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CLINICAL INVESTIGATION PROGRAM. ANNUAL RESEARCH PROGRESS REPORT--ETC(U)
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Laboratory Report No. 16

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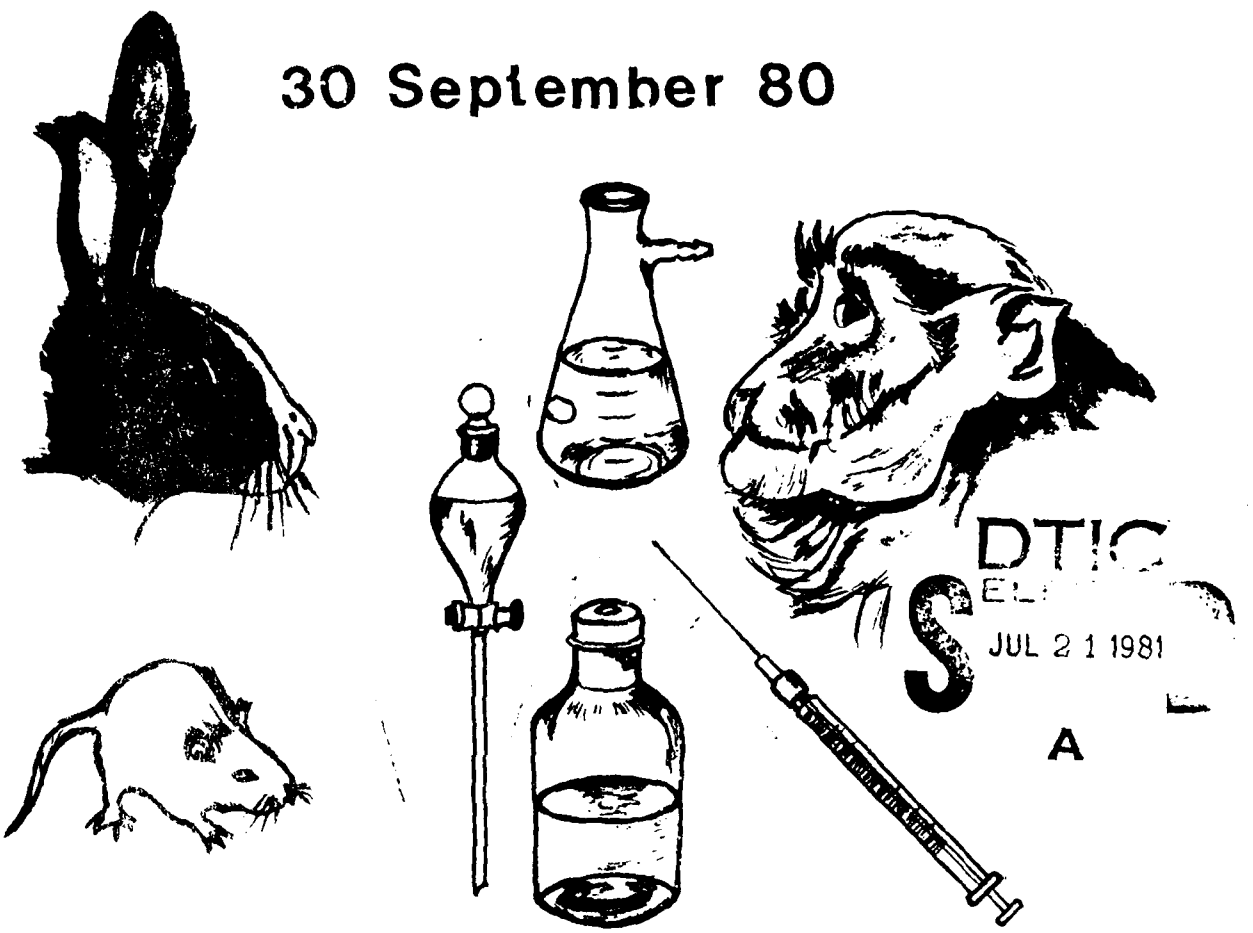

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045

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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 1980 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 Reg. 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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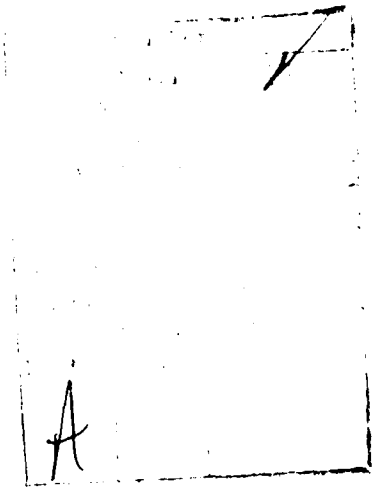

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30 SEPTEMBER 1980

CLINICAL INVESTIGATIONS (U)

FITZSIMONS ARMY MEDICAL CENTER

AURORA, COLORADO 80045

FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1980 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 Investigaton 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 MAJOR GENERAL Raymond H. Bishop, MC and BRIGADIER GENERAL William R. Dwyre, MC, Commanding Generals of Fitzsimons Army Medical Center, their professional and administrative staffs, 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

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

PUBLICATIONS

PUBLICATIONS

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Russell, J.R.: "Box" Technique for Irradiation of Esophageal Cancer and Breast Cancer: Comparison of Two Fractionation Schemes for Postoperative Radiation Therapy. Radiation Therapy Division, Collected Papers, Ninth Annual Radiation Therapy Clinical Research Seminar, Gainesville, Florida, Apr 1979.

Williams, B.D., Fisk, J.D.: Ultrasonic Diagnosis of Giant Urachal Cyst in the Adult. Am J of Roentgenology (In Press)

DEPARTMENT OF SURGERY

General Surgery Service

Davies, R.S.: Reflux Esophagitis. Chapter in book "Prognosis of Surgical Disease". W.B Saunders Co., B. Eiseman, Editor, 1980.

Ferraris, V.A., Sure, James: Retrospective Study of the Surgical Management of Reflux Esophagitis. Surg, Ob & Gyn, (In Press) (C)

Hirata, R.M.: Carcinoma of the Oral Cavity. Chapter in book "Prognosis of Surgical Disease, B. Eiseman, Editor, W.B. Saunders Co., 1980.

Mologne, L.: Varicose Veins. Chapter in book "Prognosis of Surgical Disease, B. Eiseman, Editor, W.B., Saunders Co., 1980.

Ophthalmology Service

Cottingham, Jr., A.J.: The Initial Fifty Intraocular Lens Implantations in an Ophthalmology Residency Training Program. Submitted for publication to Am J of Ophth. (C)

(C) Direct result of approved registered protocol

Department of Surgery - *continued*

Otolaryngology Service

Hasbrouck, J.M.: Performance of Students with Auditory Figure-ground Disorders under Conditions of Unilateral and Bilateral Ear Occlusion. J of Learning Disabilities (In Press)

Hasbrouck, J.M.: Speech Production and Perception as Related to the Assessment and Remediation of Auditory Perceptual Disorders. The Proceedings of the 18th Congress of Logopedics and Phoniatrics. (In Press)

Hasbrouck, J.M.: Speech Production and Perception as Related to the Assessment and Remediation of Auditory Perceptual Disorders. (Abst) Folia Phoniatrica 32:194, 1980.

Plastic Surgery Service

Rich, J.D., Shesol, B.F., Horne, D.W.: Basal Cell Carcinoma Arising in a Smallpox Vaccination Site. J of Clin Path, Feb 1980.

Rich, J.D., Zbylski, J.R., LaRossa, D.D.: Dermatofibrosarcoma Protuberans of the Head and Neck. The Am Surgeon , April 1980.

Shesol, B., Clarke, J.S.: Intrathoracic Application of the Latissimus Dorsi Musculocutaneous Flap. J of Plastic and Reconstructive Surgery (In Press)

Urology Service

Dobbs, R.M.: Clotting Predisposition in Carcinoma of the Prostate. J of Urology, 123:706, 1980. (C)

Fauver, H.E., Donohue, R.E., Whitesel, J.A., Augspurger, R.R., Pfister, R.: Prostatic Carcinoma - A Different Distribution. J of Urology, 122:397, 1979.

Fauver, H.W.: Pyelonephritis. Conn's Current Therapy (In Press)

Wilson, Torrence M., Fauver, H.W.: Leiomyosarcoma of Bladder. Urology 13:575, 1979.

(C) Direct result of approved registered protocol

PRESENTATIONS

PRESENTATIONS

DEPARTMENT OF MEDICINE

Allergy Service

Carpenter, G.B.: An Evaluation of Combined H_1 and H_2 Antagonists in the Treatment of Seasonal Allergic Rhinitis. Presented: Annual Meeting, American Academy of Allergy, Atlanta, GA, 16-20 Feb 1980. (C)

Dantzler, B.S.: Tissue Threshold Changes during the First Months of Immunotherapy. Presented: Annual Meeting, American Academy of Allergy, Atlanta, GA, 16-20 Feb 1980. (C)

Mansfield, L.E.: Canine Bronchoconstriction Provoked by Esophageal Distention and Acid Infusion. Presented: Annual Meeting, American Academy of Allergy, Atlanta,Ga, 16-20 Feb 1980. (C)

Mansfield, L.E.: Measurement of Blocking Antibody by Laser Nephelometry. Presented: Annual Meeting, American College of Allergists, Miami, FL, 22 Jan 1980. (C)

Martin, B.G.: Patterns of Cross Allergenicity Among Grasses. Presented: Annual Meeting, American Academy of Allergy, Atlanta, GA, 16-20 Feb 1980.(C)

Nelson, H.S.: Allergens: Selection and Handling. Presented: Annual Post-graduate Program Association for the Care of Asthma, Miami, FL, 18 Jan 1980.

Nelson, H.S.: Allergy Immunotherapy. Presented: 8th Annual Symposium NJH/NAC, Keystone, CO, 8 Jan 80.

Nelson, H.S.: Hyposensitization: Practical Considerations in Future Prospects. Presented: Kansas City Allergy Society Annual Meeting, Kansas City, MO, 3 May 1980.

Nelson, H.S.: Practical Application of Standardization and Studies of Extracts Stability. Presented: Annual Meeting. Kansas City Allergy Society, Kansas City, MO, 3 May 1980. (C)

Nelson, H.S.: Present Concepts of Aspirin Sensitivity in Asthma. Presented: Annual Scientific Meeting, American Thoracic Society, Washington, DC, 14 May 1980. (C)

Smith, J.A.: The Effect of an H_1 and H_2 Receptor Antagonist Alone and in Combination on Dermographism. Presented: Annual Meeting, American Academy of Allergy, Atlanta, GA, 16-20 Feb 1980. (C)

Spaulding, H.S.: Variability of Allergy Extract Prescribing. Presented: Annual Meeting American College of Allergists, Miami, FL, 22 Jan 1980.

(C) Direct result of approved registered protocol

Allergy Service - continued

Tipton, W.R.: Titrated Skin Tests, RAST and Blocking Antibody Changes with Rush Immunotherapy. Presented: Annual Meeting, American College of Allergists, Miami, FL, 22 Jan 1980. (C)

Cardiology Service

Crone, R.A.: The Effect of Volume Overload and LV Function on the Preoperative Evaluation of Subvalvular Fibrosis in Mitral Stenosis. Presented: The 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, CA, May 1980.

Febres-Roman, P.R.: Intravascular Hemolysis after Aortic Valve Replacement with the Ionescu-Shiley Xenograft. Presented: The 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, CA, May 1980.

Trnka, K.E.: Total Occlusion of the Left Main Coronary Artery. Presented: The 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, CA, May 1980.

Dermatology Service

Aeling, J.L.: An Approach to the Histopathologic Diagnosis. Presented: Practical Skin Pathology Course, Colorado Springs, CO, Oct 1980.

Aeling, J.L.: Sun Rashes and Sun Screens. Presented: University of Colorado Family Practice Review, Estes Park, CO, April 1980.

Aeling, J.L.: Superficial and Deep Fungi, Contaminants and Yeast Infections. Presented: Owen Pre-Board Slide Seminar, Chicago, IL, Sep 1980.

Eubanks, S.W.: Pseudolymphoma. Presented: Annual Meeting of the American Academy of Dermatology, Chicago, IL, Dec 1979.

Gentry, R.H.: Eruptive Collagenoma. Presented: Annual Meeting of the American Academy of Dermatology, Chicago, IL, Dec 1979.

Graff, G.E.: Current Concepts of Dermatitis Herpetiformis. Presented: 85th Annual Convention and Seminar, American Osteopathic Association, Las Vegas, Nevada, Nov 1980.

Graff, G.E.: Perforating Granuloma Annulare. Presented: Annual Meeting of the American Academy of Dermatology, Chicago, IL, Dec 1979.

Grimwood, R.E.: Herpes Gestationis. Presented: Annual Meeting of the American Academy of Dermatology, Chicago, IL, Dec 1979.

(C) Direct result of approved registered protocol

Dermatology Service - continued

May, D.L.: Common Problems in Dermatology. Presented: Regional H.E.W. Meeting, Boulder, CO, Mar 1980.

May, D.L.: Interpreting Special Stains and Artifacts. Presented: Practical Skin Pathology Course, Colorado Springs, CO, Oct 1980.

McCoy, J.A.: Localized Mycosis Fungoides. Presented: Annual Meeting of the American Academy of Dermatology, Chicago, IL, Dec 1979.

Patterson, J.W.: Bowenoid Papulosis. Presented: AFIP Annual Lectures, Washington, DC, May 1980.

Patterson, J.W.: Bowenoid Papulosis. Presented: American Society of Dermatopathology/International Academy of Pathology, New Orleans, LA, Feb 1980.

Thompson, P.B.: Desmoplastic Trichoepithelioma. Presented: Annual Meeting of the American Academy of Dermatology, Chicago, IL, Dec 1979.

Endocrine Service

Hofeldt, F.D.: Blood Glucose Control: Is It Worth It? Presented: Recent Advances in Diabetes Management Symposium, Denver, CO, 15 Oct 1980.

Hofeldt, F.D.: Osteoporosis Update 1980. Presented: Annual Meeting Colorado Academy of Family Physicians, Vail, CO, 1-3 Aug 1980.

Hofeldt, F.D.: The Estrogen Controversy. Presented: Annual Meeting of Colorado Society of Osteopathic Medicine. Broadmoor Hotel, Colorado Springs, CO, 17 May 1980.

Hofeldt, F.D.: The Lipid Controversy. Presented: Regional Conference in Internal Medicine, FAMC, Aurora, CO, 6-8 February 1980.

Jones, R.E.: Salicylic Acid Stimulation of Palmitic Acid Oxidation by Rat Skeletal Muscle Mitochondria. Presented: Hugh Mahon Lectureship Award, FAMC, Aurora, CO, 14 Jun 1980. (C)

Kidd, G.S.: Unusual Manifestations of Hyperthyroidism. Presented: USA Regional Short Course, FAMC, Aurora, CO, Jan 1980.

Hematology/Oncology Service

DiBella, Nicholas, J.: Advances in Chemotherapy. Presented: American Cancer Society Seminar for Nurses and Allied Personnel, Denver, CO, 23 Feb 80.

(C) Direct result of approved registered protocol

Endocrine Service - continued

DiBella, N.J.: Cancer Research Protocols - How and Why. 12th Annual Radiation Therapy Symposium for Technologists, 14-15 Mar 1980.

DiBella, N.J.: Myeloproliferative Disorders and Leukemias. Presented: Postgraduate Conference in Clinical Laboratory Practice, Colorado Association Continuing Medical Laboratory Education, Boulder, CO, 30 June - 3 July 1980. (C)

DiBella, N.J.: Pain Control in the Cancer Patient, Psychosocial Support of the Cancer Patient. Presented: Interim Session, Colorado Medical Society, Denver, CO, 29 Feb - 2 Mar 1980.

Pulmonary Function Lab

Kindig, N.B., Perry, M.E., Browning, R.J.: $DLCO_{SS}$ Correction Using PaCO Back Pressure Predicted from Venous Blood. Presented: AAMI, 15th Annual Meeting, San Francisco, CA, April 13-17, 1980. (C)

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

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

Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography. Presented: AAMI, 15th Annual Meeting, San Francisco, CA, April 13-17, 1980. (C)

DEPARTMENT OF CLINICAL INVESTIGATION

Damato, J.J.: Biochemical Methods for Differentiating Mycobacteria. Presented: Colorado State University, Ft. Collins, CO, May 1980. (C)

Damato, J.J., Rothlauf, M.V., McClatchy, J.K.: Differentiation of Tubercle Bacilli and Nontuberculous Mycobacteria by a Radiometric Method. Presented: Annual Meeting of the American Society for Microbiology, Miami Beach, FL, May 1980. (C)

Damato, J.J., Rothlauf, M.V., McClatchy, J.K.: Differentiation of Tubercle Bacilli and Nontuberculous Mycobacteria by a Radiometric Method. Presented: National Jewish Hospital and Research Center, Denver, CO, June 1980. (C)

(C) Direct result of approved registered protocol

Department of Clinical Investigation - continued

Glab, W.N., Corby, D.G., Decker, W.J., Coldiron, V.R.: Prevention of Propoxyphene Adsorption by Activated Charcoal in Rats: Clinical and Pharmacological Correlations. Presented: AACT/AAPCC/CACAT Meeting "Clinical Toxicology '80", Minneapolis, MN, 6 Aug 1980. (C)

Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Mouse Mammary Tissues. Presented: 31st Annual Meeting, Tissue Culture Association, St. Louis, MO, 4 June 1980. (C)

Zolock, D.T., Askew, E.W.: Carbohydrate Metabolism of the Red Blood Cell during Exercise in Rats. Presented: American Society of Biological Chemists, New Orleans, LA, June 1980. (C)

DEPARTMENT OF NURSING

Ellis, C.J.: Ethical Decisions of Neonatal Intensive Care. Presented: Academy of Health Sciences, Ft. Sam Houston, TX, August 1980. (C)

Turner, B.S.: Development of a Regionalized Neonatal Outreach Education Program at a Major Medical Center. Presented: Academy of Health Sciences, Ft. Sam Houston, TX, August 1980.

Turner, B.S.: Nursing Implications in Utilization of T_{tc} O_2 Monitoring in the Critically Ill Neonate. Presented: Colorado Nurses Association, Denver, CO, April 1980.

DEPARTMENT OF OB-GYN

Bobitt, J.R., Brown, G.L., Tull, A.H.: Group B Streptococcal Neonatal Infection: Clinical Review of Plans for Prevention and Preliminary Report of Quantitative Antepartum Cultures. Presented: OB-GYN Infectious Disease Symposium, Boca Raton, FL, Dec 1979. (C)

Bobitt, J.R., Damato, J.J., Hayslip, C.C.: Amniotic Fluid Infection in Premature Labor Patients with Intact Membranes: As Determined by Transabdominal Amniocentesis. Presented: 29th Annual Armed Forces Seminar & 19th Annual Armed Forces District Meeting of Obstetricians and Gynecologists, Orlando, FL, Oct 1980. (C)

DEPARTMENT OF PEDIATRICS

Brouchard, B.H., Berger, M., Cunningham, R.J., Petruskick, T.W., Allen, W.R., Travis, L.B.: Peritoneal Dialysis in Children. Presented: ASAIO, New York, 1979.

Cadol, R.: An Overview of Developmental Problems in Germany. Presented: Uniformed Services Pediatric Seminar, Seattle, WA, March 1980.

(C) Direct result of approved registered protocol

Department of Pediatrics - continued

Gumbiner, C., Gutgesell, H.P.: Effect of Isometric Exercise of Left Ventricular Function in Children with Left Ventricular Volume Overload. Presented: American Academy of Pediatrics Annual Meeting, Cardiology Section, San Francisco, CA, Oct 1979.

Gumbiner, C., Mullin, C., McNamara, D.: Pulmonary Artery Sling. Presented: American Academy of Pediatrics Annual Meeting, Cardiology Section, San Francisco, CA, Oct 1979.

