) Start Date: February 1982	(6) Est Compl Date: February 1983
(7) Principal Investigator: Thomas Pennington, DO CPT, MC Resident, Department of OB-GYN	(8) Facility: FAMC
(9) Dept/Svc: Dept of OB-GYN	(10) Assoc Investigators: Jay M. Hill, M.D. COL, MC Chief, Department of OB-GYN
(11) Key Words: Prostaglandin metabolites in term and preterm labor.	

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

(14) a. Date, Latest HUC Review: Feb 82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 75
d. Total Number of Subjects Enrolled to Date: N/A
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None.

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine a serum level of 13, 14 dihydro 15 keto prostaglandin F_2 (PGF-M) that differentiates true from false labor.

(16) Technical Approach: Serum samples from 50 term, 50 preterm and 50 control patients are being analyzed for levels of prostaglandin metabolites. Comparisons of these samples will allow conclusions concerning the usefulness of PGF-M as a predictor of preterm labor.

(17) Progess: Serum samples have been obtained from 49/50 of the term labor patients and 25/50 of the preterm labor patients. Sampling of the nonlabor control patients begins this month (November 1982). As expected, the controlling factor on progress of the study is the preterm labor sampling. It is expected adequate numbers for analysis will be obtained by February 1983.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/352 (3) Status: on-going
(4) Title: An evaluation of single-dose metronidazole treatment for Gardnerella Vaginalis vaginitis.

(5) Start Date: February 1982	(6) Est Compl Date: February 1983
(7) Principal Investigator: Alfred Purdon, JR, MD, CPT, MC John H. Hanna, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: OB-GYN	(10) Assoc Investigators: Pari L Morse, GS-9 Donald D Paine, GS-11 Paul G Engelkirk, PhD, LTC, MSC
(11) Key Words: Metronidazole, single dose vs standard seven day course Gardnerella Vaginalis vaginitis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: N/A
c. Number of Subjects Enrolled During Reporting Period: 83
d. Total Number of Subjects Enrolled to Date: 83
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: to ascertain clinical efficacy of single-dose vs standard seven day metronidazole treatment of Gardnerella Vaginalis vaginitis.

(16) Technical Approach: Patients with symptomatic vaginal irritation and/or discharge are initially cultured for G. Vaginalis after excluding candida albicans and trichomonas infection. Patients are then randomized to single-dose vs seven day treatment with metronidazole. Patients are re-cultured seven days later and symptom status noted.

(17) Progess: Of 83 patients thus far entered into study, 26 have had initial (+) cultures for G. Vaginalis. Forty-five of 83 patients were randomized to the single dose regimen, with the remaining 38 patients receiving the standard seven day treatment. Results to date on 83 patients show that of initial 26 positive cultures, 14 were treated with single dose regimen and 13 were treated with 7 days of metronidazole. Final culture results will not be available until conclusion of study.

CONTINUATION SHEET, FY 82 ANNUAL PROGRESS REPORT Proto No.: 81/352

Publications and Presentations: none

PEDIATRICS

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 75/401 (3) Status: Terminated

(4) Title: Effect of Prophylactic Antibiotic Therapy on Gravid Group B Beta Hemolytic Streptococcus Carriers

(5) Start Date: September 1975	(6) Est Compl Date: July 1983
(7) Principal Investigator: Gerald B. Merenstein, Col, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatric/Newborn	(10) Assoc Investigators: John R. Pierce, LTC, MC
(11) Key Words: Group B Strep, Prophylactic Penicillin	

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

(14) a. Date, Latest HUC Review: 1/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: 50 (Fifty)
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To evaluate the use of prophylactic antibiotic therapy in antepartum GBHS carriers with regard to colonization of the infant.

(16) Technical Approach:

Gravid females are evaluated for the presence of Group BHS using selective broth and are then considered candidates for prophylactic antibiotics or control. The infants are evaluated for colonization with GBHS.

(17) Progess:

It was hoped that this study could be completed by randomly evaluating preterm mothers and infant in regards to prophylactic antibiotics and the GBHS carrier state. With an expected colonization rate of 13% it would require approximately 4-5 years to complete the study here at FAMC given our number of preterm births. Because of this unreasonable length of time required for completion request that this protocol be terminated.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 75/401

SERVICE Newborn DEPARTMENT Pediatrics

1. Yost, C. C., Calcagno, J. V., Merenstein, G. B., Todd, W. A., Dashow, E. E., Brown G. L., Tull, A. H. and Kile, D. E. Group B Beta Hemolytic Streptococcus: Improved Culture Detection and a Controlled Treatment Trial. Clinical Research 24, 186A, 1976.

2. Luzier, T. L., Merenstein, G. B., Todd, W. A., Yost, C. C., Brown, G. L. The Treatment of Gravid Females at Term Colonized with Group B Streptococcus A Randomized Controlled Study. Clinical Research 26, 200A, 1978.

3. Pierce, J. R., Merenstein, G. B. Streptococcal Sudden Unexpected Death Syndrome. Clinical Research 27, 128A, 1979.

4. Merenstein, G. B., Todd, W. A., Brown, G., Yost, C. C., Luzier, T. L. Group B. Hemolytic Streptococcus: Randomized Controlled Treatment Study at Term. OB-GYN 55, 315-318, 1980.

PRESENTATIONS for FY 82 Annual Progress Report Proto No. 75/401

SERVICE Newborn DEPARTMENT Pediatrics

1. Calcagno, J. V., Brown, G. L., Tull, A. H. et al. Evaluation of Three Collection-Transport Systems for the Isolation of Group B Streptococcus from PrePartum Women and Neonates. Presented: American Society for Microbiology, Atlantic City, N. Y. 1976.

2. Luzier, T. L. The Treatment of Gravid Females at Term Colonized with Group B Beta Hemolytic Streptococcus: A Randomized Controlled Study. Presented: Military Section, American Academy of Pediatrics, New York, New York, November 1977.

3. Luzier, T. L. The Treatment of Gravid Females at Term Colonized with Group B Strep. Presented: Western Society for Pediatric Research, Carmel, California, 2 February 1978.

4. Pierce, J. Streptococcal Sudden Unexpected Death Syndrome. Presented: Aspen Conference on Perinatal Research, Aspen, Colorado, July 1978.

5. Pierce J. Streptococcal Sudden Unexpected Death Syndrome. Presented: American Academy of Pediatrics, District VIII, Section on Perinatal Medicine. Park City, Utah, May 1980.

6. Merenstein, G. B. The Prevention of Group B Streptococcal Colonization. Presented: American Academy of Pediatrics District VIII, Section on Perinatal Medicine, Park City, Utah, May, 1980.

7. Merenstein, G. B. The Spectrum of Group B Streptococcal Disease in the Newborn. Presented: Aspen Conference on Perinatal Medicine, July 1980.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 77/402 (3) Status: Ongoing

(4) Title: Evaluation of Ventricular Function and Pulmonary Vascular Resistance in Asphyxiated Infants.