Gumbiner, C., et al: The Electrophysiologic Effects of Chronic Digoxin Administration in the Healthy Awake Puppy. Presented: Society of Pediatric Research, San Antonio, TX, May 1980.

Kilbride, H.W.: Controlled Trial on the Use of Transcutaneous Oxygen Monitoring in Infants with RDS. Presented: Aspen Conference on Perinatal Research, Aspen, Colorado, July 1980.

Kilbride, H.W.: Transcutaneous Oxygen Monitoring. Presented: Aspen Conference on Perinatal Research, Aspen, CO, July 1980. (C)

Madden, W.A., Parry, W.H.: Use of the Fiberoptic Bronchoscopy in the Neonatal Intensive Care Unit. Presented: District VIII, AAP, Perinatal Meeting, Park City, Utah, Apr 1980. (C)

Merenstein, G.B.: Neonatal Update. Presented: Symposium of Children's Orthopedics, Aurora, CO, 9-11 Jan 1980.

Merenstein, G.B.: Transport and Intraventricular Hemorrhage. Presented: 3rd Annual Conference on Neonatal Transport, Children's Hospital, Denver, CO, 9-11 Apr 1980.

Merenstein, G.B.: Neonatal Transport: Where We Have Been. Presented: 3rd Annual Conference on Neonatal Transport, Children's Hospital, Denver, CO, 9-11 Apr 1980.

Merenstein, G.B.: Neonatal/Maternal Transport: Where Are We Going? Presented: 3rd Annual Conference on Neonatal Transport, Children's Hospital, Denver, CO, 9-11 Apr 1980.

Merenstein, G.B.: Spectrum of Group B Streptococcal Disease. Presented: Aspen Conference on Perinatal Research, Aspen, CO, July 1980. (C)

Merenstein, G.B.: Prevention of Group B Streptococcal Disease. Presented: American Academy of Pediatrics Section on Perinatal Pediatrics in Park City, Utah, 15-17 May 1980. (C)

Parry, W.H., Madden, W.A.: Bronchoscopy in the Neonatal Intensive Care Unit. Presented: 2nd World Congress of Bronchology Dusseldorf, West Germany, June 1980.

(C) Direct result of approved registered protocol

Department of Pediatrics - continued

Parry, W.H., Madden, W.A.: Bronchoscope Findings in Bacterial Laryngotracheobronchitis. Presented: 2nd World Congress of Bronchology, Dusseldorf, West Germany, June 1980.

Pierce, J.R.: Streptococcal Sudden Unexpected Death Syndrome. Presented: American Academy of Pediatrics Section on Perinatal Pediatrics in Park City, Utah, 15-17 May 1980. (C)

Sanders, J.: The Office Approach to the Adolescent Patient. Presented: (Visiting Professor) William Beaumont Army Medical Center, El Paso, TX, Jan 1980.

Sanders, J.: Sexually Transmitted Diseases. Presented (Visiting Professor) William Beaumont Army Medical Center, El Paso, TX, Jan 1980.

Sanders, J.: Office Approach to the Adolescent Patient. Presented: American Academy of Pediatrics CME Course, Scottsdale, Arizona, Jan 1980.

Sanders, J.: Contraception and the Adolescent. Presented: AAP CME Course, Scottsdale, Arizona, Jan 1980.

Sanders, J.: Sexually Transmitted Disease. Presented: AAP CME Course, Scottsdale, Arizona, Jan 1980.

Sanders, J.: Sexually Transmitted Diseases. Presented: 89th Annual Meeting, Arizona Medical Association, Phoenix, April 1980.

Sanders, J.: Teenage Sexuality. Presented: 89th Annual Meeting, Arizona Medical Association, Phoenix, Arizona, April 1980.

Sanders, J.: Common Gynecological Problems of Adolescent Girls. Presented: 29th Annual Assembly, Kentucky Chapter AAFB, Louisville, KY, May 1980.

Sanders, J.: Psychosocial Growth Tasks of Adolescence. Presented: 29th Annual Assembly, Kentucky Chapter AAFB, Louisville, KY, May 1980.

Sanders, J.: Talking to Teenagers about Sexuality. Presented: Spring Meeting Colorado Chapter AAP, Colorado Springs, CO, May 1980.

Sanders, J.: Sexually Transmitted Diseases. Presented: Region VIII Conference, National Health Service Corps, Boulder, CO, March 1980.

Wells, D., Sanders, J.: Adolescent Gynecology. Presented: 4th Annual Air Force Nurse Practitioner Workshop, Colorado Springs, CO, Jan 1980.

(C) Direct result of approved registered protocol

Department of Pediatrics - continued

Wells, D.,Sanders, J.: Teenage Pregnancy. Presented: 4th Annual Air Force Nurse Practitioner Workshop, Colorado Springs, CO, Jan 1980.

Yeatman, G.: Subtle Presentation of Chromosomal Disorders in Older Children and Adolescents. Presented: Section on Military Pediatrics, American Academy of Pediatrics, San Francisco, CA, Oct 1979.

DEPARTMENT OF PSYCHIATRY

Golosow, N.: DSM III. Presented: AMEDD Military Psychiatry Course, William Beaumont Army Medical Center, El Paso, TX, April 1980.

DEPARTMENT OF RADIOLOGY

Fisk, J.D.: Gastrointestinal Radiographic Features of Human Graft-Versus Host Disease. President's Award Paper 1980. Presented: American Roetgen Ray Society Annual Meeting, Las Vegas, NV, April 1980.

Fisk, J.D.: Gastrointestinal Radiographic Features of Human Graft-Versus Host Disease. President's Award Paper 1980. Presented: The Rocky Mountain Radiological Society, Denver, CO, Aug 1980.

McNeill, D.H., et al: Diagnosis of Carotid Artery Dissection/? Therapy. Presented: The Rocky Mountain Radiological Society's 42nd Midsummer Radiological Conference, Denver, CO, Aug 1980.

Orcutt, J.: CPA CT Gamuts. Presented: Radiological Society of North America, Atlanta, GA, Nov 1979.

Russell, J.R.: "Box" Technique for Irradiation of Esophageal Cancer and Breast Cancer: Comparison of Two Fractionation Schemes for Postoperative Radiation Therapy. Presented: Ninth Annual Radiation Therapy Clinical Research Seminar, Gainesville, FL, 26-28 April 1979.

Russell, J.R.: Salivary Gland Tumors. Presented: Tenth Annual Radiation Therapy Clinical Research Seminar, Gainesville, FL, 24-26 April 1980.

SOCIAL WORK SERVICE

Robichaud, M.J.: The Impact of the Fitzsimons Army Medical Center Discharge Planning Program. Presented: Biennial US Army Social Work Symposium, Ft. Sam Houston, TX, March 1980.

DEPARTMENT OF SURGERY

General Surgery Service

Ferraris, V.A., Subb[illegible]: A Prospective Study of the Surgical Management of Reflux Esophagitis. Presented: William Beaumont Army Medical Center, El Paso, TX, March, 1[illegible]

(C) Direct result of a [illegible] registered protocol

Department of Surgery - continued

Cottingham, Jr., A.A.: Residual Astigmatism-Postoperative Keratoplasty. Presented: American Academy of Ophthalmology, Chicago, IL, 7 Nov 1980. (C)

Otolaryngology Service

Bender, D.R., Causey, G.D.: The Effects of Several Competing Signals on Aided Hearing Performance. Presented: American Speech and Hearing Association Convention, Atlanta, GA, November 1979.

Hasbrouck, N.J.: Speech Production and Perception in Relation to Understanding, Evaluating and Treating Auditory Perceptual Disorders. Presented: University of Montana, Missoula, Montana, April 1980.

Hasbrouck, J.M.: Speech Production and Perception in Relation to Understanding, Evaluating and Treating Auditory Perceptual Disroders. Presented: Montana Speech and Hearing Association, Butte, Montana, April 1980.

Hasbrouck, J.M.: Speech Production and Perception as related to Assessment and Remediation of Auditory Perceptual Disroders. Presented: 18th Congress of the International Association of Logopedics and Phoniatrics, Washington, DC, August 1980.

Jarchow, R.C.: ENT Emergencies. Presented: National Public Health Service Symposium, Boulder, CO, March 1980.

Plastic Surgery Service

Gottlieb, V.: Metastatic Squamous Cell Carcinoma Presenting as a Felon. Presented: Annual Meeting, Association of Military Plastic Surgeons, Washington, DC, 1980.

Rich, J.D.: Post-traumatic Skull Defects. Presented: Annual Meeting, Association of Military Plastic Surgeons, Washington, DC, Jan 1980.

Shesol, B.: Changing Concepts of Lymphedema. Presented: Annual Meeting, Association of Military Plastic Surgeons, Washington, DC, Jan 1980.

Urology Service

Fauver, H.W.: Adverse Reactions to Drugs Used by Urologists. Presented: Postgraduate Seminar, American College of Surgeons, Chicago, IL, Oct 1979.

Fauver, H.W.: Prostatic Carcinoma: A Prospective Distribution and the Influence of Grade of Tumor or Results of Lymphadenectomy. Presented: Kimbrough Urological Seminar, Rosslyn, VA, Nov 1979.

Vaccaro, J.A.: Transrectal Prostate Biopsies-Adverse Effects of Cystoscopy. Presented: Kimbrough Urological Seminar, Rosslyn, VA, Nov 1979.

(C) Direct result of approved registered protocol

UNIT SUMMARY SHEET

UNIT SUMMARY SHEET

Clinical Investigation Program, FAMC

Clinical Investigation efforts by FAMC personnel in FY 80 culminated in the publication of 124 articles and 107 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1980, there were 138 research protocols on the DCI register. Of these, 91 projects were ongoing and 48 were new registrations.

Objectives:

To encourage the performance of clinically-oriented research 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; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of

Clinical Investigation Protocols and Reports, as amended. 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	Actual	Name
C, Dept of Clin Invest	06	60P9B	MC	1	1	Corby
C, Immuno Service	03	68A00	MS	1	1	Whiteaker
Internist	05	61F9C	MC	0	1	Charles
Lab Admin	04	68F00	MS	1	1	Quigg
C, Surg Rsch Labs Svc	03	68J00	MS	1	1	Harbell
C, Micro Svc	05	68A00	MS	1	1	Engelkirk
Veterinarian	03	64F00	VC	1	1	Stockberger
C, Biochem Svc	03	68C00	MS	1	1	Zolock
NCOIC	E7	92B4R		1	1	Underhill
Sr, Med Lab NCO	E7	92B4R		1	1	Engle
Sr. O.R. SP	E6	91D3R		1	1	Smith, N.
Bio Sci Asst	E6	01H20		0	1	Glab
Bio Sci Asst	E5	01H20		1	1	Kramer
Bio Sci Asst	E5	01H20		1	1	Kessens
Bio Sci Asst	E6	01H20		1	1	Chadwick
Bio Sci Asst	E5	01H20		1	1	Harrington
Bio Sci Asst	E5	01H20		0	1	Jones
Bio Sci Asst	E4	01H20		0	1	Nicholson
Vet SP	E6	91T3R		1	1	Rich
Supervisory Res Chem	13	1320 GS		1	1	O'Barr

Description	Grade	MOS	Br	Auth	Actual	Name
Microbiologist	11	0403 GS		2	2	Lima Paine
Microbiologist	09	0403 GS		4	4	Morse Nelson Rangel Rothlauf
Med Technologist	09	0644 GS		1	1	Rush
Research Chemist	09	1320 GS		4	4	McNamara Noble Swanson Waldrup
Microbiologist	07	0403 GS		3	2	Feuerstein Ledoux
Bio Lab Tech	07	0404 GS		1	1	Hakes
Animal Bio Lab Tech	08	0404 GS		1	1	Jones
Animal Tech	07	0404 GS		1	1	Mercill
Ed Asst	06	0318 GS		1	1	McCrill
Animal Caretaker	05	7706 WG		2	2	Beltran Hitchcock
Clerk-steno	04	0318 GS		1	1	Moran

	FY 78	FY 79	FY 80
Civilian Pay	363,962	331,352	434,911
Travel	3,660	5,584	5,240
Supplies	161,431	179,883	189,998
Equipment	28,500	108,165	104,311
Contracts	16,429	16,397	18,598
Other(Military)	293,432	349,116	345,859

Progress

DCI received from Health Services Command (HSC) a microbiology training position. This program brings in a qualified aspirant at the GS05 entrance level and, upon successful completion of a rigorous training programs, allows for non-competitive promotion to GS07 and finally the GS09 Microbiologist journeyman level.

Historically, Fitzsimons Army Medical Center has provided leadership in the identification and treatment of tuberculosis in the military community. indepth mycobacterial studies on patients, i.e., serum drug levels, serum inhibition tests, identification of mycobacteria other than M. tuberculosis, and drug susceptibility testing, are provided. In accordance with the Commanders' directive, DCI provides mycobacteriology (TB) support (processing clinical specimens and/or reference cultures) to the following centers:

MEDDAC Units: Ft. Carson, Ft. Leavenworth, Ft. McPherson, Ft. Ord, Ft. Riley, Ft. Sill

Army Medical Centers: Letterman, Madigan, Tripler

USAF Facilities: Baker's Field, Minot AFB, Scott AFB

Additionally, TB reference laboratory support is furnished to the PHS, Pine Ridge Reservation, S.D.

The Mycobacteriology Laboratory Section, Microbiology Service, DCI, has maintained College of American Pathologists (CAP) accreditation.

The Surgical Research Laboratories (SRL) Service supports research and training protocols and provides all of the laboratory animal care for Fitzsimons Army Medical Center. The research animal support includes a daily small animal population of approximately 800 animals, comprised of mice, rats, guinea pigs, chicks, rabbits, non-human primates, cats and dogs. It is projected that sheep, goats and swine will soon be added. The scope of support includes veterinary clinical laboratory services, radiology, histopathology, tissue culture, electron microscopy, medical photography, veterinary pharmacotherapeutics, and a full surgical support capability, including cardiopulmonary bypass and microsurgery, as well as the pre- and post-operative care of lab animal research subjects. The urgent minor construction request for an Animal Housing Facility has been fully approved through Congress and construction is scheduled to begin in FY 81, pending funding. A complete listing of training provided by SRL is located on DCI detail sheet, "Training Support, SRL, DCI", immediately following the DCI Annual Progress Reports.

Funding

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

MEDCASE items which were purchased for specific protocols are so annotated. The remaining items were purchased for general laboratory use.

ITEM	PROCOTOL #	COST
Zoom Stereoscope	79/118	$6149.00
Ion Generator	78/116	$5000.00
Poultry Cages	79/301	$2929.00
Microtome/Cryostat	79/304	$5494.72
Tissue Embedder	79/300	$1948.18
Forma CO_2 Incubator	77/300 and 80/400	$2250.00
Ultrasonic Cleaner		$1260.00
Infusion Pump		$1277.75
Orion PH Meter		$1728.13
Mettler Balance		$2710.47
Binocular Microscope		$2058.70
Beckman TJ-6R		$2834.00
Chromatography Chamber		$2894.00
Rabbit Cages (2)ea.		$3200.00
Guinea Pig Cage		$2337.31
Freeze Dryer		$5156.10
Fraction Collector		$1949.00
Forma Lo-Temp Freezer		$5268.00
Puffer Hubbard 50LR Refrigerator		$2443.00
Beckman L-8 Ultra Centrifuge		$28,634.04

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.

TABLE OF CONTENTS

TABLE OF CONTENTS

REPORT NO. 16

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

Ongoing (0), Completed study terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

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

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

Page

DEPARTMENT OF CLINICAL INVESTIGATION

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

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

PATHOLOGY

PSYCHOLOGY

RADIOLOGY

RESEARCH

Ongoing (O), Completed (C), [illegible] Submitted for Publication (SP), Presented [illegible]

DETAIL SHEETS

MEDICINE

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 73/135	(3) Status: on-going
(4) Title: Active Antigens in House Dust		
(5) Start Date: 1973		(6) Est Comp Date: 1981
(7) Principal Investigator Harold S. Nelson, MD		(8) Facility: FAMC
(9) Dept/Sec: Medicine/All-Imm.		(10) Assoc Investigators: Lyndon E. Mansfield, MD, LTC, MC Bruce Martin, MD, CPT, MC, USAF
(11) Key Words: House Dust		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:
To determine to what degree the reactivity of commercial house dust extract is related to its content of recognized allergens such as animal dander and mite products.

(16) *Technical Approach:
Use of pooled house dust allergic serum and RAST inhibition employing allergen disks manufactured in the allergy research laboratory.

(17) *Progress:
Additional studies were done during this period expanding the number of known allergens tested against house dust. Further studies will be required during the ensuing year.

FAMC WU No (Prot No) 1

73/135

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Mansfield, L.E., Nelson, H.S., Allergens of Commercial House Dust Extracts (Abstract), Journal of Allergy and Clinical Immunology, 63:212; 1979

FAMC WU No (Prot No) 73/135

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Mansfield, L.E., Allergens of Commercial House Dust Extracts, Annual Meeting Academy of Allergy, New Orleans, Louisiana, 25 March 1979.

(2) Martin, Bruce, Analysis of the Allergens of Commercial House Dust, Annual Allergy-Immunology Pulmonary Symposium, Fitzsimons Army Medical Center, 21 January 1981.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 74/101 (3) Status: Ongoing		
(4) Title: Immuno-chemical Evaluation of Myeloproliferative and Plasma-proliferative Diseases.		
(5) Start Date: 1 Jul 74		(6) Est Comp Date: Oct 81
(7) Principal Investigator Nicholas J. DiBella, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Medicine/Hematology Svc		(10) Assoc Investigators: George L. Brown, Ph.D.,COL,MSC R. Stephen Whiteaker, Ph.D., CPT, MSC
(11) Key Words: Immunodiagnosis Myeloproliferative Plasmaproliferative		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 1/80

(15) *Study Objective:
To determine whether there are any alterations of serum protein profiles in myeloproliferative and plasmaproliferative disease.
To determine whether there are any alterations of serum protein profiles and lymphocyte transformation in myeloproliferative and plasmaproliferative diseases.

(16) *Technical Approach:
This is in-depth immunologic evaluation of patients with myeloproliferative and plasmaproliferative disorders.

(17) *Progress:
Three patients with myeloproliferative and forty-three with plasmaproliferative disorders were studied immunologically. I. Myeloproliferative Disorders: Results recorded were as follows: No monoclonal gammopathies, serum immunoglobulin levels were recorded within normal limits, Lymphocyte blast transformation to PHA was suppressed.
II. Plasmaproliferative Disorders: Results recorded were as follows: Fifteen subjects studied had IgG monoclonal gammopathies with evidence

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 74/101

(17) continued-

of free light chains in the serum. Seven patients were found to have elevated serum IgM levels with monoclonal gammopathies, differentiated as IgM type. One patient each with IgA and IgD monoclonal gammopathy was studied. One case denoting immunoglobulin light chain disorder was recorded.

FAMC WU No(Prot No) 74/101

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Hematology-Oncology DEPARTMENT of Medicine

(1) Brown, G.L., DiBella, N.J., and Corby, D.G.: IgE-IgM Kappa Gammopathy Associated with Lymphocytic Lymphoma. Federation Proceedings 35:438, 1976.

(2) Brown, G.L., Corby, D.G., DiBella, N., and Lima, J.: IgE-IgM Gammopathy Associated with Lymphocytic Lymphoma: Immunologic Considerations. Mil Med, 142:921, 1977.

(3) DiBella, N.J., and Brown, G.L.: Immunologic Dysfunction in the Myeloproliferative Disorders. Cancer 42:149, 1978.

PRESENTATIONS:

(1) DiBella, N.J., and Brown, G.L.: Cellular and Humoral Immunity in the Myeloproliferative Disorders. Presented: Annual Joint Meeting of the American College of Physicians and American Society of Internal Medicine, Colorado Regional Meeting, Colorado Springs, CO, January 15, 1976.