(5) Start Date: December 1977	(6) Est Compl Date: Dec. 1984
(7) Principal Investigator: Carl Gumbiner, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/Newborn	(10) Assoc Investigators: None
(11) Key Words: Newborn, Asphyxia, Heart	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/81 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: None.

d. Total Number of Subjects Enrolled to Date: None.

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None.

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To serially measure left ventricular function in newborns with asphyxia neonatorum.

(16) Technical Approach:

All infants with the diagnosis of asphyxia neonatorum as defined by Apgar 6 are candidates for this study. Study infants will be serially evaluated on days 0, 1, 2, 4, 6, 10 with echocardiograph.

(17) Progess:

Limited numbers of appropriate subjects (asphyxiated infants) in our nursery have delayed progress, but interest in completing this study is ongoing.

Publications and Presentations: None

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/400 (3) Status: Terminated

(4) Title:

Effect of Adriamycin in Platelet Function

(5) Start Date: Nov/78	(6) Est Compl Date: 1982
(7) Principal Investigator: **Askold D. Mosijczuk, MD, LTC, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Pediatrics**	(10) Assoc Investigators: **T. Philip O'Barr, Ph.D., DAC** **Ellen Swanson, M.S., DAC**
(11) Key Words: **Effect of Adriamycin in Platelet Function**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 5/82 b. Review Results: ongoing

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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine and measure possible effect of adriamycin on platelet function.

(16) Technical Approach: Forty ml of blood are drawn from a healthy adult volunteer. The blood is centrifuged and PRP and PPP are drawn off. In a platelet aggregometer, 20 ml of adriamycin are added to the PRP in one cuvette, with the other cuvette with PRP serving as a control. After one minute, aggregating agents--ADP, Epinephrine, collagen--are added to each cuvette and the present aggregation compared in the two samples. Aliquots of PRP are removed at certain times to measure the amount of tromboxane released.

(17) Progress: None since last report of September 1980. Since no new work has been done in this study in the past twelve months, the Principal Investigator suggests that the protocol be terminated.

Publications and Presentations: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/403 (3) Status: Completed

(4) Title: Evaluation of Transcutaneous Oxygen Monitoring in the Acute Management of Infants with RDS.

(5) Start Date: January 1980

(6) Est Compl Date: Completed

(7) Principal Investigator:

Gerald B. Merenstein, Col, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics/Newborn

(10) Assoc Investigators:

Howard Kilbride, LTC, MC
C. Gilbert Frank, Maj, MC

(11) Key Words:
Transcutaneous Oxygen Monitoring

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 10/81 b. Review Results: ongoing

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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the efficacy of continous transcutaneous PO_2 monitoring in the acute management of infants with RDS.

(16) Technical Approach:

Infants less than 34 weeks gestation with RDS will be assigned to 24 hours of continuous transcutaneous oxygen monitoring. They will have the data blinded in either the first or second 12 hours.

(17) Progess:

Useable data was collected on 16 infants. It has been presented and is being prepared for submission for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 79/403

SERVICE Newborn Service DEPARTMENT Pediatrics

None

PRESENTATIONS:

Kilbride, H. et al: Transcutaneous oxygen monitoring. Presented: The Annual Aspen Conference on Perinatal Research, July 1980, Aspen, Colorado

Kilbride, H. et al: Transcutaneous oxygen monitoring in the acute management of infants with RDS. Presented: The Aspen Military Conference on Perinatal Research, July 1982, Aspen, Colorado

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/404 (3) Status: Completed

(4) Title: The Effect of Early Meconium Evacuation on Bilirubin Levels in Breast-Fed and Formula-Fed Health Full-Term Infants.

(5) Start Date: 1979	(6) Est Compl Date: Completed
(7) Principal Investigator: Leonard E. Weisman, Maj, M.D.	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/Newborn	(10) Assoc Investigators: Gerald B. Merenstein, Col, MC Marilyn Digirol, LTC, ANC Jan Collins, Cpt, ANC
(11) Key Words: Bilirubin Meconium, Breast Fed, Bottle Fed	

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

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 80
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine the effect of glycerine suppositories on peak bilirubin levels in breast and formula fed infants.

To compare peak bilirubin levels in breast and formula fed full term infants.

(16) Technical Approach: One hundred healthy full-term infants will be randomly assigned to one of four groups including suppository or control and breast or bottle fed.

(17) Progess:
The ttudy has been completed. A paper has been submitted for publication.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 79/404

SERVICE Newborn Service DEPARTMENT Pediatrics

Weisman, L. et al: The effect of early meconium evacuation on total serum bilirubin levels (Abstract) Ped Res 6, 119A (242) 1982.

PRESENTATIONS:

Frank, 1. G., Weisman, L. E., Merenstein, G. B.: The effect of early meconium evacution on total serum bilirubin levels. Presented at the American Academy of Pediatrics District VIII Perinatal Section Annual Meeting, Jackson Hole, Wyoming, May 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/405 (3) Status: Terminated

(4) Title: Assessment of Maternal Fever in the Immediate Prenatal Period as a Predictor of Perinatal Newborn Infections

(5) Start Date: 1979	(6) Est Compl Date: July, 1983
(7) Principal Investigator: John R. Steenbarger, M.D. LCDR, MC, USNR	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/Newborn	(10) Assoc Investigators: C. Gilbert Frank, M.D., MAJ, MC Howard Kilbride, M.D., LTC, MC
(11) Key Words: Maternal fever, re: perinatal infections	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: None

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine the incidence of serious perinatal infections in infants born to febrile mothers.

(16) Technical Approach: Mothers who are febrile within 24 hours of delivery as well as a matched control mother will have blood and placental cultures at the time of delivery. Each infant born to these study and control mothers will have peripheral blood, stool and umbilical cultures, CBC, platelet count, C-reactive protein all within 6 hours of birth. Each study infant will have a chest x-ray. The CBC and platelet count will be repeated at 24 hours.

(17) Progress: The principal investigator has completed his fellowship and has been reassigned. Because of this and other more immediate obligations, request that this protocol be terminated

Presentations and Publications: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79-406 (3) Status: Terminated

(4) Title:
Intergroup Ewing's Sarcoma of Pelvic and Sacral Bones

(5) Start Date: 27 March 1980	(6) Est Compl Date: 1982
(7) Principal Investigator: **Askold D. Mosijczuk, M.D., LTC,MC**	(8) Facility: FAMC
(9) Dept/Svc: **Pediatrics**	(10) Assoc Investigators: **None**
(11) Key Words: **Intergroup Ewing's Sarcoma of Pelvic and Sacral Bones**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 5/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0 - off study
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

1. Improve the survival of patients with localized Ewing's sarcoma of the pelvis and sacrum who have no evidence of metastases by using an intensive multimodal therapeutic approach.

2. Determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence of disease and/or metastases.

(16) Technical Approach:

Patients with Ewing's sarcoma of pelvic and sacral bones receive surgery, radiation and chemotherapy according to protocal guidelines and tumor survival and responses are measured.

(17) Progress:

To date no FAMC patients have been entered in this study. Nationally, although the study is open, survival is poor in both treatment areas. A new protocol for treating Ewing's sarcoma of pelvic and sacral bones is being proposed. Since this study at FAMC will now be under POG affiliation, this particular protocol number should be terminated.