(2) Brown, G.L., DiBella, N.J., and Corby, D.G.: IgE-IgM Kappa Gammopathy Associated with Lymphocytic Lymphoma. Presented: FASER Anaheim, CA, April 12, 1976.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: Indefinite	
(7) Principal Investigator Fred D. Hofeldt, COL, MC	(8) Facility: FAMC	
(9) Dept/Sec:	(10) Assoc Investigators: Gerald C. Kidd, LTC, MC David Zolock, MAJ, MC T.D. O'Barr, Ph.D., DAC A. Shackelford, MT, DAC Leonard E. Lobson, MAJ, MC	
(11) Key Words: reactive hypoglycemia glucose tolerance counter-regulartory hormones		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 11/79

(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, San Francisco, California.

(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 pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine,

(17) *Progress:

This study continues to be an active protocol with recruitment of patients with bona fide reactive hypoglycemia. The total number of patients started since the beginning of this protocol numbers approximately 500. The data on these patients is being stored on MISO computers and is currently undergoing a data analysis by Dr. Leonard Sanders. The project is to be continued as an ongoing Endocrine project with the assignment of new associate investigators

(16) Technical Approach (cont)

Endocrine Clinic, with the assistance of an assigned 68-5 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, is continually monitored by a cardiac monitor system and blood glucoses are assessed immediately after sampling by the Ames Reflectance Meter. 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) Progress (cont)

to replace those individuals who are currently not at Fitzsimons Army Medical Center. New interests will be directed towards to gastrointestinal factors important in the enteroinsular axis as possible pathophysiological alterations causal in this disease.

FAMC WU No (Prot No) 74/110

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Endocrine DEPARTMENT Medicine

(1) Abrams, A., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, J.: Late Reactive Hypoglycemia in Hypothyroidism. (Submitted for review to American Journal of Medical Sciences.)

(2) Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggins, J.T., and Eichner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients With Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia After Mixed Meals. (Submitted for review Annals of Internal Medicine.)

(3) Sanders, L.E., Hofeldt, F.D., Kirk, M., and Levin, J.: Food Abuse as a Cause of Reactive Hypoglycemia. American Journal of Clinical Nutrition (in press).

(4) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal, 76:30-34, 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, 144:177-179, 1979.

FAMC WU No (Prot No) 74/110

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Endocrine Service 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.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCP 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 75/107 (3) Status: on-going

(4) Title: A Comparison of the Results of Hyposensitization with Aqueous Grass Extract and Aluminum Precipitated Aqueous Extracted Grass Extract

(5) Start Date: 1975	(6) Est Comp Date: 1980
(7) Principal Investigator Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators: None.
(11) Key Words: Allergy Immunotherapy	

(12) Source of FUNDS: (13) Est Accumulative OMA Cost: (14) Man Years: 2/80

(15) Study Objective: continue

To compare the immunologic response to long term immunotherapy with aqueous and aluminum precipitated allergy extracts.

(16) Approach:

Maintaining the clinical tolerants for the extracts drawing blood twice annually for a period of four years and measuring the immune response by both the RIA IgE and IgG antibody assays.

(17) Progress:

During this fiscal year blocking antibody studies were performed on sera which had been collected over the period 1975 to 1978 with the scheduled publication of the results in the Annals of Allergy in December, 1980, the protocol will be completed.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 75/107

(4)Title: in the Treatment of Patients with Allergic Symptoms Due to Grass Allergy

FAMC WU No (Prot No)_____

75/107

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Nelson, H.S., A Three-Year Comparison of Immunotherapy with Alum Precipitated and Glycero-Saline Grass Extracts (Abstract) Annals of Allergy, 42:123;1979

(2) Nelson, H.S., A Comparison of Long-Term Immunotherapy with Aqueous and Alum Precipitated Grass Extracts, Annals of Allergy, Dec, 1980.

FAMC WU No (Prot No) 75/107

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Nelson, H.S., A Three-Year Comparison of Immunotherapy with Alum Precipated and Glycero-Saline Grass Extracts presented at the Annual Meeting of American College of Allergist, San Francisco, California, 29 Jan 79.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 75/116	(3) Status: Ongoing
(4) Title: Fractionation of Kochia Pollen with Isolation of Kochia Pollen Allergens		
(5) Start Date: 1975		(6) Est Comp Date: unknown
(7) Principal Investigator Harold S. Nelson, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec Medicine/Allergy-Immunol.		(10) Assoc Investigators: T.P. O'Barr, Ph.D., DAC
(11) Key Words: Purified Kochia Allergens		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 12/79

(15) *Study Objective:
To extract raw Kochia pollen and purify the principle allergens through chemical fractionation.

(16) *Technical Approach:
The study will employ multiple methods of separation of proteins with investigation of allergenic activity of the fractions by RAST assay.

(17) *Progress:
This project has been inactive since the original principle investigator was transferred. However, it will be resumed in the near future.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 75/118 (3) Status: Completed

(4) Title: A Study of the Stability of Allergy Extracts under Varying Conditions

(5) Start Date: 1975	(6) Est Comp Date: 1980
(7) Principal Investigator Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators: None
(11) Key Words: Extracts Stability	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/79

(15) *Study Objective:
To systematically explore the effects of several stabilizers on the loss of potency of allergy extracts at different concentrations, volumes and time intervals.

(16) *Technical Approach:
Allergy extracts were reconstituted from lyophilized sources at various time intervals prior to testing. Residual potency was compared with that of freshly reconstituted dilutions employing pooled allergic serum and RAST inhibition.

(17) *Progress:
Studies have been completed, and with the publication of the second paper on the subject currently in press in the Journal of Allergy and Clinical Immunology, this study is effectively finished.

FAMC WU No (Prot No)_____

75/118

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Nelson, H.S., Effect of Diluent and Conditions of Storage on Allergy Extract Potency (abstract), Journal of Allergy and Clinical Immunology, 63:195; 1979.

(2) Nelson, H.S., The Effect of Preservatives and Dilutions on the Deterioration of Russian Thistle (Salsola pestifer) A Pollen Extract, Journal of Allergy and Clinical Immunology, 63:417; 1979.

(3) Nelson, H.S., The Effect of Dilution and Conditions of Storage on Allergy Extract Potency, Journal of Allergy and Clinical Immunology (in press).

FAMC WU No (Prot No) 75/118

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Nelson, H.S., The Effect of Preservatives and Dilution on the Deterioration of a Pollen Extract--Russian Thistle (Salsola pestifer), Annual Meeting of the Academy of Allergy, Phoenix, Arizona, March, 1978.

(2) Nelson, H.S., Effect of Diluent and Conditions of Storage on Allergy Extract Potency, Annual Meeting Academy of Allergy, New Orleans, Louisiana, 24 March 1979.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: 1982	
(7) Principal Investigator: N. J. DIBELLA, MD, COL, MC	(8) Facility: FAMC	
(9) Dept/Sec: Hematology-Oncology	(10) Assoc Investigators: None	
(11) Key Words: Chemotherapy, CA of colon		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/80

(15) *Study Objective:

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

(16) *Technical Approach:

Clinical study.

(17) *Progress:

Four patients have been entered on this protocol. One patient is too early to evaluate, but the other three patients have failed to respond. No serious toxicities have been observed.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 76/103 (3) Status: Terminated

(4) Title: An Objective Measure of CNS Development in Children

(5) Start Date: 1 Jul 76 | (6) Est Comp Date: Terminated

(7) Principal Investigator: R. John Morgan, Jon H. Buscemi | (8) Facility: FAMC, Colorado State University

(9) Dept/Sec: Dept of Med., Neurology Svc | (10) Assoc Investigators: John W. Steadman, Ph.D. (CSU, CO); C. Norman Rhodine, Ph.D. (CSU, CO); Paul W. Daugherty, B.S. (CSU, CO); James W. Howell, B.S. (CSU, CO)

(11) Key Words: Central Nervous System Development in Children

(12) Accumulative MEDCASE Cost: | (13) Est Accumulative OMA Cost: | (14) Periodic Review Results: continue 2/80

(15) *Study Objective: A long term goal of the proposed research is to develop a clinical method of assessing central nervous system (CNS) development in children too young to be tested using behavioral methods. Early diagnosis of abnormal CNS development is of paramount importance in early institution of therapy which influences the prognosis. Such early diagnosis is not possible using testing methods which require verbal or written communication skills.

(16) *Technical Approach: The proposed research will develop a quantitative method of assessing CNS development and the data base for normal subjects. Abnormal development of the CNS, such as mental retardation, will be the subject of a later research. This study is designed to find parameters of the Electroencephalogram (EEG) which will be reliable quantitative measures of CNS development and establish the normal range of these parameters. The variation of these parameters with age in normal children will be established and
(17) *Progress: statistically tested for significance.

This protocol was terminated due to lack of sufficient number of patients and transfer of the investigator.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 76/105 (3) Status: Terminated
(4) Title: Evaluation of Testicular Function in Patients Receiving Cytotoxic Therapy

(5) Start Date: [illegible]	(6) Est Comp Date: Terminated
(7) Principal Investigator: [illegible]	(8) Facility: FAMC
(9) Dept/Sec: [illegible] Service	(10) Assoc Investigators: Nicholas J. DiBella, COL, MC
(11) Key Words: testicular [illegible] cytotoxic [illegible]	

(12) Accumulative MA Cost: Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic terminate Review Results: 5/80

(15) *Study Objective: To determine if there are abnormalities in testicular [illegible] cytotoxic therapy. To determine whether correction of [illegible] beneficial to the patients, particularly by improving testicular function or other testosterone related parameters such as muscle strength, weight gain, etc.

(16) *Technical Approach: Outpatients undergoing cancer chemotherapy were [illegible] study, if the expected survival was at least [illegible] months. Prior to treatment, the patients would be studied with LH, FSH, testosterone, estradiol, and semen analysis. Sexual history will be obtained and monitored by a questionnaire. Patients with decreased testosterone or increased LH will be treated with 200 mg of testosterone [illegible] every two weeks. All patients will continue to have endocrine [illegible].

(17) *Progress: No patients have been enrolled under this protocol. The principal investigator has left [illegible] Army Medical Center and the studies will not be continued. The study is to be terminated.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 76/105

Technical Approach, continued:

studies drawn and questionnaires filled out during the course of cancer chemotherapy.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 76/112	(3) Status: Completed
(4) Title: Study of the Effect of Tetracycline and Pleural Drainage on Pleural Effusion in Cancer Patients.		
(5) Start Date: 1976		(6) Est Comp Date: July 1980
(7) Principal Investigator: A. J. ZALOZNIK, MD, CPT, MC		(8) Facility: FAMC
(9) Dept/Sec: Hematology-Oncology		(10) Assoc Investigators: STEPHEN G. OSWALD, DO, CPT, MC
(11) Key Words: Pleural effusions, chest tube drainage.		
(12) Accumulative MA Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 10/79

(15) *Study Objective:

to determine in a prospective, randomized, double-blind fashion if pleural drainage and tetracycline are better than pleural drainage alone in the treatment of pleural effusion in cancer patients.

(16) *Technical Approach:

Patients with biopsy-proven malignancy with malignant infusion are being randomized to closed chest tube drainage alone or closed chest tube drainage with tetracycline. This is being done in a double-blind manner by the Pharmacy Service so ward physicians do not know if the patient is given tetracycline or the vitamin solution which looks the same as tetracycline.

(17) *Progress:

A complete resolution of the effusion was seen in 1 of 9 (11%) controls and 9 of 13 (69%) TCN patients; partial responses occurred in 1 of 9 controls and 1 of 13 patients; stabilization occurred in 2 of 9 controls and 2 of 13 TCN patients. Some patients treated with TCN experienced local discomfort and one patient developed a pleurocutaneous fistula.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 76/116	(3) Status: ongoing
(4) Title: The Effect of Dexamethasone on Gonadotropins in Post-menopausal Women	
(5) Start Date: [illegible]	(6) Est Comp Date: 1981
(7) Principal Investigator: Gary L. Prough, MAJ, MC	(8) Facility: FAMC
(9) Dept/Div: Obstetrics/Gynecology	(10) Assoc Investigators: William J. Georgitis, MAJ, CPT, MC
(11) Key Words: Dexamethasone; [illegible]; gonadotropins; post-menopause	
(12) Accumulative [illegible] Cost:	(13) Est Accumulative OMA Cost:
(14) Periodic Review Results: continue 12/79	

(15) Study Objectives: To clarify the mechanisms whereby glucocorticoids may interfere with gonadotropin secretion or release in post-menopausal women. This is of particular importance because of the high frequency of gonadal dysfunction in [illegible] female, with endogenous and well as exogenous [illegible] therapy.

(16) Approach: Patient population to be studied are healthy, post-menopausal women [illegible] menstruation. A post-menopausal woman will be defined as any woman with elevated plasma gonadotropin levels as a result of physiological [illegible] or prior surgical extirpation of the ovaries. A baseline AM plasma FSH, LH, cortisol and prolactin level will be drawn on two consecutive days prior to the subjects taking 2 mg qid po of Dexamethasone on three consecutive days. A.M. FSH, LH, cortisol and prolactin (Cont)

(17) *Progress: As reported in the Research Project Resume of 30 Sep 77, seven post menopausal females have been studied. Saline placebo injections prior to the [illegible] failed to alter hormone levels in three subjects. The basal levels and the response to GNRH for prolactin, FSH and LH was not significantly altered by Dexamethasone in five patients. An unanticipated new observation was that GNRH stimulated prolactin release in post-menopausal subjects with the time of the peak response being delayed by Dexamethasone. (Cont)

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 76/116

(16) Technical Approach - continued:
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 Dexamethasone treatment day. 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) Progress - continued:
Such a response by prolactin to GNRH has been reported recently in pre-menopausal women with secondary amenorrhea, but heretofore has not been reported for post-meropausal women.

FAMC WU No (Prot No) 76/116

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Endocrinology DEPARTMENT Medicine

(1). Treece, C., Hodgson, L.E., and Hofeldt, F.D.: Effect of GNRH on Post-Menopausal Gonadotropins and Prolactin Levels: Influence of Short-term Glucocorticoid Administration. Program and Abstracts, 61st Annual Meeting of the Endocrine Society, Anaheim, CA 1979.

FAMC WU No (Prot No) 76/116

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Endocrinology DEPARTMENT Medicine

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

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 77/103	(3) Status: on-going
(4) Title: Comparison of the Clinical and Immunological Response of Pre-seasonal and Co-seasonal Versus Post Seasonal Initiation of Allergy Immunotherapy		
(5) Start Date: 1977		(6) Est Comp Date: 1980
(7) Principal Investigator Brian Fortner, MAJ, MC		(8) Facility: FAMC
(9) Dept/Sec Medicine/Allergy-Immunolog.		(10) Assoc Investigators: William R. Tipton, COL, MC
(11) Key Words: Frequency of immunotherapy		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 1/80

(15) *Study Objective:
This study was altered somewhat in the protocol in order to gain more clinically meaningful data. In a double blind cross over, patients received immunotherapy to ragweed either on a weekly schedule or a monthly schedule with a cross over at two months. This was accomplished during the nonpollen season.

(16) *Technical Approach:
Immunological approaches including specific IgE (RAST), titrated skin test, blocking antibody (IgG), nasal provocation titrations, and conjunctival challenge were done on patients during a double blind cross over during four months of nonpollenating season to determine the effecacy of the immunotherapy related to the frequency of the injections. Weekly injections were compared with monthly injections.

(17) *Progress:
This data is now being accumulated for presentation in the next few months and possible publication.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 77/104	(3) Status: completed
(4) Title: Evaluation of Immunoglobulins and Immunoglobulin-Bearing Lymphocytes in Asthma		
(5) Start Date: 1977		(6) Est Comp Date: 1980
(7) Principal Investigator Harold S. Nelson, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.		(10) Assoc Investigators: Lyndon E. Mansfield, MD,LTC, MC
(11) Key words: Immunoglobulin levels in asthmatics		
(12) Accum [illegible] Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 1/80

(15) *Study Objective:
To determine whether patient's with bronchial asthma have mean immunoglobulin levels which are lower than normal for their age or have abnormalities of lymphocytes as determined by surface markers.

(16) *Technical Approach:
Blood was drawn, and a survey sheet completed on approximately 150 patients with bronchial asthma seen in the Allergy Clinic at Fitzsimons Army Medical Center. Immunoglobulin levels were performed on these blood samples.

(17) *Progress:
The data has been analyzed, and a previously unsuspected correlation between low immunoglobulin levels and beta adrenergic therapy was demonstrated. The data is currently in the final stages of preparation for publication. Upon publication this study will be completed.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 77/105 (3) Status: Completed

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

(5) Start Date: 1977	(6) Est Comp Date: unknown
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators: Richard W. Weber, LTC, MC
(11) Key Words: Chenopod cross allergenicity	

(12) Accumulative Man Year Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 5/80

(15) *Study Objectives:

To evaluate the cross allergenicity among pollens of the weed families, Chenopodiaceae and Amaranthaceae.

(16) *Technical Approach:

Twelve members of the Chenopod-Amaranth families were studied. Rabbit antisera were prepared and Ouchterlony immunodiffusion and inhibition of passive hemagglutination was performed. RAST inhibition was also performed employing pooled allergic serum and extracts of the 12 weeds.

(17) *Progress:

No further study has been performed on this protocol since the transfer of Dr. Weber to Europe two years ago.

FAMC WU No (Prot No)

77/105

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Weber, R.W., Nelson, H.S., An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae submitted to the 1978 Hugh-Mahon Lectureship Award Competition, awarded second prize.

(2) Weber, R.W., Mansfield, L.E., Nelson, H.S., Cross Reactivity among Weeds of the Amaranth and Chenopod Families (abstract), Journal of Allergy and Clinical Immunology, 61:172;1978.

FAMC WU No (Test No) 77/105

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Weber, R.W., Cross Reactivity among Weeds of the Amaranth and Chenopod Families, Annual Meeting Academy of Allergy, Phoenix, Arizona, 28 Feb 78.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 77/106	(3) Status: on-going
(4) Title: The Effect of Chronic Nonimmunologically Mediated Bronchial Constriction of Bronchial Smooth Muscle		
(5) Start Date: 1977		(6) Est Comp Date: 1981
(7) Principal Investigator David Pitman		(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm/Pathol.		(10) Assoc Investigators: L.E. Mansfield, MD, LTC
(11) Key Words: Bronchial smooth muscle		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 7/80

(15) *Study Objective:

To determine if the hyperactivity or constriction of the bronchial smooth muscle in asthmatic patients is the cause of the bronchial smooth muscle hypertrophy found in the asthmatic lung, and secondly, to determine if bronchodilators as presently used have any protective effect against this hypertrophy.

(16) *Technical Approach:

Guinea pigs were subjected to nonantigen mediated bronchoconstriction from the age of weaning to sexual maturity. The animals were then sacrificed, and bronchial muscle examined.

(17) *Progress:

All of the animals have been sacrificed. The histologic material is awaiting examination by Dr. Pitman.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-38, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 77/107	(3) Status: Terminate
(4) Title: L-Dopa Stimulation of Glucagon in Obesity		
(5) Start Date: 1977		(6) Est Comp Date: 1980
(7) Principal Investigator: Gary L. Treece, MD, LTC, MC		(8) Facility: FAMC
(9) Dept/Sec: Endocrinology Service		(10) Assoc Investigators: William J. Georgitis, MD, CPT, MC
(11) Key Words: L-Dopa, glucagon, obesity		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 4/80

(15) Study Objectives: It has been suggested that obese subjects have a deficiency of glucagon reserve. L-Dopa has been reported to cause a rise in serum glucagon levels in normal weight subjects. This study was designed to observe the effect of L-Dopa on serum glucagon levels and obese subjects compared to normal weighted controls.