Publications and Presentations: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/407 (3) Status: Terminated

(4) Title:

Intergroup Ewing's Sarcoma, Pelvic and Sacral Sites Excluded

(5) Start Date: 27 March 1980	(6) Est Compl Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators: None
(11) Key Words: Intergroup Ewing's Sarcoma, Pelvic and Sacral Sites Excluded	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 5/82 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.:

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

1. Improve the survival of patients with localized Ewing's sarcoma of bone who have no evidence of metastases at diagnosis with an intensive multimodal therapeutic approach.

2. Determine the effectiveness of high dose intermittent chemotherapy as compared to moderate dose continuous chemotherapy to prevent local relapse and/or metastases.

(16) Technical Approach:

Patients with Ewing's sarcoma, except those involving pelvic and sacral bones, receive surgery, radiation, and chemotherapy according to protocol guidelines and tumor response and survival are measured.

(17) Progress:

To date, no FAMC patients have been entered on this study. Nationally, the study is progressing satisfactorily, with approximately a 60%, 3-year survival and no statistical difference amonth the three treatment areas. Since this study at FAMC will now be under POG affiliation, this particular Protocol Number should be terminated.

Publications and Presentations: none.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/408 (3) Status: Ongoing

(4) Title:
Intergroup Rhabdomyosarcoma Study II

(5) Start Date: 27 March 1980	(6) Est Compl Date: 1982
(7) Principal Investigator: **Askold D. Mosijczuk, MD, LTC, MC**	(8) Facility: FAMC
(9) Dept/Svc: **Pediatrics**	(10) Assoc Investigators: None
(11) Key Words: **Intergroup Rhabdomyosarcoma**	

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

(14) a. Date, Latest HUC Review: 5/82 b. Review Results: ongoing
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 studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
The objectives of this study are to determine if cyclophosphamide can be dropped from the standard VAC regimen with radiation omitted without jeapardizing disease control and survival, and if so, if there would be less side effects without it, particularly testicular, ovarian and renal dysfunction in Clinical Group I Disease. In Clinical Group II Disease, it is to determine if repetitive courses of "pulse" VAC improve the duration of complete remission and survival beyond that which is now (cont'd).

(16) Technical Approach:
Patients with rhabdomyosarcoma received surgery, radiation, and chemotherapy according to protocol guidelines, and tumor response and survival is measured.

(17) Progress:
To date, two FAMC patients have been enrolled on this study. One patient with II-b disease involving upper extremity is in CR seventeen months from diagnosis of chemotherapy. The second patient, with a Stage III head and neck, is in CR at sixteen months from diagnosis. Nationally, no advantage is seen in group I and II disease between IRS-I and the current IRS-II. For stage III and IV patients, significant improvement is seen on IRS-II as compared to IRS-I. Since this study at FAMC will now be under POG affiliation, this particular Protocol Number should be terminated.
Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/409 (3) Status: Terminated

(4) Title:
National Wilm's Tumor Study III

(5) Start Date: 27 March 1980	(6) Est Compl Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators: None
(11) Key Words: National Wilm's Tumor Study	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 5/82 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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To gain a better understanding of the Wilm's tumor by gathering detailed information regarding gross and histologic morphology, and to correlate this information with treatment and clinical outcome. To refine methods of treatment according to staging, so as not to incur the adversities of unnecessary treatment in patients requiring minimal therapy. To test treatment hypotheses by randomized, prospective clinical trials according to stage and histologic grade of disease. To gather information regarding patients and their families, including patterns of cancer within families, in an attempt to identify children and families at high risk for cancer. To study the late consequences of successful treatment given for Wilm's tumor.

(16) Technical Approach:

Patients with Wilm's tumor receive treatment with surgery, radiation and chemotherapy according to protocol guidelines and then tumor response and survival are measured.

(17) Progress:

To date no patients from FAMC have been enrolled on study. Nationally, the study is progressing satisfactorily, but thus far no advantage between the regimens for any group of patients (by stage) is apparent. Since this study at FAMC will now be under POG affiliation, this particular protocol number should be terminated.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/400 (3) Status: Transfer to WRAMC

(4) Title: Evaluation of Lymphocyte Blast Transformation in Breast Milk and Peripheral Blood Lymphocytes.

(5) Start Date: 1980	(6) Est Compl Date: indefinite
(7) Principal Investigator: Leonard E. Weisman, Maj, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/Newborn	(10) Assoc Investigators: R. Stephen Whiteaker, Ph.D., Cpt, MSC
(11) Key Words: Breast Milk, Lymphocyte, Blast Transformation	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To obtain data on lymphocyte blast transformation of human breast milk lymphocytes and compare them to maternal post-partum peripheral blood lymphocytes.

(16) Technical Approach: Simultaneous breast milk and peripheral blood samples from post-partum subjects are evaluated for lymphocyte blast transformation using a microtehcnique after: 1) utilizing various isolation procedures, or 2) utilizing various selected patient populations or 3) utilizing various laboratory storage conditions.

(17) Progess:

The principal investigator has been transferred to WRAMC/USUHS. He will continue the studies there.

Publications and Presentations: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **80/401** (3) Status: **Terminated**

(4) Title: **Investigation of Heparin Induced Platelet Aggregation Secondary to Prostacyclin Interference in the Rabbit Model**

(5) Start Date: **June 1980**

(6) Est Compl Date: **1982**

(7) Principal Investigator:
Larry G. Maden, MAJ, USAF, MC

(8) Facility: FAMC

(9) Dept/Svc: **Pediatrics/Newborn**

(10) Assoc Investigators:
John W Harbell, PhD, CPT, MSC
Donald G. Corby, MD, COL, MC
Peter W. Blue, MD, LTC, MC
Gerald B. Merenstein, MD, COL,MC

(11) Key Words:
heparin, prostacyclin, platelet, aggregation

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **6/82** b. Review Results: **Terminated**
c. Number of Subjects Enrolled During Reporting Period: **NA**
d. Total Number of Subjects Enrolled to Date: **NA**
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **To investigate heparin induced prostacyclin inhibition as manifested by increased platelet adhesion at the tip of an arterial catheter in a rabbit model.**

(16) Technical Approach: Four groups of rabbits will have arterial catheters placed and infused with varying concentrations of heparin. Platelets will be harvested from the animals labelled and reinfused. The rabbits will be scanned by a gamma counter at six and 24 hours. After euthanized, four rabbits from each group will have an autocradiograph of the aorta. The remaining two rabbits in each group will have the aorta analyzed for prostacyclin and heparin at the catheter site.

(17) Progress: All experiments have been completed. Data have been retrieved from computer storage and analyzed. No significant correlation between dose and clot formation could be established.

PUBLICATIONS and PRESENTATIONS: none

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/402 (3) Status: Completed

(4) Title:
Incidence of Latent Iron Deficiency

(5) Start Date: 20 June 1981	(6) Est Compl Date: Jan/82
(7) Principal Investigator: Stephen N. Nelson, MD, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/Hem/Onc.	(10) Assoc Investigators: Askold D. Mosijczuk, MD, LTC, MC William H. Parry, MD, COL, MC LeRoy M. Graham, MD, CPT, MC
(11) Key Words: Latent Iron Deficiency	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 250
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine the incidence of latent iron deficiency in a population of children who present for routine physical examination.