(16) Technical Approach: The patient populations to be studied include 10 normal weight, non-diabetic subjects; 10 obese, non-diabetic subjects; and 10 obese diabetic subjects. In the latter group, subjects taking insulin and/or oral hypoglycemic agents will be excluded from the study. Diabetic subjects will be defined on the basis of standard 3-hour glucose tolerance tests. Subjects with a history of cardiovascular disease, glaucoma, melanoma, peptic ulcer disease, psychosis, and patients taking MAO inhibitors will be excluded (cont)

(17) Progress:

Concern that normal weighted and obese subjects might not receive an equivalent stimulus from a fixed dose of L-Dopa prompted an attempt to assess the dose response relationship of L-Dopa and serum glucagon. Oral doses of 500, 750 and 1000 mg of L-Dopa were tested in a single subject. Basal levels were very reproducible (coefficient of variation 5%). The lower dose produced no nausea, but severe, transient nausea was encountered at the higher doses about 30 minutes after ingestion of the drug. The well known (cont)

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 77/107

(16) Technical Approach - continued:
from the study. All subjects will be on a weight maintaining 150 gm carbohydrate diet three days prior to the study. If not previously documented in the subject's medical records, a 3-hour GTT will be performed on a day prior to L-Dopa administration. Subsequently, after an overnight fast, all will be given a 7.5 mg/kl dose of L-Dopa by mouth at 0800 hours. In the supine position, venous blood samples will be obtained from an indwelling scalp vein catheter at -15, 0, 15, 30, 45, 60, 90, 120 and 180 minutes for determinations of plasma glucose, growth hormone, insulin, glucagon and prolactin.

(17) Progress - continued:
suppression of prolactin and elevation of serum growth hormone levels was observed consistantly but glucagon did not show a consistant or even graded response.

Three additional studies of normal weighted subjects were done with a 500 mg dose of L-Dopa. Nausea occurred in one subject again at 30 minutes. Of the 4 tests done in normal weighted subjects with a 500 mg dose, 2 showed a rise in serum glucagon with peak values at 45 and 60 minutes of roughly 60% basal. One subject had a flat response and another a 25% fall from basal at 60 minutes. Again, prolactin and growth hormone responses were present in all subjects except for one who failed to show a growth hormone response. This implies that the L-Dopa had been taken and was active in all subjects.

Statistical analysis of the 4 normal weighted subjects' response by paired-t test analyzing absolute peak levels in pg/ml, peak percentage change from basal, or the areas under the curves by a method of intergrated rectangles failed to achieve a significant t value for $p < .05$ (the p value for areas under the curve was $> .20$). Although this represents a small sample it seems reasonable to conclude that it would be hazardous to continue the study further since a dose response in serum glucagon to oral L-Dopa was not demonstrated even though reasonable prolactin growth hormone responses were seen. The mean peak response of 4 normal weighted subjects was positive but small with a great deal of variability (mean = 38 pg/ml at both 30 and 60 minutes with standard deviations of 67 and 69, and standard errors of 33 and 34 at 30 and 60 minutes, respectively). This suggests that the assessment of glucagon reserve in obese subjects compared to normal weighted subjects is beyond the sensitivity of this method. This may be a result of the measurement of peripheral rather than portal venous levels of glucagon, poor sensitivity of the glucagon assay in the lower range, inadequate glucagon stimulation by L-Dopa, or some other undetermined factors. The hypothesis that glucagon reserve is diminished in obesity might be tested in peripheral blood by a more potent secretagogue if one is found in the future. It is possible that higher doses might provide an accurate assessment of glucagon reserve in peripheral blood, but the severe nausea encountered with higher doses makes this approach unreasonable.

Publications and Presentations: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 77/108 (3) Status: completed
(4) Title: A Comparison of the Clinical and Immunologic Responses to Grass Pollen Extract with or without the Addition of [illegible]
(5) Start Date: 1977 (6) Est Comp Date: 1980
(7) Principal Investigator (8) Other Investigators
William R. Tipton, COL, MC
(9) Dept/Sec: Medicine/Allergy-Immunol. (10) Contract No.
(11) Key Words:
Immunotherapy
Grass pollen extract

(12) Accumulated Manpower Cost: (13) Est Accumulated DMA Cost: (14) Continue or Results: 7/80
(15) *Study Objectives:
To determine whether there is a difference in the immunologic response to allergy injection therapy if the patients' maintenance extract contains glycerin as opposed to saline.

(16) *Technical Approach:
Alternate patients beginning immunotherapy with Timothy, were placed on one of the two types of grass pollen extract. Immunotherapy with this extract through one year was completed for IgE and blocking antibody levels before and after comparison.

(17) *Progress:
This data has been accumulated for [illegible] patients. Initial evaluation of the data [illegible] between the aqueous extract and glycerinated extract using the IgE (RAST) levels. Initially [illegible] were lower, due to the mobile population [illegible].

Publications and Presentations:

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: [illegible]	(3) Status: [illegible]
(4) Title: Effect of Chronic Oral Propranolol [illegible]		
(5) Start Date: [illegible]78	(6) Est Comp Date: [illegible]	
(7) Principal Investigator Gary L. Treece, [illegible]	(8) Facility: FAMC	
(9) Dept/Sec: Endocrine Service	(10) Assoc Investigators: None.	
(11) Key Words: Propranolol diabetes		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 6/80

(15) *Study [illegible]ive: To determine what effect propranolol given [illegible] for the treatment of hypertension and angina pectoris has on intravenous and oral [illegible] in light of recent case reports of hyper-glycemia [illegible] to propranolol therapy [illegible].

(16) *Technical approach: Patients with hypertension [illegible] started on [illegible] therapy will [illegible] for this study. [illegible] and [illegible] will be obtained [illegible]. The initial dose of proprano-lol will be 80 mg/[illegible] will be obtained at 2 and 6 weeks of therapy. [illegible] will be [illegible] to the propranolol therapy [illegible] obtained after [illegible] months of combined therapy. [illegible]

(17) *Progress:

[illegible] patients have been studied [illegible]. The principal investigator has left Fitzsimons Army Medical Center. The study is to be terminated.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 77/110

Technical Approach, continued.

disappearance rate (K value) and glucose tolerance will be examined. The effect of propranolol on insulin and glucagon levels will also be examined.

Publications and Presentations. None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(RCS 40-23, App. [illegible]) (Detail Summary Sheet)

(1) Date: 22 SEP 80 (2) Prot No.: 77/113 (3) Status: completed
(4) Title: A Study of Terbutaline Aerosol in the Treatment of Patients with Bronchial Asthma
(5) Start Date: 1977 (6) [illegible] Date: 1980
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC
(8) Facility: [illegible]
(9) Dept/Svc: Medicine/Allergy-Immunol. (10) Associate Investigators: .A. Smith, LTC, USAF, MC; R.W. Weber, LTC, MC
(11) Key Words: Terbutaline Bronchodilator subsensitivity
(12) Accumulative [illegible] Cost: (13) [illegible] Accumulative OMA Cost: (14) [illegible] continue; Review [illegible] 12/79
(15) Study [illegible]

To determine the effectiveness of freon propelled metered dose aerosolized Terbutaline as a bronchodilator administered on a regular, four-times daily [illegible]

Secondary considerations were to determine the development of subsensitivity and to compare the effectiveness of Terbutaline with that of Theophylline.

Fifteen patients [illegible] for a period of 12 weeks four times daily. [illegible] was measured initially and at the end of this [illegible] well as at two week intervals while receiving the drug. The first and last studies were performed double blind. Following completion of [illegible] long-term study, the patients were placed on optimal doses [illegible] and entered a double blind--cont.

This study was completed. The [illegible] between aerosolized Terbutaline and Theophylline is currently in press in the journal, Chest, while the 12-week subsensitivity [illegible] submitted for possible publication in the American Review of [illegible] Diseases with completion of these results. This study is [illegible]

16. cross over study in which a placebo was substituted for either the inhaled Terbutaline or the oral Theophylline. Response was monitored by four times daily measurement of pulmonary function.

PUBLICATIONS for FY 80 Annual Progress Report (End Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Smith, J.A., Weber, R.W., Nelson, H.S., Comparison of Aerosolized Terbutaline and Optimal Dose Theophylline in the Management of Bronchial Asthma (abstract), Annals of Allergy, 42:121;1979.

(2) Smith, J.A., Weber, R.W., Nelson, H.S., Long-Term Use of Aerosolized Terbutaline in the Treatment of Bronchial Asthma--The Development of Subsensitivity (abstract), American Review of Respiratory Disease, 119:170S;1979.

FAMC WU No (Prot No) 77/113

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Smith, J.A., Comparison of Aersolized Terbutaline and Optimal Dose Theophylline in the Management of Bronchial Asthma, presented at the Annual Meeting American College of Allergist, San Francisco, California, 29 Jan 1979.

(2) Smith, J.A., Long Term Use of Aerosolized Terbutaline in the Management of Bronchial Asthma--The Development of Subsensitivity, presented at the Annual Meeting of American Thoracic Society, Las Vegas, Nevada, 14 May 1979.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 77/114	(3) Status: Ongoing
(4) Title: Effect of Propranolol in Patients with Reactive Hypoglycemia		
(5) Start Date: FY78		(6) Est Comp Date: [illegible]
(7) Principal Investigator Gary L. Treece, MD, WTC, MC		(8) Facility: FAMC
(9) Dept/Sec: Endocrine Service		(10) Assoc Investigators: [illegible]
(11) Key Words: Propranolol reactive hypoglycemia		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(15) *Study Objective: To investigate the [illegible] oral propranolol [illegible] administration [illegible] defects of patients with postabsorptive (reactive) hypoglycemia.

(16) *Technical Approach: [illegible]

(17) *Progress:

[illegible] will be available in the next progress report.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 77/114

Technical Approach, continued:

second questionnaire obtained at the end of the month. For a second month the alternate drug is administered and another 5-hr GTT and questionnaire obtained. The effect of glucose, insulin, glucagon, growth hormone, cortisol and prolactin levels during the 5-hr GTT will be compared.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 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 Comp Date: 1981

(7) Principal Investigator: William Ronald Tipton, MD, COL, MC (8) Facility: FAMC

(9) Dept/Sec: Medicine/Allergy-Immunol. (10) Assoc Investigators: Fellows, Allergy-Immunology Svc, FAMC

(11) Key Words:
Subsensitivity
cyclic nucleotides
Beta adrenergic agonist

(12) Accumulative Research Cost: (13) Est Accumulative OMA Cost: (14) Periodic Review Results: continue 4/80

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

(16) Methodology:
Guinea pig tracheal and peripheral lung strips will be analyzed for cyclic nucleotide levels as well as physiological responses to various mediators as previously described. Modifications to existing equipment will enable the investigators to do the tension studies at Fitzsimons Army Medical Center.
Manpower (in professional man years) FY 80: .3/yr
Funding (in thousands) FY 80: $5.6

(17) Progress:
This study has been completed in the initial phase including presentation at the Pulmonary Symposium in 1979, presentation at the American Thoracic in May, 1979. The equipment is now available for the entire experiment to be performed here at FAMC, and currently we are awaiting the arrival of an additional polygraph in order to facilitate further study.

FAMC WU No (First No)

78/102

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Tipton, W.R.: The Development of Specific and Cross Sensitivity in The Tracheal Tissue of Guinea Pigs Treated with Isoproterenol and Aminophylline. (Accepted for Publication in Lung.)

FAMC WU No (Prot No) 78/102

PRESENTATIONS for FY 80 Annual Progress Report

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Tipton, W.R., Jacobson, K., Nelson, H.S., Morris, H., Souhrada, J.: Dynamics and Mechanism of Guinea Pig Trachea Subsensitivity to Isoproterenol. Present: 31st Annual Pulmonary Disease Symposium, Fitzsimons Army Medical Center, Aurora, CO, Sept, 1978

(2) Tipton, W.R., Jacobson, K., Nelson, H.S., Morris, H., Souhrada, J.: Dynamics and Mechanism of Guinea Pig Trachea Subsensitivity to Isoproterenol. Presented: American Thoracic Society, Las Vegas, Nevada, May, 1979,

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/104	(3) Status: Terminated
(4) Title: Study of Coagulation Parameters in Patients with Suspected Deep Vein Thrombophlebitis Before and After Venography		
(5) Start Date: 1978		(6) Est Comp Date: 1980
(7) Principal Investigator Joseph R. Haskett, Jr., CPT, MC		(8) Facility: FAMC
(9) Dept/Sec: Hematology-Oncology Clinic Coag Lab, Dept Pathology		(10) Assoc Investigators: John C. Michalak, LTC, MC
(11) Key Words: clotting, coagulation parameters, thrombophlebitis		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 4/80

(15) *Study Objective:
To determine if coagulation parameters which have been associated with hypercoagulable states are altered by lower extremity venography.

(16) *Technical Approach:
Following informed consent all adult patients who are referred to the Department of Radiology for venography are screened with a variety of clotting studies to include: fibrinogen and fibrin degradation products, protamine sulfate paracoagulation test, thrombin generation index, and serum anti-thrombin 3 before venography and 24 hours after to determine if there is a change in the patients coagulation parameters from the procedure and dye. Funding (in thousands) FY 80: 0

(17) *Progress:
Study was revised prior to initiation; essentially it has been replaced by 80/102

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/106 (3) Status: Completed

(4) Title: **Effects of the Evaluation of the Frequency of Pollen Allergen Injections During the Pollen Season.**

(5) Start Date: February 1980 (6) Est Completion Date: July 1980

(7) Principal Investigator: Bryant R. Fortner, Jr., Maj.MC (8) Facility: FAMC

(9) Dept/Sec: Medicine/Allergy

(10) Associate Investigators:
William R. Tipton, Col MC
Harold S. Nelson, Col MC
Brian S. Dantzler, Maj MC

(11) Key Words:
Pollen
Hyposensitization injections
ragweed immunotherapy

(12) Accumulative DEPARTMENT Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic Review Results: continue 6/80

(15) *Study Objective:
To establish if the more frequent use of hyposensitization injections during the specific pollen season for which the patients are receiving immunotherapy, is immunologically or clinically better than a less frequent schedule.

(16) Technical Approach: Nine patients were involved in a double-blinded crossover study. All were on maintenence ragweed immunotherapy and were evaluated monthly for four months, measuring tissue threshhold sensitivity to ragweed (titrated skin tests, conjunctival sensitivity, nasal airway resistance). For two months, the patients received ragweed injections at weekly intervals and for two months at monthly intervals.

(17) *Progress:
This study has been completed and is being written for presentation and publication.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/106

16 cont. Blood was drawn at each visit and stored until completion of the study at which time specific serum IgG and IgE antibody to ragweed was measured.

Publications: none

Presentations: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/107 (3) Status: Ongoing

(4) Title: **AN EVALUATION OF THE EFFICACY OF ANIMAL DANDER ALLERGY IMMUNOTHERAPY IN PERENNIAL RHINITIS**

(5) Start Date: July 1979 (6) Est Comp Date: 1 June 1981

(7) Principal Investigator
Bryant R. Fortner, Jr., Maj, MC

(8) Facility: [illegible]

(9) Dept/Sec: **Medicine/Allergy**

(10) Other Investigators:
Harold S. Nelson, Col. MC
Alvin J. Aubry, Ltc MC
Gary P. Carpenter, Maj MC

(11) Key Words:
Animal dander
skin test
antibody titers

(12) Accumulative Medical Cost: None (13) Est Accumulative OMA Cost: None (14) Periodic Review Results: continue 6/80

(15) *Study Objective:

To evaluate the response to immunotherapy with commercial cat and dog extracts in patients with marked skin test reactivity to these antigens and their response in their perennial symptoms.

(16) Clinical Approach:

Patients markedly sensitive to dog or cat dander extract and having perennial symptoms are randomly placed on either dog or cat dander or placebo extracts for a period of at least one year. During this period of time the tissue threshhold is measured by periodic titrated skin tests and titrated nasal challenges and the immunologic response is measured by specific RAST and blocking antibody titers.

(17) *Progress: **Twenty-three patients are currently enrolled in the study, with seven having completed the study and the remainder are at maintenence and require one further visit for measurement of tissue threshhold to cat and dog dander allergens. At the same time blood will be obtained and stored until completion of this study at which time the antibody levels will be determined.**

Publications and Presentations: None

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CLINICAL INVESTIGATION PROGRAM. ANNUAL RESEARCH PROGRESS REPORT--ETC(U)
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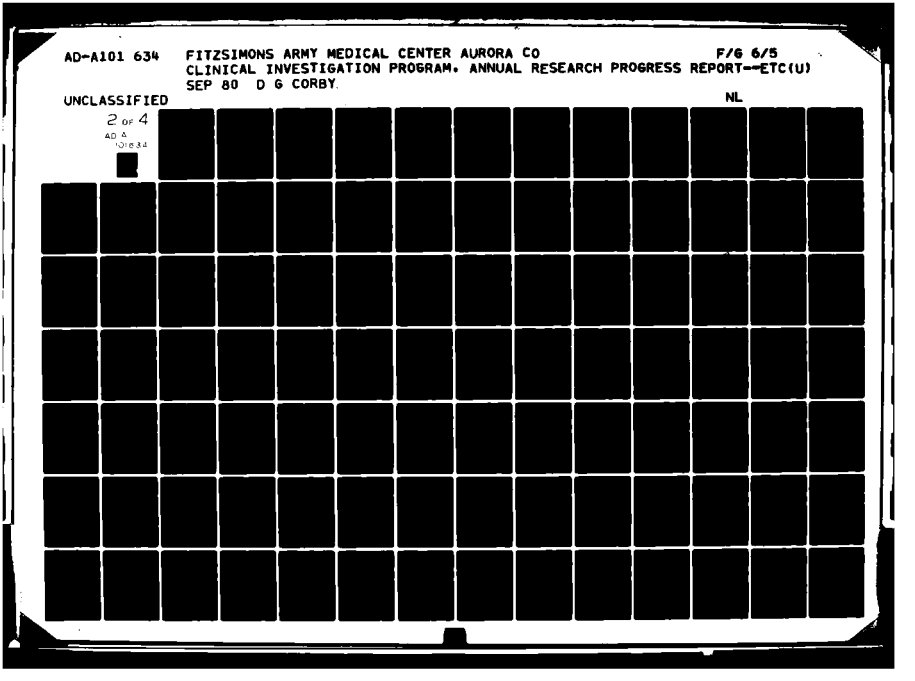

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/108 (3) Status: terminated

(4) Title: Investigation into the Generation of Antigen Specific Suppressor Cells during Allergy Immunotherapy

(5) Start Date:	(6) Est Comp Date:
(7) Principal Investigator L.E. Mansfield, MD, G.L.Brown	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm./CI	(10) Assoc Investigators: none
(11) Key Words: Suppressor cells	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:
To evaluate the development of antigen specific regulatory cells during allergy immunotherapy and to ascertain whether these cells suppress formation of IgE.

(16) *Technical Approach:
NA since no work was done on this study.

(17) *Progress:
Both of the principal investigators have departed Fitzsimons, and this protocol is consequently terminated. A similar study was conducted by a group of investigators from Italy and reported in the Journal of Immunology in 1980.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/109 (3) Status: Terminated

(4) Title: Are Chirrhotic Patients at Increased Risk for Bacteremia Following UG Endoscopy?

(5) Start Date: 30 Sep 79 (6) Est Comp Date: 1980

(7) Principal Investigator
Hugh P. McElwee, MAJ, MC (cont'd)

(8) Facility: FAMC

(9) Dept/Sec: Dept. of Med/Gastro

(10) Assoc Investigators:
None

(11) Key Words:
bacteremia, cirrhosis

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic Terminate Review Results: 8/80

(15) *Study Objective: To determine if patients with cirrhosis have a higher incidence of bacteremia following endoscopy than normal patients.

(16) *Technical Approach: Control patients and patients with cirrhosis have baseline and serial post procedural blood cultures drawn. Blood cultures are collected for both aerobic and anaerobic organisms. Positive results are recorded and if necessary patients are notified and treated.

(17) *Progress: This protocol was terminated due to Dr. McElwee's leaving FAMC.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/109

7. continued -

James J. Damato, MAJ, MSC

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/113	(3) Status: Ongoing
(4) Title: Effects of Salicylic Acid on Fatty Acid Oxidation in Rat Skeletal Muscle Mitochondria		
(5) Start Date: 4 January 1979		(6) Est Comp Date: June 1982
(7) Principal Investigator Robert E. Jones, CPT, MC		(8) Facility: FAMC
(9) Dept/Sec: Endocrinology Service, DOM		(10) Assoc Investigators: Gerald S. Kidd, LTC, MC David T. Zolock, CPT, MC Fred D. Hofeldt, COL, MC
(11) Key Words: mitochondrial fatty acid metabolism long chain fatty acid:CoASH ligase (AMP) salicylic acid		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/80

(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 of the lines generated by double-reciporical plots.

(17) *Progress:

Salicylic acid enhances the rate of fatty acid:CoASH ligase by lowering the Michaelis constant (Km) of palmitic acid from 0.0030 mM in controls to 0.0019 mM ($p < 0.001$) without effecting the maximal velocity of the reaction. Dose response curves for salicylate are hyperbolic with maximal stimulation (40% over controls) occurring at concentrations of 0.05 mM or greater. At half saturating concentrations of palmitate (preliminary studies), phosphate (5 mM) and NaF (.25 mM) both stimulate the ligase

reaction by approximately 50% ($p < 0.005$). The effects of salicylic acid and phosphate are not additive which suggests a possible common mechanism of action whereas the trend of the salicylate and fluoride data suggest that fluoride inhibits ligase stimulation by salicylate. These observations are compatible with the possibility that salicylic acid may indirectly enhance the ligase reaction by facilitating the rate of pyrophosphorolysis (e.g., inorganic pyrophosphatase). Additionally, the fluoride enhancement of the ligase enzyme may imply the presence of an additional controlling factor for mitochondrial fatty acid activation such as a fluoride-sensitve protein kinase. Further studies aimed at clarifying these interactions are being planned.

FAMC WU No (Prot No) 78/113

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Endocrine DEPARTMENT Medicine

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

FAMC WU No (Prot No) 78/113

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Endocrine DEPARTMENT Medicine

(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. Submitted to Biochim. Biophys. Acta.

(2) Jones, R.E., and Hofeldt, F.D.: Stimulation of Mitochondrial Long Chain Fatty Acid:CoASH Ligase (AMP) by Salicylic Acid. J. Colorado-Wyoming Acad. Sci. (In press).

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(USCP 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 80 (2) Prot No.: 78/114 (3) Status: ongoing

(4) Title: Treatment of Systemic Scleroderma with Minoxidil (U-1858)

(5) Start Date: Jun 79	(6) Est Comp Date: Feb 81
(7) Principal Investigator: JAMES A. MCCOY, M.D., LTC, MC	(8) Facility: FAMC
(9) Associate: Dermatology, DOM	(10) Associate Investigators: JOHN L. AELING, M.D., COL.,MC ROBERT G. CLAYPOOL, M.D.,COL,MC STEVEN R. BAILEY, M.D.,CPT, MC
(11) Key Words: Systemic Scleroderma/Minoxidil	

(12) Est Cumulative MEDCASE Cost: (13) Est Accumulative OMA Cost: (14) Periodic Review Results: continue 10/79

(15) Research Objective:

To determine if Minoxidil is a useful, vasoactive drug for the control of systemic scleroderma and the associated Raynaud's phenomena.

(16) Technical Approach:
Patients with systemic scleroderma are entered into this double-blind cross-over study, using Minoxidil in low doses and followed at bi-weekly and monthly intervals. Hospital admissions as indicated for dosage increase and the performance of laboratory studies.

(17) Progress:
In June 1979 the first patient was admitted to the protocol; since then a total of 8 patients have entered; five patients have completed the study to date. Computer analysis of objective data is pending; no significant side effects necessitating withdrawal from the study have occured to date. All patients completing the study felt they experienced subjective improvement during the six months they received Minoxidil.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/116 (3) Status: on-going
(4) Title: The Effect of Positive and Negative Air Ions on Pulmonary Functions in Patients with Bronchial Asthma
(5) Start Date: 1978 (6) Est Completion Date: indefinite
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC (8) Facility: DCI
(9) Dept/Sec: Medicine/Allergy-Immunol. (10) Associate Investigators: Brian Bantzler, Bruce Martin
(11) Key Words: Small air ions
(12) Accumulative Research Cost: (13) Est Accumulative OMA Cost: (14) Periodic Review Results: continue 10/79

(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 consecuetive days for periods of [illegible] hours to either an increased concentration of positive or negative small air ions. The response will be monitored by pulmonary function studies.

(17) Progress:

Nine patients were studied in the room with manipulation of small air ion concentration. The results of this first preliminary study are being analyzed and will be presented at the Pulmonary Symposium at Fitzsimons in January, 1981.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/117 (3) Status: on-going

(4) Title: The Effect of Parasitic Infestation on Immediate Skin Test Reactions

(5) Start Date: 1980	(6) Est Comp Date: 1981
(7) Principal Investigator Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Allergy, DOM	(10) Assoc Investigators: L.E. Mansfield, MD, LTC Praphan Phanupahak, MD, PhD
(11) Key Words: IgE parasites	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 10/80

(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) *Progress:

The clinical portion of this study is currently being performed in Thailand.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 86 (2) Prot No.: 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 Comp Date: 1982
(7) Principal Investigator Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, PhD
(11) Key Words: Deadspace Steady state diffusion	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/79

(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 exporatory 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 the inert gases deadspace is deduced.

(17) *Progress: Extensive modification was made concerning recording techniques of both methods of deadspace determination. Data on normal individuals has been collected and very precise measurements were made by both techniques. Consistent differences between the two techniques were noted however. A theoretical explanation of these differences was worked out and will be tested using a different sequence of the inert gas mixtures, using the same inert gases.

(4) to Steady State Diffusion Estimates.

Publications:

(1) Kinding, N.B., Martin, B., MOrgan, E. Filley, G.F.: Ventilation Variations at Constant Load Exercise. Federation Proceedings 38:1050, 1979.

(2) Kindig, N.B., Zimmerer, R.W., Hazlett, D.R.: Automation and Profile; Computer Simulation. Clinical Engineering, 6:68-69, 1978.

(3) Hazeltt, D.R., Zimmerer, R.W., Kindig, N.B.: Ultrasonic [illegible] Tissue Characterization. Medical Instrumentation [illegible] 1979.

(4) Kindig, N.B., Editor: Proceedings of the [illegible] Annual Rocky Mountain Bioengineering Symposium and [illegible] International ISA Biomedical Sciences Instrumentation Symposium. Biomedical Sciences Instrumentation, 15, Instrument Society of America, Pittsburg, 1979

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

Presentations:

(1) Kindig, N.B.: Physiologic Deadspace; Influence of Pattern of Breathing. Presented: 32nd Annual Pulmonary Symposium, FAMC, Aurora, CO, September 1979.

(2) Kindig, N.B., Perry, M.E., Filley, G.F.: Gas-Mixing Deadspace: Measurement with Tracer Gases. Presented: [illegible] Symposium on Gas Exchange Function of Normal and Disease Lungs, Max Planck Institute for Experimental Medicine, Goettingen, Germany, July 9-11, 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/119	(3) Status: on-going
(4) Title: The Effect of Aspirin on Platelet Aggregation in Aspirin Sensitive Asthmatics		
(5) Start Date: 1978		(6) Est Comp Date: indefinite
(7) Principal Investigator H.S. Nelson, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immun.		(10) Associate Investigators: J.A. Gillham, LTC, USAF, MC R. E. Danziger, CDR, USN, MC P.T. O'Parr, PhD, DAC
(11) Key Words: Aspirin sensitivity platelet aggregation		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/79

(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) *Progress:
The patient study portion of the protocol is completed. The results are presently being analyzed and prepared for submission.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/120 (3) Status: Terminated

(4) Title: Diabetic Treatment Study: Assessment of Metabolic Control and Change in Quality of Life Following Short Term Treatment of Diabetic Patients with Tolazamide

(5) Start Date: FY 78 (6) Est Comp Date: Terminated

(7) Principal Investigator: Fred D. Hofeldt, COL, MC (8) Facility: FitzMC

(9) Dept/Sec: Endocrine Service

(10) Assoc. Investigators:
Gary L. Treece, LTC, MC
Francis G. Henderson, MD, Upjohn Monitor
J.T. Keene, Upjohn Medical Assoc.
Annie Shackelford, MT, DAC
Leonard R. Sanders, CPT, MC

(11) Key Words:
diabetic treatment oral agent
Tolinase
Tolazamide

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic Review Results: continue 1/79

(15) *Study Objective: The objective of this double blind pilot study is to determine if the methodology employed will adequately determine whether maturity-onset non-ketotic diabetic patients feel and function differently when their blood sugars are controlled.

(16) *Technical Approach: Patients with moderate diabetes mellitus are introduced into a double blind study where they will be treated with placebo or with Tolazamide tablets. The dose of the placebo and the Tolinase is regulated according to blood sugar determinations on frequent follow-up of patients. In addition to controlling the metabolic parameters of the disease as measured by hemoglobin A1C, fasting blood glucose determinations and symptomatic state of the patient, the patient will complete a questionnaire which will assess his quality of life.

(17) *Progress:

Seven patients have entered the study and have completed their long-term follow-up and termination of the study. The study has been terminated as patient recruitment has been determined to be sufficient to merit that data analysis by the Upjohn Company.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/121 (3) Status: on going

(4) Title: The Determination of Cross Allergenicity between Western Grass Pollens and Common Northern Grass Pollens

(5) Start Date: 1978	(6) Est Comp Date: 1981
(7) Principal Investigator H.S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators:
(11) Key Words: Grass pollen and cross allergenicity	B.G. Martin, MAJ, USAF, MC

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 12/79

(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) *Progress:
Extensive studies were performed under this protocol during the preceding year. The data is currently being analyzed and prepared for publication.

FAMC WU No (Prot No) 1

78/121

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immurology DEPARTMENT Medicine

(1) Martin, B.G., Mansfield, L.E., Nelson, H.S., Patterns of Cross Allergenicity among Grasses (abstract), Journal Allergy-Clinical Immunology, 65:229;1980.

FAMC WU No (Prot No) 78/121

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Martin, B.G., Patterns of Cross Allergenicity among Grasses, presented at the annual meeting of the American Academy of Allergy, Atlanta, Georgia, 20 Feb 1980

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/122 (3) Status: Ongoing

(4) Title: Effects of Dietary Fructose in Diabetes Mellitus.

(5) Start Date: FY78 | (6) Est Comp Date: FY81

(7) Principal Investigator
Fred D. Hofeldt, COL, MC | (8) Facility: FAMC

(9) Dept/Sec: Endocrine | (10) Assoc Investigators:
Phyllis A. Crapo, UCHSC, Denver, CO
Jerrold M. Olefsky, MD, UCHSC, Denver,
Orville G. Kolterman, MD, UCHSC, Denver
Jon Insel, MD, UCHSC, Denver, CO

(11) Key Words:
fructose
diabetes mellitus

(12) Accumulative MEDCASE Cost: | (13) Est Accumulative OMA Cost: | (14) Periodic continue Review Results: 12/79

(15) *Study Objective: To assess the post prandial response of simple carbohydrates (fructose, glucose and sucrose) and natural cooked foods (cake and ice cream) which are prepared with either sucrose or fructose. The aim of this study is to determine if fructose, a natural occurring nutrient, can substitute as an artificial sweetener in diabetic patients. The plasma glucose insulin responses to the various test meals will be assessed to determine which substance is the most diabetogenic. Fructose plays an unimportant role in (cont)

(16) *Technical Approach:

Three groups of subjects will be studied to include 1) chemical diabetics, 2) adult onset, non-ketotic diabetics with significant fasting hyperglycemia (plasma glucose levels greater than 140 mg% on three different occasions) and 3) age and weight matched diabetic control patients. These patients will undergo acute studies where their hormonal responses will be determined to glucose, sucrose and fructose and chronic studies where the patient will be fed

(17) *Progress:

Only 2 patients have been referred to the medical school for this study. A number of cases have been studied at the medical school and preliminary data suggests that fructose is not diabetogenic and can serve an important role as an artificial sweetener for diabetic patients. The study is ongoing.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/122

(15) Study Objective (continued):
carbohydrate metabolism; its use as a food sweetener might have therapeutic value in the management of the large diabetic population.

(16) Technical Approach (continued):
diets containing mixed test meals of various starches containing calories of fructose or sucrose and glucose. Postprandial hormonal responsiveness again will be measured. Each of the diets will be fed for a period of 3 weeks. At the end of this time the postprandial plasma glucose, insulin and glucagon responses will be determined following the ingestion of 50 grams of glucose, sucrose and fructose. (As described above.) Likewise, each patient's tolerance will be tested with a standard glucose to tolerance test before and after the 3 weeks of the chronic dietary period. The influence of diet on triglyceride metabolism will be determined by the measurement of VLDL-TG production rate and fasting triglyceride levels, before and after the dietary period.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/123 (3) Status: Ongoing

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

(5) Start Date: January 1979 (6) Est Comp Date: 1982

(7) Principal Investigator
Michael E. Perry, LTC, MC

(8) Facility: FAMC

(9) Dept/Sec: Medicine/Pulmonary

(10) Assoc Investigators:
Robert W. Zimmerer, PhD
Robert J. Browning, BS

(11) Key Words:
Alveolar Pressure
Airway Resistance
Body Plethysmography

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 1/79

(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) *Progress: A heated screen pneumotach was selected to reduce uneven heat flux as much as possible. Valving arrangements were adopted to allow venting just prior to forced manuevers, which further reduced leak artifact. The computer program was modified to allow for box drift and to account for pneumotach back pressure and to account for non-linear pneumotach airflow response. The computer program was altered and the numerical integration procedure discontinued because of problems with cumulative error. A significant relationship was found between great fluctuations in

(17) alveolar pressure at constant flow rates when flow maximums have been reached on the flow volume envelope.

FAMC WU No (Prot No) 78/123

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Medicine DEPARTMENT Pulmonary

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

(2) Parry, 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.

FAMC WU No (Prot No) 78/123

PRESENTATIONS for FY 80 Annual Progress Report

SERVICE Medicine DEPARTMENT Pulmonary

(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.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/124	(3) Status: Ongoing
(4) Title: A Self Consistent Method of Single Breath DLCO Measurement		
(5) Start Date: September, 1978		(6) Est Comp Date: 1982
(7) Principal Investigator Michael E. Perry, LTC, MC		(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary		(10) Assoc Investigators: Neal B. Kindig, PhD Robert J. Browning, BS
(11) Key Words: Single breath diffusion Alveolar gas Breathing patterns		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 1/79

(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 offline 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) *Progress: Special instrumentation was designed specifically for this protocol by Fogg Systems, Inc. There were many unanticipated difficulties in proper instrumentation design, but over the past year these have all been corrected and the assembled control mechanism is in place in the Pulmonary Function Laboratory. All valving assembly is now complete. At this time the actual computer program is being written by the computer specialist. Much delay was encountered late in the fiscal year because of failure of ADP equipment, which has since been corrected. We anticipate operation of this system

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 78/124

(17) within sixty days at which time data collection for the protocol itself can begin.

Publications:

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

Presentations:

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

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/12b (3) Status: Terminated

(4) Title: Adjuvant Therapy of Premenopausal patients with EBP (+) Breast Cancer with CMF alone versus CMF plus Tamoxifen and EBP (-) (CONT'D)

(5) Start Date: March 1979 (6) [illegible] March 1980

(7) Principal Investigator
JOHN C. MICHALAK, MD, LTC, MC

(8) [illegible]

(9) Dept/Sec: HEM-ONC, Medicine

(10) [illegible]

(11) Key Words:
Breast CA, chemotherapy

R. J. DIBELLA, MD, COL, MC

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative [illegible] continue
OMA Cost: [illegible] Results: 3/80

(15) *Study Objective:
1. To determine whether therapy with the antiestrogen tamoxifen has an additive effect to adjuvant chemotherapy in premenopausal patients with EBP (+) breast cancer who are at high risk for recurrence.

2. To determine whether the results of adjuvant chemotherapy with CMF can be improved by first giving 3 cycles of intensive chemotherapy with adriamycin and vincristine in premenopausal patients with EBP (-) breast cancer.

(16) *Technical Approach:
This is a randomized clinical study of the Colorado Oncology Group.

(17) *Progress:
Six patients have been [illegible] this study. Grade II moderate myelosuppression has been observed in the patients requiring dose reductions. One patient (#6) experienced an allergic reaction and had to be taken off the study. Allergy evaluation preliminarily suggests the reaction was due to Methotrexate. Five of six patients continue on study without evidence of disease. The sixth patient relapsed (BW) after being off CMF for one month, with bony metastasis.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT Proto No: 78/125
(Blocks 1 through 17)

TITLE: Breast Cancer with CMF alone versus Adriamycin and Vincristine followed by CMF.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/126 (3) Status: terminated

(4) Title: The Systematic Evaluation of Urticaria. I. Response to Therapy. II. Evaluation with Skin Biopsy.

(5) Start Date: 1978	(6) Est Comp Date: terminated
(7) Principal Investigator H.S. Nelson, MD, COL , MC	(8) Facility: [illegible]
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators:
(11) Key Words: Chronic urticaria Cimetidine	G.B. Carpenter

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 3/80

(15) *Study Objective:
To ascertain the effectiveness of Cimetidine combined with an H1 blocker in the treatment of chronic urticaria, and to examine the histologic features of chronic urticaria.

(16) *Technical Approach:
A double blind evaluation of the effectiveness of combined H1 and H2 blockers together compared to H1 blockers alone was planned. In addition, patients with chronic urticaria were to obtain skin biopsies.

(17) *Progress:
By the time permission had been obtained to complete the study and the appropriate active and placebo drugs had been performed, the several investigators had reported the results of similar studies. Therefore, it did not appear appropriate to continue the protocol.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/127 (3) Status: Terminated
(4) Title: Does Neoplastic Disease Produce a Positive Secretin Test?

(5) Start Date: 30 Sep 79	(6) Est Comp Date: 1980
(7) Principal Investigator Hugh P. McElwee, M.D., MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Dept of Med/Gastro	(10) Assoc Investigators: David Jarvis, SP5
(11) Key Words: secretin	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(15) *Study Objective: To determine if the secretin test is positive in neoplastic disease.

(16) *Technical Approach: The secretin test is felt to be specific for diagnosis of the Zollinger Ellison syndrome. We have an index case of one patient with oat cell carcinoma who had a positive secretin test and no evidence of Z-E at autopsy. We are therefore testing certain patients with hormonally active cancers to see if they produce positive secretin tests.

(17) *Progress: This protocol has been terminated due to Dr. McElwee's leaving FAMC.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/127

7. continued -

Nicholas J. DiPella, LTC, MC
Steven Bailey, CPT, MC

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/128 (3) Status: Completed

(4) Title: Assessment of Postprandial Plasma Glucose, Insulin and Glucagon Response to Different Orally Administered Complex Carbohydrates in Diabetic Subj.

(5) Start Date: FY78 (6) Est Comp Date: Completed

(7) Principal Investigator
Fred D. Hofeldt, COL MC

(8) Facility: FAMC

(9) Dept/Sec: Endocrine Service

(10) Assoc Investigators:
Phyllis A. Crapo, RD, UCHSC, Denver, CO
Jerrold M. Olefsky, MD, UCHSC, Denver
Orville G. Kolterman, MD, UCHSC, Denver

(11) Key Words:
diabetes
complex carbohydrates
hormonal responses

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic complete Review Results: 5/80

(15) *Study Objective: To establish if feeding different simple and complex carbohydrates substantially affect plasma glucose and insulin values. This project will use mild diabetics, moderately severe diabetics and age and weigt-matched, non-diabetic controls in a paired analysis of their response in plasma glucose, plasma insulin and plasma glucagon to 50 grams of carbohydrate presented as various meals.