(16) Technical Approach:

Ten cc's of venous blood was obtained from 270 random and nonrandom volunteers after informed consent. This blood was analyzed for hemoglobin, hematocrit, red cell indices, serum iron, TIBC and serum ferritin. The number of patients with abnormal results will be compared to the total number of patients enrolled, yielding the incidence of latent iron deficiency as defined in this study.

(17) Progress:

All blood samples obtained on the 270 volunteers have been analyzed. Review of a small number of patients strongly suggests that the incidence of latent iron deficiency is very low, less than 5%, a precise incidence depends on which parameters are used. Study is completed.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-400 (3) Status: Completed

(4) Title:

Phencyclidine (PCP) Removal by Hemoperfusion

(5) Start Date: 1 March 1981

(6) Est Compl Date: June 1982

(7) Principal Investigator:
William R. Allen, MD, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics/Gen Ped

(10) Assoc Investigators:
T.P. O'Barr, Ph.D., DAC
Donald G. Corby, MD, COL, MC

(11) Key Words:
Charcoal hemoperfusion
phencyclidien (PCP

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
Determine whether charcoal hemoperfusion removes adequate amounts of PCP to alter the course of clinical intoxication.

(16) Technical Approach: A single dose of PCP is given intravenously. Blood sampling is then done for pharmacodynamic data. In control experiments, blood and urine PCP levels are then monitored for six hours. In hemiperfusion experiments, blood and urine PCP levels are measured, including measurements of cartridge drug removal rates. Duration of coma and other behavior is monitored to detect changes brought about by hemoperfusion.

(17) Progess:
The study has been completed, the data is being analyzed and a paper will be submitted for publication.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#:81/401 (3) Status: Completed

(4) Title: Evaluation of Transcutaneous Oxygen Monitoring During Labor Puncture of the Neonate

(5) Start Date: June 1981	(6) Est Compl Date: Completed
(7) Principal Investigator: Leonard E. Weisman, Maj, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/Newborn	(10) Assoc Investigators: John R. Steenbarger, LCDR, MC Gerald B. Merenstein, Col, MC
(11) Key Words: Transcutaneous Oxygen Lumbar Puncture Newborn	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 6

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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine if the sick newborn becomes hypoxic during lumbar puncture. To determine if hypoxemia is position dependent.

(16) Technical Approach:
Neonates less than 24 hours old requiring lumbar puncture were randomized, after parental permission was obtained, into four groups. A. On side, open transcutaneous oxygen monitor. B. On side, blinded transcutaneous oxygen monitor. C. Sitting, open. D. Sitting, blinded.

(17) Progess:
Completed, presented and published. Winner of the Uniformed Services Pediatric Seminar Margileth Award for Outstanding Clinical Research.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/401

SERVICE Newborn Service DEPARTMENT Pediatrics

Weisman, L. E. et al: Oxygen Tension Changes During Lumbar Puncture in symposium on Continuous Transcutaneous Blood Gas Monitoring, Huch and Huch, ed. M. Dekker Inc., New York in press.

Weisman, L. E. et al: Oxygen Tension Changes During Lumbar Puncture, AJDC accepted for publication.

PRESENTATIONS:

Merenstein, G. B., Weisman, L. E., Steenbarger, J. R.,: Oxygen tension changes during lumbar puncture of the neonate and mechanisms of action. Presented: Continous Transcutaneous Blood Gas Monitoring Second International Symposium, Zurich, Switzerland, October 1981.

Weisman, L. E., Steenbarger, J. R., Merenstein, G. B.: Oxygen Tension Changes During Lumbar Puncture of the Neonate. Presented: Uniformed Services Pediatric Seminar, Bethesda, MD. March 1982.

Steenbarger, J. R., Weisman, L. E., Merenstein, G. B.: Oxygen Tension Changes During Lumbar Puncture. Presented: American Academy of Pediatrics District VIII Perinatal Section Meeting Jackson Hole, Wyoming, May 1982.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-402 (3) Status: Ongoing

(4) Title:
Diagnosis of Respiratory Syncytial Virus Infection in Infants by Enzyme-Linked Immunosorbent Assay

(5) Start Date: 7 January 1981

(6) Est Compl Date: 1 June 1983

(7) Principal Investigator:
Donald R. Moffitt, MD, MAJ,MC
Donald D. Paine

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics/Pulmonary

(10) Assoc Investigators:
William H. Parry, MD, COL, MC
Paul G. Engelkirk, LTC, MSC

(11) Key Words:
ELISA
RSV Infection

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: Development of ELISA procedures for the detection of RSV antigen and RSV antibodies, using commercially available reagents, and determining the eddicacy of these procedures for the diagnosis of RSV infections in infants.

(16) Technical Approach: This project has been approached first from the laboratory in developing reliable ELISA tests for use with clinical specimens. This has been done with commercial reagents and controls, and with human serum obtained from Letterman Virology Laboratory. The clinical aspects of the protocol involves sampling nasal secretions, urine, and serum from infants with suspected RSV infection. Results of the ELISA assay will

(17) Progess: To date, 16 inpatients have been studied. Ten nasal secretions were ELISA positive for RSV antigen; of these, five were also culture-positive. The remaining six were ELISA-/culture-negative. None were ELISA-negative/ Culture-positive. Of 15 urine specimens, four had positive ELISA results; of these, two were culture-positive. Of the 11 urines which were ELISA-negative, three were culture-positive. The protocol was expanded during FY '82 to include outpatient urines. Testing of these specimens is ongoing. Testing for anti-RSV antibodies was discontinued because paired sera results do not provide a rapid diagnosis.

(16) Technical Approach (cont'd):
be compared with virsu cultures and complement fixation seroconversion rates.

PUBLICATIONS AND PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81-403 (3) Status: TERMINATED

(4) Title: Use of Theophylline in Wheezing Associated Respiratory Illness (WARI) in Young Children.

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator: Max V. Bryant, MD, LTC, MC.	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/ Ped Pul	(10) Assoc Investigators: W.H. Perry, MD, COL, MC.
(11) Key Words: Theophyllene Use in Wheezing Associated Respiratory Illness WARI	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. *Note any adverse drug reactions* reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To demonstrate effectiveness of intravenous Theophylline on the clinical course of children with a wheezing associated respiratory illness.

(16) Technical Approach: The technical approach did not deviate from that spelled out in detail in the original protocol.

(17) Progess: This protocol has been terminated due to the ETS of the investigators.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/400 (3) Status: Ongoing

(4) Title: The Effect of Glycerin Suppository Administration on Bilirubin Levels in Infants Receiving Phototherapy

(5) Start Date: October, 1982

(6) Est Compl Date: Sep, 1983

(7) Principal Investigator:
W. Woods Blake, M.D.
MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatric/Newborn

(10) Assoc Investigators:
Tom Kueser, M.D., CPT, MC
John R. Pierce, M.D., LTC, MC
Gerald B. Merenstein M.D.LTC, MC

(11) Key Words: Hyperbilirubinemia
re: glycerin suppositories

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: None

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To determine whether the utilization of glycerin suppositories to enhance stooling effects peak serum bilirubin or influences changes in bilirubin levels in infants $\geq$ 36 weeks gestational age being treated with phototherapy for hyperbilirubinemia.

(16) Technical Approach: Sixty infants $\geq$ 36 weeks gestation and $<$ 1 week of age who require phototherapy for treatment of hyperbilirubinemia will be studied. Infants will be randomly assigned to a treatment group of glycerin suppositories every 4 hours or a control group. Bilirubin levels will be determined every 6-8 hrs while under phototherapy for treatment and control patients. Results will be tabulated and statistically evaluated for any benefit.

(17) Progress: The previous principal investigator has completed his fellowship and has been reassigned. A new principal and new associate investigators have been named. The initial patients should be enrolled beginning in Oct 1982.

Presentations and Publications: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/401 (3) Status: Ongoing

(4) Title: Modified Immune Serum Globulin in Neonates.

(5) Start Date: 1 Apr 82

(6) Est Compl Date: 30 Sep 83

(7) Principal Investigator:
JOHN R. PIERCE, M.D.
LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatric/Newborn

(10) Assoc Investigators:
GERALD W. FISCHER, M.D.
LTC, MC

(11) Key Words: Modified immune serum globulin, kinetics, neonates

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 15

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: To analyze the ability of Modified Immune Serum Globulin (MISG) to elevate neonatal IGG levels. We will specifically look at pre and post MISG serum for evidence of increased activity against Group B streptococcus using invetro assays for opsonic antibody.

(16) Technical Approach: Infants will be assigned to the control or treatment group. The treatment group will receive an infusion of MISG given over 4-8 hours. Blood samples will be drawn prior to and following the infusion at specific intervals. Sera will be forwarded to the Uniformed Services University of the Health Sciences in Bethesda, Maryland for all determinations. Infants will be monitored closely during the infusion for any side-effects or adverse reactions.

(17) Progress: There have been 10 infants enrolled in the initial 250 mg infusion group, five control and five treatment infants. In the 500 mg infusion group there have been five infants enrolled, three control and two treatment infants.

Presentations and Publications: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/402 (3) Status: Completed

(4) Title:

Considerations in Rational Prescribing of Nebulized Medication: The Relationship between Nebulized Dose and Target Organ Dose.

(5) Start Date:	(6) Est Compl Date: Complete
(7) Principal Investigator: Edward N. Squire, Jr., MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: MC/ALLERGY IMMUNOLOGY	(10) Assoc Investigators: Cheryl Smith DVM, DCI John W. Harbell, Phd, MSC, DCI
(11) Key Words: nebulized medication, asthma therapy, inhaled aerosols	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

to extimate in animal subjects the dose of medications delivered to the lungs using a face mask and continuous nebulization technique, so that improved dosage estimates may be made for young children who are unable to use more controlled approaches to inhalation therapy.

(16) Technical Approach:

Animal experiment to approximate effective dose in humans.

(17) Progess:

One percent of nebulized dose enters animal. A mean of 0.2% enters the lungs.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 82/402

SERVICE ALLERGY IMMUNOLOGY DEPARTMENT MEDICINE

none

PRESENTATIONS:

(1) Squire, E., Jr.: Considerations in Rational Prescribing of Nebulized Medication: The Relationship between Nebulized Dose and Target Organ Dose. Presented: New York City Academy of Pediatrics, Section on Allergy-Immunology, 24 October 1982.

RADIOLOGY

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 74/600 (3) Status: Terminated

(4) Title:
Bone Marrow Scintigraphy and Scintigraphic Localization of Soft Tissue Tumors by Use of Indium-111 Chloride

(5) Start Date: 1974	(6) Est Compl Date: Terminated
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Indium 111 Chloride Bone Marrow	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: None
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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

Clinical evaluation of Indium-111 Chloride supplied by Medi-Physics, Inc. The evaluation of the agent is significant in that it represents a method of studying sites of erythropoiesis in bone marrow and allows scintigraphic localization of soft tissue tumors by non-invasive techniques. In selected patients, this affords clinical information which could not be obtained by other methods.

(16) Technical Approach:

Up to 2mc of Indium-111 Chloride or proportionally less depending on body weight supplied by Medi-Physics, Inc. will be administered intravenously to patients referred to Nuclear Medicine Laboratory for either scintigraphic evaluation of sites of erythropoiesis in bone marrow or the presence of soft tissue tumors.

(17) Progess:

No studies performed in the previous year. The study is terminated.

PUBLICATIONS and PRESENTATIONS: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 74/602 (3) Status: Terminated

(4) Title:
The Use of Indium 111 DTPA for the Study of Cerebrospinal Fluid Pathways.

(5) Start Date: 1974

(6) Est Compl Date: Terminated

(7) Principal Investigator:
Peter W. Blue LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nuclear Medicine Svc

(10) Assoc Investigators:
Nasser Ghaed, COL, MC

(11) Key Words:
Indium 111 DTPA
Cerebrospinal Fluid

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 17 since 1 Oct 80
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
Clinical evaluation of Indium 111 DTPA in aqueous ionic solution (ph 7 to 8) for study of cerebrospinal fluid pathways as supplied by Medi-Physics, Inc.

(16) Technical Approach: Evaluation of this agent represents a method of studying cerebrospinal fluid pathways in selected patients with a compound that will result in significantly less absorbed radiation doses to patients than the methods currently used. The incidence of side reactions, such as fever, headaches and mild meningitis, will probably be decreased in comparison to the compound presently used.

(17) Progess:
10 studies using Indium 111 DTPA have been performed since 1 Oct 81. This agent is commercially available and the study is terminated.

PUBLICATIONS AND PRESENTATIONS: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 79/600 (3) Status: Terminated

(4) Title: Non-Invasive Realtime Ultrasonic Evaluation of Carotid Occlusive Vascular Disease

(5) Start Date: 1979	(6) Est Compl Date: Terminated
(7) Principal Investigator: Gloria Hubred Komppa, M.D.	(8) Facility: FAMC
(9) Dept/Svc: Radiology/Ultrasound	(10) Assoc Investigators: Lewis Mologne, Col John Eielson, Ltc Nasser Ghaed, Col
(11) Key Words: Carotid Artery Thrombus Ulcerative plaque	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 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.: Not applicable.

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To objectively evaluate the patency of the carotid artery; to evaluate the presence and extent of a thrombus and/or ulcerative plaque in the carotid; and to employ a full pulsed doppler to measure bidirectional flow in the carotid artery.

(16) Technical Approach: Approximately 120 patients will be evaluated. Patients will be divided into four groups as follows (with approximately 30 patients in each group); 1) Control population; 2) Patients with asymptomatic carotid bruits; 3) Symptomatic patients with or without carotid bruits; 4) Patients who have experienced a previous stroke within the last 12 months. This entire patient population will be evaluated.

(17) Progess:

There has been no progress made on this project due to Special MEDCASE funding for real-timer ultrasound not being available during the fiscal year.