(16) *Technical Approach: Selected diabetic patients suitable for the study were studied at the University of Colorado Medical Center, General Clinical Research Unit, where their plasma glucose, insulin and glucagon responses were determined following the ingestion of glucose, potato, rice, corn and wheat (breach starch). The test meals were given in a random order to these diabetic subjects. Statistical analysis on data will be carried out by the use of the paired t test for dependent means.

(17) *Progress:

The study is completed. Approximately ¼ of the group of patients studied were from Fitzsimons Army Medical Center. The major findings of the study were that the postprandial glucose response to different starches is quantitatively different. In order of less carbohydrate intolerance to more carbohydrate intolerance, the following ranking of starches was noted: rice, wheat bread, corn, potatoes. Noteworthy, potatoes and glucose were equally diabetogenic in this group of patients.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/129 (3) Status: Completed
(4) Title: Respiration During Sleep in Myxedema and Hypothyroidism

(5) Start Date: FY78	(6) Est Comp Date: FY80
(7) Principal Investigator Leonard R. Sanders, CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Endocrine	(10) Assoc Investigators: Fred D. Hofeldt, COL, MC Clifford Zwillich, MD, Consultant
(11) Key Words: myxedema respiration hypothyroidism	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 8/80

(15) *Study Objective: The objective of this study is to determine whether patients with myxedema have abnormalities in respiration which occur during sleep which in turn might explain the daytime symptoms of fatigue and hypersomnolence.

(16) *Technical Approach: At least six uncomplicated, adult myxedema patients will be studied after their myxedema is confirmed by clinical examination and laboratory determinations. After myxedema is determined, the patient will have his ventilatory drives to hypoxia and hypercapnia as well as normal ventilation studies determined. He will then go to the Cardiopulmonary Research Unit at the University of Colorado where a sleep study will be performed. The study will consist of two consecutive nights of sleep where the patient will

(17) *Progress:

Eight patients have been studied with varying degrees of hypothyroidism to profound myxedema. These patients have been noted to have a sleep apnea syndrome with marked cardio-pulmonary variations when monitored in the sleep laboratory in the hypothyroid state. These abnormalities are reversed with thyroid hormone.

(16) Technical Approach (continued):
have his EEG monitored, heart monitored with an electrocardiogram, respiratory pattern monitored with a strain gauge attached to the patient's chest wall and oxygen saturation determined by the means of an ear oximeter. The patient will then be replaced with thyroid hormone and after there is documentation that the patient is euthyroid both by clinical examination and laboratory values, the above sleep study will be repeated.

FAMC WU No (Prot No) 78/129

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Endocrine DEPARTMENT Medicine

(1) Zwillich, C., Sanders, L., Pickett, C., Hofeldt, F.D., and Weil, J.: Prolonged Apnea and Hypoxemia During Sleep in Myxedema. (Abst.) Clinical Research 28:86A, 1980.

Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/100 (3) Status: Completed

(4) Title: Investigation of the Tumor Reduction Effect of Combined Sodium-L-Ascorbate and 5-FU Chemotherapy in Transplanted B16 Melanoma of Mice

(5) Start Date: February 1979 (6) Est Comp Date: March 1980

(7) Principal Investigator: N. J. MARTIN, MD, MAJ, MC (8) Facility: FAMC

(9) Dept/Sec: HEM-ONC, Medicine (10) Assoc Investigators: WILSON C. BOURG, MD, MAJ, MC

(11) Key Words: 5FU, Ascorbic acid

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic continue Review Results: 2/80

(15) *Study Objective:
To evaluate the possible synergism of 5-fluorouracil and sodium-L-ascorbate against tumor cells in vivo.

(16) *Technical Approach:
The B16 melanoma was transplanted into the BFD_1 Jackson Laboratory male mouse hosts. An optimal tumor cell number was established to provide and 18-22 day range of mouse death. This was 75,000 cell/cu.mm. In addition to this, the maximum safe dose range for 5FU was established in the BFD_1 hybrid Jackson mouse and this maximum safe dose of 5FU was found to be 20mg/kg. (See Continuation Sheet)

(17) *Progress:

No additive or synergistic effect was observed with 5-FU and ascorbic acid compared with 5-FU alone.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/100

16. The mice were divided into five groups; groups 1 through 4 received the B16 melanoma. Group 5 was a controlled group which received only sodium chloride injections. Group 1 received only oral vitamin C as therapy in a concentration of 0.1%. Group 2 received no ascorbate but only 5FU given on Days 2 through 10 via intraperitoneal injection. Group 3 received oral vitamin C in the previously mentioned concentration and intraperitoneal 5FU in the previously mentioned dose and concentration. Group 4 received B16 melanoma only. Group 5 received no B16 melanoma but received vitamin C at 0.1% daily until death and 5 FU at the previously mentioned concentration.

Publications and Fresentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/101	(3) Status: ONGOING
(4) Title: The Relationship of Granuloma Annulare (GA) To Diabetes Mellitis (DM).		
(5) Start Date: Mar 79	(6) Est Comp Date: Jun 81	
(7) Principal Investigator: GENE E. GRAFF, D.O., MAJ, MC	(8) Facility: FAMC	
(9) Dept/Sec:	(10) Assoc Investigators: BERNARD F. DAVIES, M.D., MAJ, MC JOHN L. AELING, M.D., COL, MC FRED D. HOFELDT, M.D., COL, MC D.M. STRONG, M.D., WRAMC GEORGE L. BROWN, PhD., COL, MSC	
(11) Key Words: Granuloma Annulare Diabetes Mellitis HLA Typing		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 5/80

(15) Study Objective:

To determine if an association exists between GA and DM by special laboratory procedures, including HLA typing.

(16) Technical Approach:

Patients with biopsy proven GA are studied for concurrent DM historically, clinically, and following oral and intravenous glucose challenge. HLA typing is also done. Baseline studies include: Complete physical exam, CBC, sedimentation rate, SMA-18, triglycerides, cholesterol, HLDL, two-hour pc blood glucose, TSN, T-3, T-4, Resin uptake T-3, EKG if indicated. Parameters monitored following glucose challenge include: Serum insulin, glucose, glucagon, growth hormone, cortisol.

(17) Progress:

Since the beginning of this study eleven patients have been identified and included in this study. Ten have been completely studied (except for HLA typing, which will be done terminally). Thus far, two patients have been shown to be diabetic and one has idiopathic reactive hypoglycemia. There has been a paucity of cases identified over this past year.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/102	(3) Status: Completed
(4) Title: Mechanism(s) of Insulin Resistance in Obesity (Cooperative Study Between Fitzsimons and Endocrine Division, University of Colorado Medical Center)		
(5) Start Date: FY79		(6) Est Comp Date: Terminated
(7) Principal Investigator Mary L. Treece, MD, LTC, MC		(8) Facility: FAMC
(9) Dept/Sec:		(10) Assoc Investigators: None.
(11) Key Words: obesity insulin resistance		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 7/80

(15) *Study Objective: Insulin resistance is a characteristic feature of obesity and has been casually implicated in many of the clinical complications of the obese state. However, the mechanisms responsible for insulin resistance in obesity are not known. The plan is to develop in vivo insulin dose response curves in obese human subjects in order to delineate the mechanisms of insulin resistance in obese humans and to assess the relationship between in vitro insulin binding and in vivo insulin action.

(16) *Technical Approach:

The overall plan will be to utilize the glucose clamp technique to elucidate the in vivo insulin-glucose uptake dose response curves in insulin resistant obese patients. Additionally, hepatic glucose production will be simultaneously determined in all studies to quantitate the contribution of this variable to total glucose turnover, and to assess the ability of different steady state

(17) *Progress:

One patient in this study was referred to the University of Colorado for study. The study has subsequently been completed by UC using their own subjects from their own patient population. Analysis of data is pending.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/102

(16) Technical Approach (cont):

plasma insulin levels to suppress the liver's capacity to secrete glucose. Finally, in vitro measurements of adipocyte insulin receptors will be performed so that the relationships between overall in vivo insulin sensitivity and insulin receptors can be assessed.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/103 (3) Status: on-going

(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 Comp Date: 1981
(7) Principal Investigator Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators:
(11) Key Words: Histamine receptor blocking agents	C.B. Carpenter, MAJ, MC A. Bunker-Soler, MAJ, MC

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 7/80

(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 cross over 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) *Progress:
The clinical study was performed during the weed season of 1979. The data is still in preparation for final publication.

FAMC WU No (Prot No)_____

79/103

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Allergy-Immunology DEPARTMENT Medicine

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

FAMC WU No (Prot No) 79/103

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Allergy-Immunology DEPARTMENT Medicine

(1) Carpenter, G.B., An Evaluation of Combined H1 and H2 Antagonists in the Treatment of Seasonal Allergic Rhinitis, Annual Meeting of American Academy of Allergy, Atlanta, Georgia, 18 Feb 80.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/104	(3) Status: Ongoing
(4) Title: Vindesine in the Treatment of Cancer		
(5) Start Date: Sep 1979		(6) Est Comp Date: 1981
(7) Principal Investigator: N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Hematology-Oncology		(10) Assoc Investigators: None
(11) Key Words: Chemotherapy		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 9/80

(15) *Study Objective:

To test the efficacy of this agent in melanoma, CA of the esophagus, CA of the breast and lymphoma

(16) *Technical Approach:

Clinical study

(17) *Progress:

Four patients have been treated with this agent. One patient with lymphoma has experienced a complete response, but the other three have progression of disease. Neurotoxicity and marrow suppression have been observed.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/105 (3) Status: Ongoing

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

(5) Start Date: November 1979 (6) Est Comp Date: 1981

(7) Principal Investigator
Michael E. Perry, LTC, MC

(8) Facility: FAMC

(9) Dept/Sec: Medicine/Pulmonary Disease

(10) Assoc Investigators:
Neal B. Kindig, PhD

(11) Key Words:
Steady state DLCO
Breathing pattern

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic continue Review Results: 10/79

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

(16) *Technical Approach: Various breathing patterns consisting of a normal pattern with end expiratory breath hold, similar pattern without end expiratory breath hold, a square rated breathing pattern with breath hold after inspiration, and a square rated breathing pattern at end expiration will be performed while the subject performs the standard steady state diffusion protocol.

(17) *Progress: Because of other priorities with other protocols very little progress was made this past year except for establishing the response time of the carbon monoxide sampling head. However, a theoretical analysis was worked out which allows us to correct for back pressure occurring in the pulmonary capillaries as carbon monoxide slowly accumulates during the manuevers.

FAMC W.U No (Prot No) 79/105

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Medicine DEPARTMENT Pulmonary Disease

(1) Kindig, N.B., Perry, M.E., Browning, R.J.: $DLCO_{SS}$ Correction Using PaCO Back Pressure Predicted From Venous Blood (Abstract) Page 107, April 1980.

FAMC WU No (Prot No) 79/105

PRESENTATIONS for FY 80 Annual Progress Report

SERVICE Medicine DEPARTMENT Pulmonary Disease

(1) Kindig, N.B., Perry, M.E., Browning, R.J.: DLCOss Correction Using PaCO Back Pressure Predicted From Venous Blood, AAMI 15th Annual Meeting, San Francisco, April 13-17, 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/106 (3) Status: Ongoing

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

(5) Start Date: January 1979	(6) Est Comp Date: Dec, 1981
(7) Principal Investigator Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary	(10) Assoc Investigators: Robert Zimmerer, PhD
(11) Key Words: Wedge pressure	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/79

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

(16) *Technical Approach: Using simultaneous measurements of intrathoracic pressure via Swan Ganz Catheter and intraesophageal balloon, as well as inhaled lung volume using a pneumotachograph, and airway pressure with pressure transducer attached to the endotracheal tube. Relationships between wedge pressure, esophageal pressure, airway pressure and lung volume will be sought and attempts at correlation made. The monitoring of these various parameters and their correlation with each other will require special

(17) *Progress: The design of this special unit has been completed and most of the necessary parts have been ordered and received. Actual construction of the apparatus is in progress at this time.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/106

(16) equipment to record and correlate data.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/107 (3) Status: Ongoing

(4) Title: The Effects of Fructose on Reactive Hypoglycemia

(5) Start Date: FY79	(6) Est Comp Date: FY81
(7) Principal Investigator Fred D. Hofeldt, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Endocrine	(10) Assoc Investigators: None.
(11) Key Words: reactive hypoglycemia fructose	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 3/80

(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 will be further studied under Clinical Research Unit,

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

(17) *Progress: Approximately 7 patients have entered the protocol. The preliminary findings in this group indeed support the hypothesis that reactive hypoglycemia has not been observed in individuals when exposed to either fructose solution or fructose cakes. This has been an observation in patients with diabetic reactive hypoglycemia, idiopathic reactive hypoglycemia and alimentary reactive hypoglycemia. Inasmuch as patients with reactive hypoglycemia have been shown to be food abusers, it may well be that fructose food substitution may be an important (cont)

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/107

(15) Study Objective (continued):
University of Colorado Health Sciences Center. Each patient will be studied with varying test meals consisting of simple carbohydrates (glucose, sucrose, fructose), or natural foods in a chocolate cake containing either sucrose or fructose. Patients will be monitored for 5 hours post prandially with measurements of plasma glucose, insulin and counter-regulatory hormones. It is hypothesized that fructose inasmuch as it is not metabolized along traditional glucose pathways will serve as an artificial sweetener for patients with reactive hypoglycemia as this food substance will not be a potent glycemic stimulus and will not cause a marked release in insulin discharge.

(17) Progress (continued):
therapeutic modality in this group of patients.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/108 (3) Status: on-going

(4) Title: The Effect of Beta Adrenergic Bronchodilators on Serum Immunoglobulin-G Levels

(5) Start Date: 1981	(6) Est Comp Date: 1981
(7) Principal Investigator H.S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol	(10) Assoc Investigators: none
(11) Key Words: Immunoglobulin bronchodilators bronchial asthma	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 1/80

(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) *Progress:
This study has not yet been started.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 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 Comp Date: 1981

(7) Principal Investigator
NICHOLAS J. DiBELLA, M.D., COL, MC

(8) Facility: FAMC

(9) Dept/Sec: C, Hematology/Oncology Svc

(10) Assoc Investigators:
RICHARD A. ARTIM, M.D., CPT,USAF,MC
MICHAEL L. LANGIN, CPT, MSC, Pharmacist

(11) Key Words:
Chemotherapy, nausea, and vomiting control.

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic continue Review Results: 2/80

(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) *Progress:
Twenty three (23) patients have been entered on this protocol, approximately 1/3 double blinded. Four (4) patients have died from their disease. Two (2) patients were removed from the study due to mild CNS changes at their request. The rest of the patients tolerated the THC very well with good control of their nausea and vomiting.

Publications and Presentations: None

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FITZSIMONS ARMY MEDICAL CENTER
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 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 Comp Date: indefinite
(7) Principal Investigator H.S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators:
(11) Key Words: Local anesthetic adverse drug reaction	multiple

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 1/80

(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) *Progress:

Patients are being studied under this protocol at several instillations.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/111 (3) Status: on-going

(4) Title: A Comparison of the Development of Sensitivity to Penicillin in Normal and Atopic Individuals

(5) Start Date: 1980	(6) Est Comp Date: 1981
(7) Principal Investigator H.S. Nelson, MD. COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators: A. Bunker-Soler C. Wagner
(11) Key Words: Penicillin allergy	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 2/80

(15) *Study Objective:
To determine the frequency with which normal and atopic individuals develop positive immediate 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. Data will be analyzed in terms of the frequency with which patients have unexpected positive skin test to Penicillin that they develop positive--cont.

(17) *Progress:
Patients are currently being studied under this protocol.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/111

16 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

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: 1983
(7) Principal Investigator N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: HEM-ONC, Medicine		(10) Assoc Investigators:
(11) Key Words: Hyperuricemia, allopurinol		MICHAEL LANGIN, CPT, MSC
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 3/80

(15) *Study Objective:

To provide 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) *Progress:

One patient has been treated successfully and without ill-effects.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/113	(3) Status: Terminated
(4) Title: Vindesine in the Treatment of Metastatic Adenocarcinomas		
(5) Start Date: June 1980		(6) Est Comp Date: January 1981
(7) Principal Investigator: N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Hem-Onc, DOM		(10) Assoc Investigators: MICHAEL LANGIN, CPT, MSC
(11) Key Words: CA colon, chemotherapy		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 6/80

(15) *Study Objective:
To determine the efficacy of vindesine given by infusion in recurrent or metastatic CA of the colon.

(16) *Technical Approach:
Clinical study.

(17) *Progress:
One patient was treated with this regimen and failed to respond; no significant toxicity was observed.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/114	(3) Status: Ongoing
(4) Title: Vindesine and Cis-platinum in the Treatment of Unresectable Carcinoma of the Lung		
(5) Start Date: Jun 1980		(6) Est Comp Date: 1981
(7) Principal Investigator: N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Hematology-Oncology		(10) Assoc Investigators:
(11) Key Words: CA lung, chemotherapy		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:

To test the efficacy of these drugs in two different schedules in advanced CA of the lung.

(16) *Technical Approach:

Clinical study.

(17) *Progress:

Three patients have been treated with this protocol. One partial response has been observed. One patient had progression of tumor and the third patient is too early to evaluate.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/115 (3) Status: Terminated

(4) Title: The Effect of Split-Course, Continuous Infusions of 5-Fluorouracil on Metastatic Colo-Rectal Cancer

(5) Start Date: Jun 1980	(6) Est Comp Date: Mar 1980
(7) Principal Investigator N. J. DIBELLA, MD, COL, MC	(8) Facility: FAMC Hematology-Oncology
(9) Dept/Sec: Medicine	(10) Assoc Investigators:
(11) Key Words: Colon CA, 5-FU, chemotherapy	None

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:

To test the efficacy of 5-FU given by this schedule for metastatic adenocarcinoma of the colon.

(16) *Technical Approach:

Clinical study.

(17) *Progress:

Three patients received this treatment All tolerated it well. One patient had a partial response (JS), but the other two patients experienced progressive disease.

Publications and Presentations: None

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FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/116 (3) Status: Terminated
(4) Title: Adiamycin, Cyclophosphamide, and Cis-Platinum in the Treatment of Diffuse Pleural and Peritonal Mesothelioma. Phase II: Combination Chemotherapy Program.

(5) Start Date: June 1980	(6) Est Comp Date: March 1980
(7) Principal Investigator N. J. DIBELLA, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: HEM-ONC, Medicine	(10) Assoc Investigators:
(11) Key Words: Mesothelioma, chemotherapy	MICHAEL LANGIN, CPT, MSC

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:

To determine the efficacy of this drug combination in patients with recurrent or advanced mesothelioma.

(16) *Technical Approach:

Clinical study.

(17) *Progress:

No patients were seen with this rare tumor who were eligible for this protocol.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/117 (3) Status: Terminated

(4) Title: 5-Fluorouracil, Cytoxan, and Aldactone in Advanced (Stage D) Carcinoma of the Prostate

(5) Start Date:

(6) Est Comp Date: 1980

(7) Principal Investigator
NICHOLAS J. DiBELLA, M.D., COL, MC

(8) Facility: FAMC

(9) Dept/Sec: Hematology/Oncology Service

(10) Assoc Investigators:
None

(11) Key Words: Dept of Medicine
Chemotherapy, Ca. prostate

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic Review Results: continue 6/80

(15) *Study Objective:
To determine the efficacy of this drug combination in patients with cancer of the prostate.