Publications and Presentations: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/600 (3) Status: Terminated

(4) Title:
Tc99m - PIPIDA for diagnosis of Hepatobilary disease

(5) Start Date: 1980	(6) Est Compl Date: Terminated
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Tc-99m-PIPIDA, Diagnostic hepatobiliary, Diagnostic Isotopes	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 9/82 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 60
d. Total Number of Subjects Enrolled to Date: 102
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To evaluate the clinical efficacy of Tc-99m-PIPIDA as a diagnostic hepatobiliary and gallbladder agent for Diagnostic Isotopes, Incorporated, Bloomfield, New Jersey, as an FDA Phase III study. Information concerning the efficacy will be furnished to Diagnostic Isotopes in support of the company's New Drug Application (NDA) on a cost recovery basis.

(16) Technical Approach:
Each patient will be studied following a 6-8 hour period of fasting when possible. Following intravenous administration of the Tc-99m-PIPIDA sequential scintiphotos will be obtained at 5 minute intervals for up to 1 hour following injection.

(17) Progess:
60 studies using 99m-Tc-PIPIDA were performed since 1 October 1981. A new agent is commercially available and this study was terminated.

PUBLICATIONS AND PRESENTATIONS: None

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: **80/601** (3) Status: **Terminated**

(4) Title: **Comparison of Growth Adjusted Sonographic Age (GASA) with the Clinical Newborn Aging Examination (Dubowitz)**

(5) Start Date: **1980**	(6) Est Compl Date: **1982**
(7) Principal Investigator: **Stanley, F. Smazal, Jr., MD, DAC**	(8) Facility: FAMC
(9) Dept/Svc: **Radiology/Ultrasound**	(10) Assoc Investigators: **Kenneth Hopper, CPT, MC** **Leonard Weisman, MAJ, MC** **Nasser Ghaed, COL, MC**
(11) Key Words: **GASA**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: **9/82** b. Review Results: **Terminated**
c. Number of Subjects Enrolled During Reporting Period: **NA**
d. Total Number of Subjects Enrolled to Date: **NA**
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: **NA**

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **This study proposes to evaluate the efficacy of the growth adjusted sonographic age described by Sabbagha by comparing the growth adjusted age to the gestional age determined at birth by the Dubowitz method.**

(16) Technical Approach: Approximately 100 normal pregnancies will be evaluated by ultrasonographic methods prior to 26 weeks of gestation and again after 33 weeks of gestation. The GASA will be used to determine age. This gestational age will be compared to the gestational age determined by examination at birth (Dubowitz Method). Statistical correlations and reflections will be made from this data.

(17) Progress: This study has been terminated due to the Principal Investigator leaving FAMC.

CONTINUATION SHEET for Annual Progress Report FY 82 Proto No. 80/601

PUBLICATIONS: none

PRESENTATIONS:

1. Weisman, L., Smazal, S.F., and Hopper, K.: "GASA". Presented: Aspen Military Conference, Perineonatal Research, Aspen, Colorado, July 1981.

2. Smazal, S.F., Weisman, L., and Hopper, K.: "GASA". Presented: Rocky Mountain Radiological Society Annual Conference, Denver, Colorado, August 1981.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 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, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: iodocholesterol adrenal	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

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.: None

(Continue on a separate sheet and designate this continuation 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 the thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicure dose of N9-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progess:

One study with 131-I-NP-59 for evaluation of patients with possible adrenal function adnormalities have been performed since 1 Oct 81. The radiopharmaceutical proved adequate for the intended diagnostic purpose. No detectable side effects were observed.

PUBLICATIONS and PRESENTATIONS: None

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/600-N (3) Status: Completed

(4) Title:
Pharmacalogic Attempts at Bone Suppression in 99mTc Pyrophosphate Myocardial Scanning

(5) Start Date: 1 Sep 82

(6) Est Compl Date: 7 Oct 82

(7) Principal Investigator:
Kenneth D. Hopper, CPT, MC
Peter W. Blue, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nuc Med Svc

(10) Assoc Investigators:
Nasser Ghaed COL, MC

(11) Key Words:
myocardial scan
Bone suppression

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: None b. Review Results: N/A
c. Number of Subjects Enrolled During Reporting Period: 13 rabbits
d. Total Number of Subjects Enrolled to Date: N/A
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To evaluate the ability of various agents to suppress bone uptake of bone scanning tracer in an attempt to enhance myocardial uptake in myocardial scans.

(16) Technical Approach:
10 rabbits were studied using various pharmacologic agents and bone to background ratios calculated every 15 minutes through 120 minutes after injection of bone scanning tracer.

(17) Progess:

The study is complete and results are being evaluated.

PUBLICATION and PRESENTATIONS: None

PRIMARY CARE and COMMUNITY MEDICINE

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 74/651 (3) Status: Ongoing

(4) Title: Establishment of and Training in Methods for Special Studies of Abnormal Hemoglobins

(5) Start Date: January 1974	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators: Joseph Lima, DAC
(11) Key Words: Abnormal Hemoglobins Techniques on Identification	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/81 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To establish and conduct training in methods for special studies of abnormal hemoglobins.

(16) Technical Approach: To acquaint and to train existing personnel in the performance of various procedures as they pertain to biochemical study of hemoglobins and red cell enzymes involved in hemoglobin function.

(17) Progess: Since 1974 the following can now be performed. Column chromatography, electrophoresis and iso-electrofocusing of hemoglobin; column chromatography and electrophoresis and iso-electrofocusing of globin and electrophoretic demonstration of iso-enzymes of both NADH and NADPH dependent methemoglobin reductases. Quantitation of NDAH-cytochrome b_5 and NADPH MR, glutathione, glutathione reductase now can be done. G-6 PD iso-enzyme patterns now can be determined. Recently equipment for the determination of hemoglobin oxygen dissociation curve has been obtained, and is operational. Carbohydrate and nucleoside utilization of red cells can now be assessed using cold or radioactive substrates.

PUBLICATIONS: None.

PRESENTATIONS: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/650 (3) Status: Ongoing

(4) Title: **Evaluation of Thalassemia as Cause of Hypochromic Microcytic Anemia and in Interaction with Hemoglobin Variants**

(5) Start Date: March 1978	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators: Joseph Lima, DAC
(11) Key Words: Thalassemia-hemoglobin variants	

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

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 40
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To establish phenotype and genotype in patients with microcytic hypochromic anemia due to imbalance in globin chain synthesis.

(16) Technical Approach:

Patients with (a) hypochromic-microcytic anemia (b) patients whose hemoglobin electrophoretogram reveals a variant hemoglobin in amounts greater than 50 or less than 40% will be evaluated. Peripheral blood will be incubated with ^{14}C leucine. Alpha/beta globin synthetic ratios will be calculated.

(17) Progess: Since the inception of the study, 40 patients were evaluated resulting in the identification of the following conditions: HbC/alpha thalassemi HbS/beta plus thalassemia HbS/beta 0 thalassemia, HbH disease, *acquired, 2 cases! HbH disease (a de-novo genetic event) alpha-thalassemia - 1 and type II normal HbA_2 - beta plus thalassemia. Active consultation is provided, in selected case to the Staff Division of Hematology, University of Colorado Medical Center, Denve under this protocol. In collaboration with investigators at the University of

California, San Francisco, CA and the University of Oxford, England, hybridization experiments of peripheral mononuclear cells with mouse erythroleukemia cells are now performed on selected patients aiming at isolation of human chromosome #16 to study the expression and structure of the alpha globin gene complex.

Publications and Presentations: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 78/651 (3) Status: Terminated

(4) Title: Evaluation and Structural Identification of Unusual Human Hemoglobin Variants

(5) Start Date: March 1978	(6) Est Compl Date: Terminated
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators: Joseph E. Lima, MS, DAC
(11) Key Words: Abnormal Hemoglobins	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 2/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To demonstrate that variation at critical sites in hemoglobin structure is one of the reasons for anemia, polycythemia or a hemolytic state in man.

(16) Technical Approach:

Cases of chronic hemolytic anemia and cases with left or right shifted oxygen dissociation curves will be studied by means of electrophoresis, chromatography and isoelectric focusing.

(17) Progess:

Study Terminated.

Publications and Presentations: None.

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/650 (3) Status: Ongoing

(4) Title: **The Ontogenesis of Hemoglobin in the American Opossum (Didelphis Virginia).**

(5) Start Date: 18 March 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators: Dr. P. O'Barr, DAC J.E. Lima, DAC T. Waldrup, DAC
(11) Key Words: Opossum Hemoglobin Red Cell Energy Metabolism Methemoglobin formation & Reduction	

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

(14) a. Date, Latest HUC Review: 4/82 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
This is a continuation of a previous Clinical Investigation study that was completed in June 1975. The overall objective is to follow and define the kinetics of methemoglobin reduction of opossum hemoglobin, in specific, as part of the overall energy metabolish of the red cell of this species.

(16) Technical Approach:
In-vivo and in-vitro reduction of nitrite induced methemoglobinemia will be followed hourly by quantitative, electrophoretic and spectroscopic means. Methemoglobin reductases will be quantitated and electrophoretically demonstrated, and compared to human reductases.

(17) Progess: Opossum Hb was found to oxidise faster than human Hb in solution, the converse was observed on intact, glucose depleted erythrocytes even at acidic pH. Although opossum red cells were shown to be permeable to glucose, they did not require this substrate for methemoglobin reduction in-vitro

methylene blue was found to accelerate methemoglobin reduction on intact opossum erythrocytes at a rate exceeding that seen in human erythrocytes. This reaction, in contrast, was shown to be dependent on glucose in the red cell environment.

Work has begun to study the utilization of various cold and radioactive carbohydrates by opossum red cells in-vitro. Studies of glutathione metabolism, red cell glycolytic intermediates and glycolytic enzymes are to follow.

Two papers and an invited chapter to a book on the above work are currently in press.

An additional paper has been submitted for publication.

Publications and Presentations: None.

NURSING

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 80/704 (3) Status: Completed

(4) Title: Liver Enzyme Levels in Nurse Anesthetist Students Prior To and At Six and Twelve Months After Initial Occupational Exposure. Does The Operating Room Present a Hazard?

(5) Start Date: 26 Nov 1980	(6) Est Compl Date: 1 Dec 1981
(7) Principal Investigator: Lance C. Campbell Captain, Army Nurse Corps	(8) Facility: FAMC
(9) Dept/Svc: Nursing	(10) Assoc Investigators: Kenneth Duggan Captain, Army Nurse Corps
(11) Key Words: Liver Enzyme Levels Operating Room Hazard Occupational Exposure Anesthetic Pollution	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/81 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 31
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: The objective of this study is to quantify the occupational risk of the modern operating room environment to nurse anesthetists. We plan to compare pre exposure liver enzymes during student classroom - only training to enzyme levels at six months and at one year after commencing regular occupational exposure with currently used medical center operating room scavenger systems.

(16) Technical Approach: The plan utilized a sample of 31 nurse anesthesia students. A single tube of blood was drawn July 1980 (pre-occupational exposure), March 1981,(after six months of exposure),and September 1981, (after 12 months of exposure). These samples were submitted for liver profile, (SGPT, SGOT, LDH, GGT, Alkaline Phosphatase, Total and Direct Bilirubin).

(17) Progess: This study has been completed December 1981. A copy of the completed study is attached.

SUMMARY: Several of the inhalation anesthetics in current use have the potential to produce changes in the anzymatic and defensive systems of the organism. In anesthesia personnel, the chronic exposure to ambient OR pollution is a potential occupational hazard.

At this point, the number of subjects in our sample is inadequate for meaningful conclusions, however, an interesting trend did appear. SGOT, SGPT and GGT increased after 6 months of OR occupational exposure and then decreased

slightly to a point still greater than original levels at 12 months' exposure. LDH rose at the 6 month level then increased only slightly to 12 months exposure. Alkaline phosphatase decreased to the 6 month point, then increased to almost original levels at the 12 month point. Curiously, total bilirubin decreased significantly up to the 6 month point and continued to decrease slightly to the 12 month point. The clinical significance of this last finding remains unclear.

A statistical trend in the enzymes seems evident indicating a degree of hepatic insult although results never approached "abnormal" levels.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/701-N (3) Status: Complete

(4) Title:

A Non-Invasive Measurement of Carbon Dioxide During Laproscopic Tubal Ligation

(5) Start Date: 15Oct81	(6) Est Compl Date: complete
(7) Principal Investigator: Linda C. Allen CPT. ANC Mark Skidmore CPT. ANC Doyle Robison CPT. ANC	(8) Facility: FAMC
(9) Dept/Svc: Nursing/ Anes.	(10) Assoc Investigators: NA
(11) Key Words: carbon dioxide insufflation end-tidal carbon dioxide laproscopy	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/81 b. Review Results: ongoing

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.: none

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To determine if carbon dioxide levels can be adequately measured utilizing a simple non-invasive method during laproscopy for tubal ligation.

(16) Technical Approach:

A nonrandom sample of patients presenting for laproscopy was selected from a population a FAMC. Only ASA I patients were selected meaning there were no organic, physiologic, biochemicl or psychiatric disturbances present.

(17) Progess:

Study complete. A statistically significant increase in end-tidal carbon dioxide was found. This supports data from previous studies using arterial carbon dioxide samples and end-tidal carbon dioxide level. This data suggests that an estimate of carbon dioxide levels of the blood can be monitored using the simple, non-invasive technique described in the research protocol.

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 81/701-N

SERVICE Phase II Anes. School DEPARTMENT Nursing

(Item 16 cont) Following standard non-complicated anesthetic induction, patients were connected to an expired carbon dioxide analyzer via the endotracheal tube. End tidal carbon dioxide levels were recorded prior to insufflation, five minutes post-insufflation, fifteen minutes post-insufflation and at the closure of the skin.

The students t-test for difference between means was used to analyze statistical differences of the recordings.