(16) *Technical Approach:
Clinical study

(17) *Progress:
One patient received this combination but experienced progression of disease after two courses.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(USCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/118 (3) Status: Ongoing

(4) Title:

Treatment of Severe Erythema Multiforme with Systemic Steroids

(5) Start Date: 15 Sep 1980 (6) Est Comp Date: 1 Jul 1983

(7) Principal Investigator: JAMES E. FITZPATRICK, M.D., MAJ, MC

(8) Facility: FAMC

(9) Dept/Sect: Medicine/Dermatology

(10) Key Words: Erythema Multiforme, Stevens-Johnson, Steroids

(11) Associate Investigators: DENNIS L. MAY, M.D., LTC, MC
JOHN L. AELING, M.D., COL, MC

(12) Est Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Termination Date: continue

(15) Last Update: 8/80

(16) Objectives:

To determine if Systemic Steroids are useful in the treatment of severe erythema multiforme.

(17) Methodology:

Patients with severe erythema multiforme will be admitted as an inpatient and randomized to placebo or Prednisone treated groups and treated for three weeks. Various parameters, including photographs of lesions, duration of fever, duration of arthralgias and complications secondary to systemic steroid will be followed.

(18) Progress:

Since the inception of the protocol, one patient had been entered and completed the protocol. The protocol has been given to the Dermatology Services at Walter Reed Army Medical Center, Letterman Army Medical Center, and Brooke Army Medical Center but has not yet been locally approved.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/119	(3) Status: Ongoing
(4) Title: Captorpril For Refractory Hypertension		
(5) Start Date: 1979		(6) Est Comp Date: 1982
(7) Principal Investigator Lawrence G. Smith, M.D., CPT, MC		(8) Facility: FAMC
(9) Dept/Sec: Medicine/Nephrology		(10) Assoc Investigators: None
(11) Key Words: Captopril Hypertension		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 10/79

(15) *Study Objective:
To test the use of Captopril in patients with severe hypertension, refractory to standard medication therapy.

(16) *Technical Approach:
The patient qualifying for study has hypertension medications tapered, is placed on increasing doses of Captopril to a maximum dose of 400 mg./day. In a set sequence, beta blockade, diuretics, and vasodilators are added to the regimen until no more tension is achieved. The patient is monitored for all potential side effects.

(17) *Progress:
The patient has received Captopril since the initiation of the protocol and his blood pressure has not returned to the normotensive range, but it has been under better control than under any prior medication regimen.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/100 (3) Status:on-going

(4) Title: Further Studies on the Reflex Mechanism of Bronchoconstriction in dogs with Esophagitis. The Effects After Therapeutic Healing of the Esophageal Lesions

(5) Start Date: 8 Dec 80 (6) Est Comp Date: 1 Apr 81

(7) Principal Investigator
Harry S. Spaulding, MD, COL, MD

(8) Facility: FAMC

(9) Dept/Sec:Medicine/All-Imm

(10) Assoc Investigators:
Nigel Smith, SP6, Technician
Richard E. Danziger, MD, CDR, USN
Joseph S. Rice, MD, MAJ, MC

(11) Key Words:
reflex mechanism in bronchoconstriction

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results continue 2/80

(15) *Study Objective:
To determine if the previously demonstrated reflex-mediated bronchoconstriction secondary to stimulation of hte lower inflamed esophagus can be ablated by treatment and resolution of the chemical esophagitis.

(16) *Technical Approach:
A recent protocol demonstrated bronchoconstriction in a group of dogs who had a chemical esophagitis. This study is designed to firm up this earlier investigation after healing of the lesion. Pulmonary function studies will be done pre- and post esophagitis and confirmed with biopsy.

(17) *Progress:
The project will begin on 8 Dec 80. To date only the techniques of the esophageal biopsy have been perfected.

Publications and Presentations: None

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/101 (3) Status: Terminated

(4) Title: The Evaluation of Stool Hemoccult Positivity in Patients on Coumadin-type Anticoagulants.

(5) Start Date: 3 Nov 79	(6) Est Comp Date: 1980
(7) Principal Investigator F.M. Moses, CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Dept of Med/Gastro	(10) Assoc Investigators: none
(11) Key Words: carcinoma, guaiac testing, lesions	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continued Review Results: 4/80

(15) *Study Objective: To determine the frequency of hemoccult positive stool in patients anticoagulated on Coumadin and evaluate the cause of this blood loss.

(16) *Technical Approach: A control group consisting of 100 patients will undergo serial stool guaiac monitoring. All patients identified as occult blood positive will undergo proctoscopy and upper and lower GI series. Appropriate medical care will be obtained for all identified lesions. Those patients with negative evaluation and hemoccult positivity will be referred to the Gastroenterology Clinic, FAMC. Results will be forwarded to investigators. According to

(17) *Progress: This protocol has been terminated due to the transfer of the Principal Investigator.

7. continued -

H.P. McElwee, MAJ, MC

16. continued -

to the results of these tests, additional studies could include upper and lower endoscopy and angiography.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 80/102	(3) Status: Ongoing
(4) Title: Study of Coagulation Parameters Prior To and Following Intravenous Injection of Radiographic Contrast Media.		
(5) Start Date: 20 March 1979		(6) Est Comp Date: 1 December 1980
(7) Principal Investigator STEPHEN G. OSWALD, CPT, MC		(8) Facility: FAMC
(9) Dept/Sec: Dept of Hematology/Oncology		(10) Assoc Investigators: JOHN C. MICHALAK, LTC, MC DAVOR A. LUKETIC; CPT, MC PATRICIA STRANAHAN, MAJ, MC JUDY BARBER (A.S.C.P.) PATRICIA RUSH (A.S.C.P.)
(11) Key Words: Radiographic contrast media, Hypercoagulation		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(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. 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) *Progress:
At present 14 patients have been studied. Thus far there has been no significant coagulation abnormalities from the baseline studies.

Publications and Presentations: None

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FITZSIMONS ARMY MEDICAL CENTER
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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: Jun 1980		(6) Est Comp Date: 1982
(7) Principal Investigator N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Department of Medicine		(10) Assoc Investigators:
(11) Key Words: Chemotherapy protocol Small cell lung cancer		Michael Langin
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(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) *Progress:

Three patients have been entered on the study. Two patients have experienced a partial response and one patient has had stable disease for five months. No serious toxicities have been observed.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 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: June 1980	(6) Est Comp Date: 1983
(7) Principal Investigator: N. J. DIBELLA. MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: HEM-ONC, Medicine	(10) Assoc Investigators:
(11) Key words: Small cell CA, chemotherapy	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(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 or (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) *Progress:

No patients entered to date.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 80/105	(3) Status: Ongoing
(4) Title: Dibromodulcitol in Stage IV Metastatic Malignant Melanoma.		
(5) Start Date: June 1980		(6) Est Comp Date: 1982
(7) Principal Investigator: N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Hem-Onc, DOM		(10) Assoc Investigators:
(11) Key Words: Melanoma, chemotherapy		MICHAEL LANGIN, CPT MSC
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:
To determine the efficacy, duration of response and toxicity of DBD in melanoma.

(16) *Technical Approach:
Clinical study.

(17) *Progress:
No patients have been entered.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/107	(3) Status: on-going
(4) Title: Cross Allergenicity among Grasses Determined by Tissue Threashold Changes	
(5) Start Date: 1980	(6) Est Comp Date: 1981
(7) Principal Investigator H.S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Immunol.	(10) Assoc Investigators:
(11) Key Words: Immunotherapy cross allergenicity	B.G. Martin, MAJ, USA, FAMC R. Renard, CPT, MC

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(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 threashold technique.

(16) *Technical Approach:
Patients with broad reactivity to grasses 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 which they are sensitive or only Timothy and Bermuda. 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:

Patients have been enrolled in this study and are currently receiving one year of immunotherapy.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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: October 1980		(6) Est Comp Date: 1981
(7) Principal Investigator N. J. DIBELLA, MD, COL, MC		(8) Facility: FAMC
(9) Dept/Sec: HEM-ONC, Medicine		(10) Assoc Investigators:
(11) Key Words: Chemotherapy, Cocaine		RICHARD A. ARTIM, MD, CPT, MC
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 9/80

(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) *Progress:

No patients have been entered to date.

Publications and Presentations: None

SURGERY

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 71/202	(3) Status: Ongoing
(4) Title: Evaluation of Peripheral Nerve Injuries at FAMC		
(5) Start Date:		(6) Est Comp Date:
(7) Principal Investigator: William W. Eversmann, Jr., COL, MC		(8) Facility: FAMC
(9) Dept/Sec:		(10) Assoc Investigators: Bertram Goldberg, COL, MC
(11) Key Words: neurorrhapy, peripheral nerve		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 7/80

(15) *Study Objective:

To establish a pattern of peripheral nerve repair and recovery following injuries to pheripheral nerves and in most cases following neurorrhapy of the peripheral nerve.

(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 questionnaires. The questionnaires are devided into specific detailed questions and are customized for the level and type of nerve injury.

(17) *Progress: During FY 1980 we have continued the ongoing clinical data mostly by questionnaires supplemented with an occasional outpatient visit and continue to accumulate data for this important nerve injury evaluation.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.:73/219	(3) Status: Ongoing
(4) Title: Treatment of Urinary Tract Trauma in the Laboratory Animal		
(5) Start Date: May 1973		(6) Est Comp Date: Indefinite
(7) Principal Investigator Major John A. Vaccaro, M.D., MC		(8) Facility: FAMC
(9) Dept/Sec: Surgery-Urology Service		(10) Assoc Investigators: Major Mary L. Osborne, M.D., MC Captain John H. Mani, M.D., MC Colonel Edward G. Buck, M.D., MC Colonel Howard E. Fauver, M.D., MC
(11) Key Words: Trauma-Renal transplantation		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(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 and autotransplantation.

(16) *Technical Approach:
Various techniques of vascular reanastomosis and autotransplantation will be performed. This will be followed by IVPs 2-4 weeks postoperatively to ascertain success or failure.
Manpower (in professional man years): 24 hours
Funding (in thousands) FY 79: 1.3
FY 80: 2.5

(17) *Progress:
Continuing experimentation with various techniques of autotransplantation continue. It is anticipated that this particular protocol will enjoy increased use in the coming year as various compounds such as Inosine are used experimentally to prolong warm ischemia time. In addition to the invaluable experience gained with vascular anastomoses, this protocol represents a potential source of experimental data of great use in the military setting where renal trauma is to be anticipated.

PUBLICATIONS for FY 80 ANNUAL PROGRESS REPORT FAMC WU No 73/219
(Prot No)

(1) Levisay, G.L.: Renal Autotransplantation in the Dog. Proc. of the Kimbrough Urological Seminar, January 1974

(2) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Proc. of the South Central Section, AUA, Denver, CO, 15-19 September 1974. (Published)

(3) Page, M.E.: Renal Autotransplantation wiith Venal Caval Occlusion, Proc. of the Kimbrough Urological Seminar, Seattle, Washington, 5 October 1975.

PRESENTATIONS for FY 80 ANNUAL PROGRESS REPORT AMC WU No 73/219
(Proto No)

(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, Colorado, September 1974.

(3) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: South Central Section of the AUA, Denver, Colorado, 15-19 September 1974.

(4) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy. in the Dog. Presented: Kimbrough Urological Seminar, San Antonio, Texas, 14-19 November 1974.

(5) Page, M.E.: Renal Autotransplantation with Venal Caval Occlusion, 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.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: **76/203**	(3) Status: **Ongoing**
(4) Title: **Screening Program for Military Children at High Risk for Hearing Loss**		
(5) Start Date: **17 Oct 76**		(6) Est Comp Date: **Undefined**
(7) Principal Investigator **Susan T. Slibeck,M.S.,DAC**		(8) Facility: FAMC
(9) Dept/Sec:**Surgery/Otolaryngology/Audiology**		(10) Assoc Investigators: **None**
(11) Key Words: **Parent Interview Chart Review**		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 1/80

(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 will screen 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 wil review the gathered data for indications of high risk for hearing loss and designate children as AT RISK or NOT AT RISK. AT RISK children will be tested or until hearing status is definitely established.**

(17) *Progress: **The value of other High Risk Registers is well-documented in the literature. Reports of some other registers indicate that 1 out of 57 AT RISK children will be hearing impaired. The registry procedures used in this protocol have yielded a more economical result: 1 out of 19 AT RISK children were hearing impaired. Once again, it is reported that the effectiveness of this program is reduced by a shortage of Red Cross Volunteers. Alternate screening techniques may be tried in the future.**

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT Proto No: 76/203

Publications: none

Presentations:

(1) Slibeck, Susan T.: High Risk Factors for Hearing Loss. Presented: Pediatric Department, Fort Carson, CO, December 1976.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 77/204 (3) Status: Ongoing

(4) Title: The Anatomical and Physiological Development of the Flexor Tendon Sheaths in the Human Fetus.

(5) Start Date: September 1979 (6) Est Comp Date: indef.

(7) Principal Investigator
William W. Eversmann, Jr., COL, MC

(8) Facility: FAMC

(9) Dept/Sec: Orthopedic Ser, Dept of Surg

(10) Assoc Investigators:
none

(11) Key Words:
Flexor Anatomical Development Flexor Tendon

(12) Accumulative MEDCASE Cost: -

(13) Est Accumulative OMA Cost: -

(14) Periodic Review Results: continue 12/79

(15) *Study Objective: The objective of this study is to detail the anatomical development embryologically of the flexor tendon sheaths of the human fetus to 20 weeks of age and to corrulate this development with biochemical chanbes within the flexor muscle mass which are indicative of developing contractility.

(16) *Technical Approach: Collection of human fetal specimens to 20 weeks of age gestation and combined anatomical and correlative biochemical studies of the flexor muscle mass.

(17) *Progress: The commerce of the United States has continued to delete funding for interruption of pregnancy on military personnel and their dependents. Obtaining specimens for this study has been extemely difficult or impossible during the past fiscal year. Should this policy by the congress continue consideration is currently being given to convert this study to a primate study rather than a human use study.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/200	(3) Status: Ongoing
(4) Title: Anastomosis of the Dog Vas Deferens Using Microsurigcal Technique		
(5) Start Date: April 1978		(6) Est Comp Date: Indefinite
(7) Principal Investigator Col Howard E. Fauver, M.D., MC		(8) Facility: FAMC
(9) Dept/Sec: Dept of Surgery, Urology Svc		(10) Assoc Investigators: Col Edward G. Buck, M.D.,MC Maj John A. Vaccaro, M.D., MC Maj Mary L. Osborne, M.D., MC Maj Daniel W. Horne, M.D., MC
(11) Key Words: Microsurgery-vasovasostomy		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 4/80

(15) *Study Objective:

To master the microsurgical anastosis 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) *Progress:
Thirty vasovasotomies were performed using a variety of suture and microsurgical techniques. Investigators have mastered the rudiments of microsurgical vasovasostomy and Colonel Buck, Colonel Fauver and Major Vaccaro have developed sufficient skill to perform the procedure on human subjects.

Continued experimentation with various sutures and microsurgical techniques 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,

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/200

(17) Progress, Continued:

this current protocol represents an indispensible tool for training new staff and residents. Due to the expertise gained in this area, referrals are now being obtained not only throughout CONUS but also Europe.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/201	(3) Status: Ongoing
(4) Title: Clinical Study for Intraocular Lenses		
(5) Start Date: September 1976		(6) Est Comp Date: Unknown
(7) Principal Investigator: Andrew J. Cottingham, Jr., M.D.		(8) Facility: FAMC
(9) Dept/Sec: Dept of Surgery		(10) Assoc Investigators:
(11) Key words: Cataract Intraocular Lens Pseudophakos		Richard A. Manson, M.D., COL, MC Lance P. Steahly, M.D., LTC, MC Kevin J. Chismire, M.D., Major, MC Craig A. Peterson, M.D., Cpt, MC Thomas H. Mader, M.D., Major, MC
(12) Accumulative REDCAS Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(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 subjects and for control subjects. (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 good visual potential in only one eye, proliferative diabetic retinopathy (cont)

(17) *Progress:
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 200 intraocular lenses.
As a result of the past four years experience, we have evolved better guidelines for patient selection, better surgical techniques and improved guidance in postoperative care. Our study includes tabulations of operative (cont)

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17) Proto No: 78/201

(10) William G. Carey, M.D., Cpt, MC

(15)
3). To compare the occurence of adverse reactions and ocular complications in the implant group and in the control group, in order to delineate any significant differences.
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)
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.

FAMC WU No (Prot No) 78/203

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Ophthalmology DEPARTMENT Dept of Surgery

(1). Cottingham, Jr., A.J: The initial Fifty Intraocular Lens Implantations in an Ophthalmology Residency Training Program. Submitted for publication to the American Journal of Ophthalmology.

FAMC WU No (Prot No) 78/201

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Ophthalmology DEPARTMENT Dept of Surgery

(1) Cottingham, Jr., A.J.: **Keratoplasty.** Presented: Optometry Meeting, FAMC, October 1978.

(2) Cottingham, Jr., A.J.: **Endopthalmitis** - Cause and Treatment. Presented: University of Colorado Health Sciences Center, January 1979.

(3) Cottingham, Jr.A.J.: Corneal Keratomycoses. Presented: Universit 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 Implantations in an Ophthalmology Training Program. Presented: Bascom Palmer Eye Institute Annual Resident Alumni Meeting, June 1978.

(8). Cottingham, Jr., A.J.: **Residual Astigmatism** - Postoperative Keratoplasty. Presented: **American** Academy of Ophthalmology Chicago, Illinois, 7 Nov 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/202	(3) Status: Ongoing
(4) Title: Evaluation of the Nitroblue Tetrazolium Test (NBT) in Pyogenic Arthritis Using Synovial Fluid.		
(5) Start Date: September 1979		(6) Est Comp Date: indefinite
(7) Principal Investigator Robert M. Campbell, Jr., CPT MC		(8) Facility: FAMC
(9) Dept/Sec: Orthopedic Service, FAMC		(10) Assoc Investigators: Thomas G. Fry, III, CPT, MC
(11) Key Words: NBT Test Pyogenic Arthritis		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 12/79

(15) Study Objective:
To correlate the NBT test performed on synovial fluid with culture proven progenic arthritis in the knee joint.

(16) Technical Approach: The coordinated effort to evaluate the use of NBT test to predict pyogenic arthritis of the knee joint and correlation of this test with proven bi culture pyogenic arthritis.

(17) Progress: A small series of patients have been completed are in this protocal. A greater number is needed to determine the usefullness of this method as an adjunct to the diagnosis and consequently institutional in pyogenic arthritis.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/203 (3) Status: Terminated

(4) Title: The Effects of Heterotopic Lymph Node Transplantation on Surgically Induced Lymphedema

(5) Start Date: 30 Sep 79 (6) Est Comp Date: 30 Sep 81

(7) Principal Investigator
Viktor Gottlieb, Major, MC (8) Facility: FAMC

(9) Dept/Sec: Plastic Surgery (10) Assoc Investigators:
John D. Rich, Colonel, MC

(11) Key Words:
lymphedema
lymph node tissue
lymphadnectomy

(12) Accumulative MEDCASE Cost: (13) Est Accumulative OMA Cost: (14) Periodic Review Results: continue 12/79

(15) *Study Objective: The objective is to study the effect of transplanted lymph nodes to surgically induced lymphedema in rats.

(16) *Technical Approach: Five groups treated in various ways will be examined following translocation of lymph node tissue. An initial group of six Fisher rats underwent resection of ipsilateral popliteal and inguinal lymph nodes. The long term demonstration of lymphedema in the operated leg will be observed. Following the occurrence of lymphedema the various research groups will be developed.

(17) *Progress.
Ten patient's were studied. The protocol was terminated due to ETS of Principal Investigator.

FAMC WU No (Prot No) 78/203

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Plastic Surgery DEPARTMENT of Surgery

(1) Shesol, B.F., Viktor, Gottlieb: Preliminary Data and Technique for The Effects of Heterotopic Lymph Node Transplantation on Surgically Induced Lymphedema. J of Plastic & Reconstructive Surgery, Vol 63:6, June 1979.