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/702-N (3) Status: Completed

(4) Title: **Are There Correlations Between Exacerbations in Multiple Sclerosis and Anesthesia Agents and Medications.**

(5) Start Date: Oct 81	(6) Est Compl Date: Oct 82
(7) Principal Investigator: **Robert D. Reid CPT, USA, ANC**	(8) Facility: FAMC
(9) Dept/Svc: Nursing	(10) Assoc Investigators: None
(11) Key Words: **Anesthesia, Multiple Sclerosis**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

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.: None

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective: **This study was to determine any correlation between anesthesia and multiple sclerosis patients exacerbations. The previous data was scarce and non-conclusive and this study is designed to add support to previous findings.**

(16) Technical Approach: **This is a retrospective study of the charts of patients with multiple sclerosis who have had general anesthesia in the past five (5) years. Each chart was approached in the same manner using a specific data collection form.**

(17) Progess: **This study is complete now and final typing is in progress. The results of the study show that I could not support previous data and in part it added more controversy. I am unable to correlate any anesthetic with exacerbation. In fact, even the drugs previously incriminated as causing exacerbation were used and no exacerbations were noted. This study does show, however, that there is further need for investigation in this matter.**

Publications and Presentations: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82-700 (3) Status: Completed

(4) Title:
The Effects Of Discontinuing Cover Gowns on a Postpartal Ward Upon Bacterial Cord Colonization Rates in Newborns

(5) Start Date: ~~15 April, 1982~~	(6) Est Compl Date: July, 1982
(7) Principal Investigator: CPT. Michelle Renaud	(8) Facility: FAMC
(9) Dept/Svc: Nursing	(10) Assoc Investigators: LTC P. Englekirk Pari Morse, GS 9
(11) Key Words: Colonization Cover Gown Neonate	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
c. Number of Subjects Enrolled During Reporting Period: 130
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.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine the relationship between discontinuing cover gowns on a postpartal ward and umbilical cord colonization rates for well infants.

(16) Technical Approach:
Infants were cultured at the umbilicus using a sterile culturette, The cultures were plated either by the lab or Ms. Morse, and were read and compiled by Ms. Morse.

(17) Progess:
The study is completed in fiscal year 1982. The study demonstrated no increase in colonization when cover gowns were discontinued..

PUBLICATIONS for FY 82 Annual Progress Report Proto No. 82/700

Renaud, M.T.: The Results of Discontinuing Cover Gowns on a Post-partal Ward Upon Bacterial Cord Colonization of the Neonate. Accepted for publication in the Journal of Obstetric, Gynecological and Neonatal Nursing.

PRESENTATIONS: none

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-I Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 82/701 (3) Status: Completed

(4) Title:
Patients' Perception of Pain from Arterial Puncture

(5) Start Date: 15 Jun 82	(6) Est Compl Date: 15 Aug 82
(7) Principal Investigator: Shirley A. Davis CPT, ANC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: none
(11) Key Words: Arterial Puncture Lidocaine Pain Perception	

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

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
c. Number of Subjects Enrolled During Reporting Period: 58
d. Total Number of Subjects Enrolled to Date: 58
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:
To determine if patients perceive significantly less pain from arterial puncture if lidocaine is used to anesthetize the puncture site prior to drawing the arterial blood sample.

(16) Technical Approach: Subjects requiring radial artery puncture to obtain a blood gas sample will be asked to rate their perceived discomfort using a simple descriptive pain scale. Each of four groups will be compared for differences between the first and second ABG.

(17) Progess: Correlated t-tests and analysis of variance were performed. The results suggest that the five-point pain scale used in this study was a valid measure of pain. In general, the hypothesis, that subjects would perceive significantly less pain from arterial puncture when lidocaine is used than when local anesthesia is not used, was supported by this study
(cont'd)

(17) Progress: cont'd

at the 0.01 level of confidence. No significant main effects were found for age, sex, or order of ABG (first or second). An unexpected finding was that patients overall do not perceive radial artery puncture for obtaining a blood gas sample to be very painful. The degree of discomfort prevented may not warrant the extra expense, both in supplies and nursing time, to use lidocaine for all patients having arterial puncture. Clinican skill and proficiency may be sufficient to minimize the discomfort inflicted by this diagnostic procedure.

Publications and Presentations: none

PHYSICAL MEDICINE and REHABILITATION

FAMC ANNUAL PROGRESS REPORT (RCS MED 300)

(Detail Summary Sheet)

(Ref: HSCR 40-23 &
HSPA-1 Ltr dtd 8Jul82)

(1) Date: 30 Sep 82 (2) Protocol WU#: 81/750 (3) Status: Completed

(4) Title: Evaluation and Comparison of Acupuncture, Electrical Transcutaneous Nerve Stimulator and Trigger Point Stimulation (Neuroprobe) in the Treatment of Musculoskeletal Pain

(5) Start Date: 8 May 81	(6) Est Compl Date: 31 Mar 82
(7) Principal Investigator: COL Angelo Scavarda	(8) Facility: FAMC
(9) Dept/Svc: Phys Med & Rehab Svc	(10) Assoc Investigators: MAJ Ernie Lin, M.D. CPT Joan Beebe, Physical Therapist
(11) Key Words: Acupuncture Trigger Point Stimulation	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 6/82 b. Review Results: Completed
c. Number of Subjects Enrolled During Reporting Period: 91
d. Total Number of Subjects Enrolled to Date: n/a
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: n/a

(Continue on a separate sheet and designate this continuation as (14)e.)

(15) Study Objective:

To evaluate and compare the efficacy of acupuncture and electrical trigger point stimulation as modalities in treating musculoskeletal pain syndromes in patients seen in Physical Medicine & Rehabilitation Service at Fitzsimons Army Medical Center.

(16) Technical Approach:

Fifty-two patients who were referred to the Physical Medicine Service with musculoskeletal pain were treated with transcutaneous nerve stimulation (TENS) in the Physical Therapy Clinic. Electrode placement was according to location of pain. Thirty-six patients were treated with acupuncture using the appropriate points for their particular pain locale. Three patients were treated with neuroprobe. This is an insufficient number to include in this study. This is due to equipment breakdown.

(17) Progress:

Out of thirty-six patients who received acupuncture twenty-nine had a favorable response and seven had no respon e - eighty-one percent success. Of fifty- two patients treated using TENS, forty-five had a favorable response

and nine had no response - eighty-nine percent success. Neuroprobe patients were not included due to insufficient number (3). There were no complications reported from either modality. In conclusion, it is indicated by this study that for musculoskeletal problems referred to Physical Medicine that both TENS and acupuncture provide a significant improvement in pain relief. The efficacy of acupuncture vs TENS is equal. This would indicate that both modalities would be effective in a large percentage of commonly referred problems and that the use of these modalities is warranted both on the basis of efficacy and safety.

Publications and Presentations: none

INVESTIGATORS INDEX

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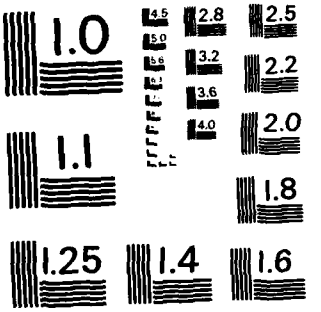

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