Presentations:

(1) Shesol B.F.: Heterotopic Lymph Node Transplantation. Presented: Ivy Society Resident's Competition, Hershey, Penna., 1978.

(2) Shesol, B.F.: Heterotopic Lymph Node Transplantation. Presented: Chief Resident's Meeting, Hershey, Penna., 1978.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No. 79/200 (3) Status: Terminated

(4) Title: Alterations of Hematostatic Mechanisms in Patients Undergoing Cardiopulmonary Bypass.

(5) Start Date: 1979 (6) Est Comp Date: 1980

(7) Principal Investigator
Douglas D. Pritchard, MAJ, MC (cont'd)

(8) Facility: FAMC

(9) Dept/Sec: Surgery

(10) Assoc Investigators:
Donald G. Corby, COL, MC
Judy A. Barber, MT, DAC

(11) Key Words:
cardiopulmonary bypass
hemolysis
platelet function

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 2/80

(15) Study Objective:

1. To evaluate platelet function in patients undergoing cardiopulmonary by pass procedures.

2. To evaluate the effect of red cell hemolysis on circulating platelets.

(16) Technical Approach:

Twenty adult patients scheduled to undergo cardiopulmonary bypass procedures will be evaluated. All patients taking drugs: aspirin, persantin, (dipyridamole) or other agents known to alter platelet function, will be excluded from the study. Platelet function will be evaluated pre-operatively, in the operating room after anesthesia is induced and chest opened, hourly during the pump procedure, 10 min

(17) Progress:

This study has been terminated due to the ETS of the Principal Investigator. A similar study evaluating platelet function in patients undergoing Cardiopulmonary bypass has recently been published in Blood, November 1980.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/200

(7) continued -
John Samuel Clark, COL, MC

(15) continued -

3. To investigate the cause of platelet dysfunction in patients undergoing cardiopulmonary bypass - platelet activation vs. platelet refractoriness secondary to release of red blood cell ADP.

4. To attempt to correlate the degree of hemolysis with alterations of platelet function and clinical hemorrhage post-operatively.

(16) continued -

post protamine administration, and 1,4, and 24 hours post-operatively.

The following laboratory procedures will be done, prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT) after heparin reversal, fibrinogen, and aggregation to adensine diphosphate (ADP), (2 and 5 um), collagen, epinephrine, (5.5 um) evaluation of circulating platelet aggregates according to method of Wu, evaluation of spontaneous aggregation of platelets in PRP, platelet counts, shape change estimated by electron microscopy, plasma hemoglobin, and RIA measurements of thromboxane B_2, and nucleotide content of platelets and plasma. Platelets Cyclic AMP (cAMP) and adenyl cyclase measurements will be performed on selected samples. All blood will be obtained through a central venous line which is normally placed in these patients at the time of surgery for clinical reasons.

Estimates of blood loss will be charted and compared with plasma hemoglobin levels. Alterations of platelet function tests vs. time will be analyzed using analysis of variance with intergroup comparisons.

Ten surgical patients meeting same criteria not undergoing cardiopulmonary bypass will also be studied.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/201	(3) Status: Ongoing
(4) Title: Platelet Function in Disease States.		
(5) Start Date: 7 Aug 79	(6) Est Comp Date: June 82	
(7) Principal Investigator: Victor Ferraris, M.D., Ph. D.	(8) Facility: FAMC Aurora, CO. 80045	
(9) Dept/Sec: DOS/Gen Surg Svc	(10) Assoc Investigators: T. P. O'Barr, D. Corby, J.R. Smith, E. Swanson	
(11) Key Words: Prostaglandins, Thromboxane, Arachidonic Acid, Prostacyclin, Platelets		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 8/80

(15) *Study Objective:

a. To develop and assess methods of measuring in vitro platelet function.
b. To investigate the importance of arachindonic 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. (Contd Incl 1)

(16) *Technical Approach:

To use tests of platelet function to screen surgical patients for platelet related abnormalities.

(17) *Progress:

Aspirin irreversibly inhibits platelet arachidonic acid metabolism. The Thromboxne radioassay can reliably measure the degree of this inhibition (see fig. 1). Patients requiring emergency operation are being screened using tests of platelet function (including TXB_2 levels in serum & bleeding time) in order to detect the presence of ASA-like effect on platelets in these preoperative patients. The question being asked is, "Does the presence

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/201

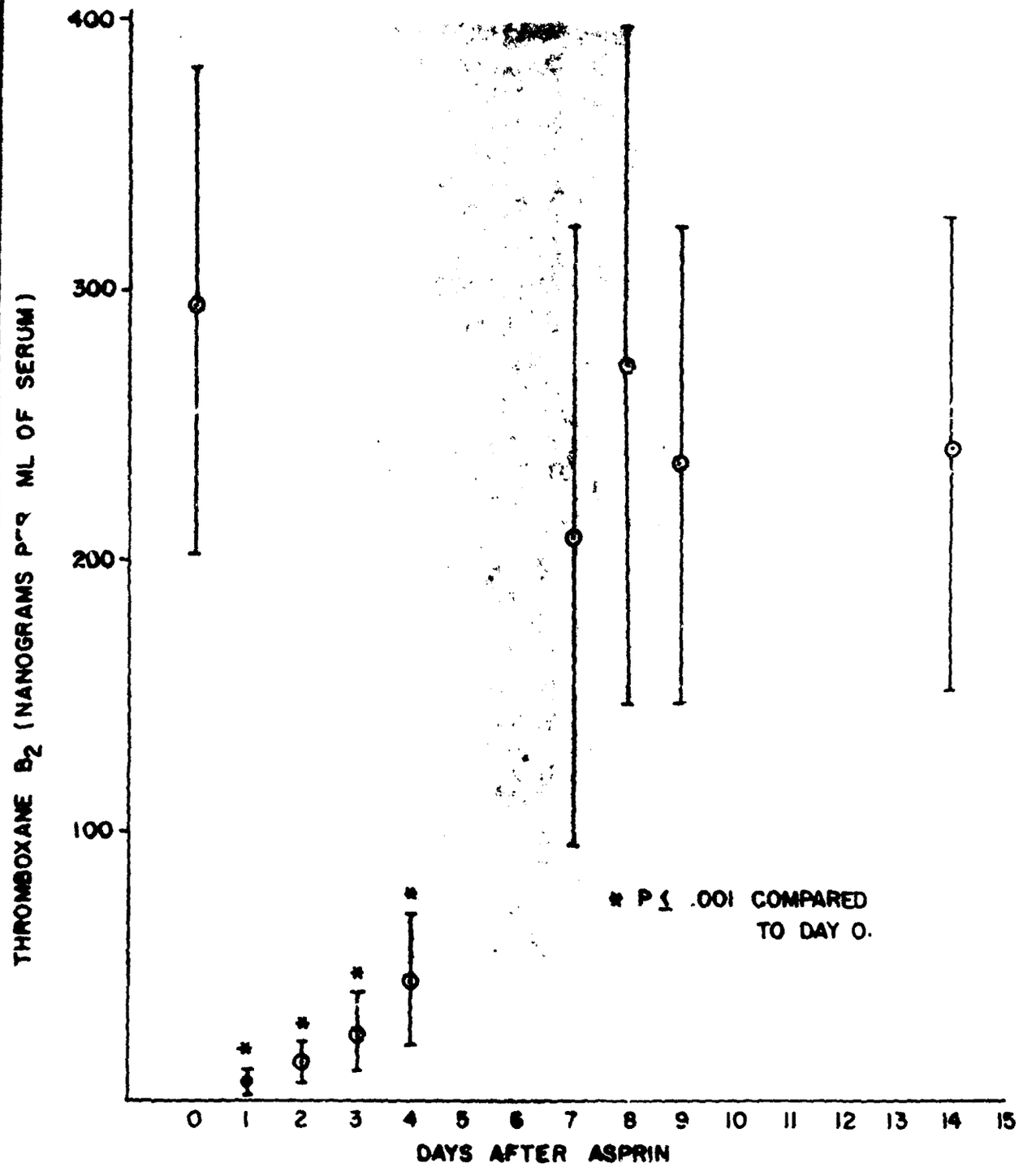
Objectives Continued:

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.

17. *Progress Continued:

of ASA platelet inhibition cause increased bleeding problems in patients requiring emergency operation"? Preliminary results indicate that ASA is commonly taken prior to emergency operation and there is no major increase in bleeding complications in patients who have taken ASA preoperatively.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300
200
100
THROMBOXANE B_2 (NANOGRAMS PER ML OF SERUM)
* P ≤ .001 COMPARED TO DAY 0.
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
DAYS AFTER ASPRIN

FAMC WU No (Frot No) 79/201

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE General Surgery Service DEPARTMENT of Surgery

(1) Eiseman, B.:
Prognosis of Surgical Disease:
W. B. Saunders Company, 1980

The following chapters were contributed by our staff doctors:

Carcinoma of the Oral Cavity by Richard M. Hirata, M. D.

Reflux Esophagitis by Ross S. Davies, M. D.

Varicose Veins by Lewis Mologne, M. D.

(2) Ferraris, V.A., and Sube, Janis:
Retrospective Study of the Surgical Management of Reflux Esophagitis Surgery, *Obstetrics and Gynecology*, 1980 (in Press).

FAMC WU No (Post No) 79/201

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE General Surgery DEPARTMENT of Surgery

(1) Ferraris, V. A., Subr, Janis:
Retrospective Study of the Surgical Management of Reflux Esophagitis,
Presented:
William Beaumont Army Medical Center, El Paso, Texas, March, 1980.

AD-A101 634 FITZSIMONS ARMY MEDICAL CENTER AURORA CO F/G 6/5
CLINICAL INVESTIGATION PROGRAM. ANNUAL RESEARCH PROGRESS REPORT--ETC(U)
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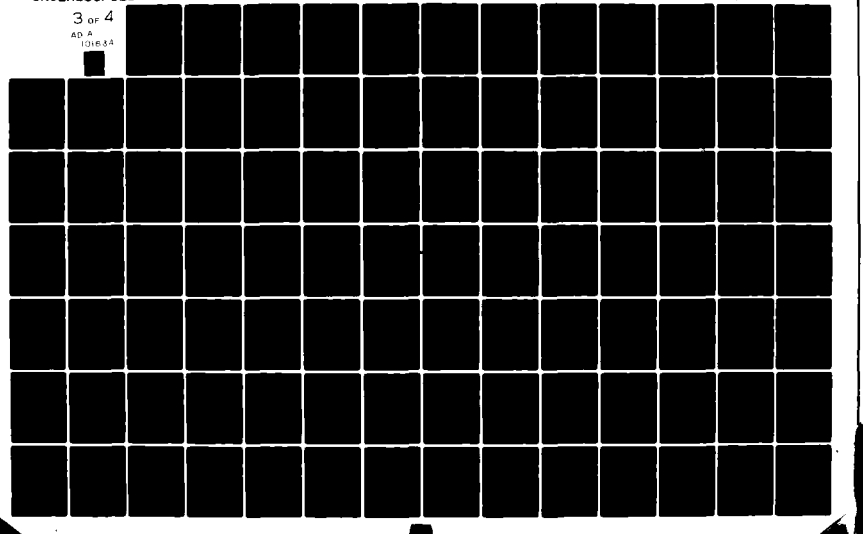

CLINICAL INVESTIGATION

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 72302		(3) Status: Ongoing
(4) Title: Comparison of Metabolic and Functional Changes in Defects of Platelet Function.			
(5) Start Date: 1972		(6) Est Comp Date: 1981	
(7) Principal Investigator Donald G. Corby, M.D., COL, MC		(8) Facility: FAMC	
(9) Dept/Sec: Clinical Investigation		(10) Assoc Investigators: John W. Harbell, Ph.D., CPT, MSC Thomas P. O'Barr, Ph.D., DAC	
(11) Key Words: cyclic nucleotides, platelet function, prostaglandins, prostacyclins			
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:		(14) Periodic continue Review Results: 11/79

(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

(17) *Progress:
During the past fiscal year, three manuscripts have been accepted for publication. The newborn platelet "affect" now most certainly appears to be a "transient membrane phenomenon".

The original protocol has recently been revised. Future work will concentrate on "breaking down" membrane activation. Procedures are now being developed to quantitate platelet membrane glycoproteins,

(16) Technical Approach - continued

evaluation of patients with functional platelet syndromes associated with the "hemorrhagic state".

Blood Collection: Samples of cord blood will be taken from the umbilical vein as follows: Immediately after delivery, the umbilical cord will be clamped and an 18 gauge disposable needle will be inserted into the umbilical vein. Blood will be drawn into a plastic syringe and immediately transferred to a plastic centrifuge tube containing either (1) 10% by volume of 0.1 M buffered citrate anticoagulant or (2) a purple-topped tube containing EDTA. Samples from the mother which will serve as controls will be taken either prior to or at the time of delivery using a two-syringe technique where a butterfly-type needle is inserted into the antecubital vein. A small amount of blood (0.5-1 ml) is drawn into this syringe at this time ; then a second syringe containing the appropriate anticoagulant is connected to the end of the butterfly needle and the desired sample is drawn directly into this syringe, mixed well by inversion, and transferred to a plastic centrifuge tube. Samples from patients or normal adult volunteers will be collected in the same manner when needed.

Platelet Function Studies:

When indicated clinically, platelet counts, bleeding times, platelet adhesion, and platelet 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.

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) content and release of adenonine nucleotides and serotonin in the dense granules.
b) assessment of cyclooxygenase activity by measuring Thromboxane$_2$ and malondialdehyde formation.
c) electron microscopy and mepacrine staining of dense granules.
d) content of platelet factor 4 and B-thromboglobulin activity in the alpha granules.
e) production of platelet-derived growth factor by ^{3}H-thymidine incorporation in 3T3 mouse fibroblasts by platelet lysates.
f) measurement of secretable acid hydrolases (B-glucuronidase, B-galactosidase, and membrane P-nitrophenyl phosphatase) activities.
g) membrane glycoprotein and phospholipid content.
h) release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase.
i) mobilization of Ca++.
j) other studies as they become available.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT Proto No:72/302
(Blocks 1 through 17)

(16) Technical Approach - continued

Other studies to be conducted include the measurements of ADP receptors and alpha-adrenergic receptors, adhesion of platelets to deendothelialized rabbit aortic subendothelium and prostacyclin activity in umbilical veins.

Procedures already available in the Biochemistry Service, Department of Clinical Investigation, are designated by an asterisk. Other procedures are readily available in the literature and will be developed as needed.

Statistical Analysis:

Differences between the platelets of new infants and their mothers will be compared using the unpaired Student's t-test. Clinically oriented studies will be performed and compared with normal adult volunteers as controls.

(17) Progress - continued

formation of diglyceride and arachidonate from membrane phospholipids will also be assessed. Other studies planned include assessment of alpha granules content (B-thromboglobulin and platelets factor 4).

FAMC WU No (Prot No) 72/302

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE _____ DEPARTMENT of Clinical Investigation

(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 (T A). (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. L: 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. L: 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, In Press.

(11) Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. Haemostasis, In Press.

Publications for FY 80 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, In Press.

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.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 73/305	(3) Status: Terminated
(4) Title: Computer Storage and Analyses of Mycobacteriologic Laboratory Data from Tuberculosis Patients.		
(5) Start Date: 1968		(6) Est Comp Date: Nov 1980
(7) Principal Investigator G.L. Brown, Ph.D., COL, MSC (cont'd)		(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation		(10) Assoc Investigators: Mary V. Rothlauf, M.S., DAC
(11) Key Words: Computer Storage Mycobacteria Tuberculosis		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 9/80

(15) *Study Objective:
To establish and maintain an indepth data base of mycobacteriological data on FAMC tuberculosis service patients.

(16) *Technical Approach:
Since 1968, all mycobacteriologic results on FAMC tuberculosis patients have been stored in a computer file. Presently 2641 patient records encompassing 59,269 messages have been accumulated in the computer file. Patient data include: smear and culture results, drug susceptibilities of mycobacterial isolates, initial drug therapy data, serum tests, data on special study patients, and experimental data on methodology studies.

(17) *Progress:
No data has been added during FY 1980 due to the fact that no positive patients have been admitted during this period. Due to the rarity of positive patients, this protocol has been administratively terminated.

(7) continued-

J.J. Damato, MAJ, MSC

Publications: None

Presentations:

(1) Brown, G.L., and Rothlauf, M.V.: Laboratory Management of the Tuberculosis Patient. Computer File Analyses of Six Year Data. Presented: Society of Armed Forces Laboratory Officers, San Antonio, Texas, September 1976.

(2) Brown, G.L., and Rothlauf, M.V.: Computer Utilization in the Laboratory. Presented: Colorado State University, Ft. Collins, CO, April 1977.

(3) Brown, G.L., and Rothlauf, M.V.: Computer File Analyses and Utilization of Mycobacteriology Laboratory Data. Presented: Colorado State University, May 1978.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 74/300	(3) Status: Terminated
(4) Title: Microbiological Research in Tuberculosis.		
(5) Start Date: 1974		(6) Est Comp Date: 1980
(7) Principal Investigator G.L. Brown, Ph.D., COL, MSC (cont'd)		(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation		(10) Assoc Investigators: Mary V. Rothlauf, M.S., DAC Donald D. Paine, B.S., DAC
(11) Key Words: Tuberculosis Research		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(15) *Study Objective:

To evaluate and/or design new methods for improving diagnostic laboratory procedures *in mycobacteriology* and to maintain an in-depth data base of laboratory results on tuberculous patients.

(16) *Technical Approach:

1. Comparison of Middlebrook 7H11 CA Agar with modifications thereof.
2. Tests for identification of mycobacterial species.
3. Evaluation of drug susceptibility test media.
4. Characterization of non-mycobacterium tuberculosis species isolated from experimental media.
5. Characterization of contaminants growing on experimental media.(cont'd)

(17) *Progress:

Administratively terminated and rewritten as protocol 80/301.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 74/300

(7) continued - James J. Damato, MAJ, MSC
(16) continued-

6. Comparison of smears before and after decontamination to determine possible loss of staining characteristics and viability.

FAMC WU No (Prot No) 74/300

PUBLICATIONS for FY 80 Annual Progress Report

SERVICE Microbiology DEPARTMENT of Clinical Investigation

(1) Kolb, J.G., Rothlauf, M.V., and Brown, G.L.: 'solation of Mycobacterium kansasii on Mitchison's Selective 7H11 medium. (Abst.) American Society for Microbiology, C-69:47, 1977.

(2) Rothlauf, M.V., Brown, G.L., and Blair, E.B.: Isolation of Mycobacteria from Undecontaminated Specimens with Selective 7H10 Medium. (In Press)

Presentations:

(1) Kolb, J.G., Rothlauf, M.V., and Brown, G.L.: Isolation of Mycobacterium kansasii on Mitchison's Selective 7H11 Medium. Presented: American Society for Microbiology, New Orleans, LA, May 1977.

(2) Brown, G.L., and Rothlauf, M.V.: Effects of Alpha-tocapheral and/or Altitude Stress on BCG Vaccinated Mice. Presented: National Jewish Hospital, Denver, CO, June 1978.

(3) Damato, James J.: Rapid Methods for Differentiative Mycobacterial Species. Presented: University of Northern Colorado, Greely, CO, October 1979.

(4) Damato, J.J.: Biochemical Methods for Differentiating Mycobacteria. Presented: Colorado State University, Ft. Collins, CO, May 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 76/301 (3) Status: Ongoing **

(4) Title: Pancreatic Islet Transplantation in Diabetic Animals.

(5) Start Date: 1976	(6) Est Comp Date: 1982
(7) Principal Investigator David T. Zolock, Ph.D., CPT(P), MSC	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation	(10) Assoc Investigators: Donald G. Corby, M.D., COL, MC
(11) Key Words: Diabetic, Pancreatic Islets, Transplantation	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/79

(15) *Study Objective:

Information derived from islet transplantation experiments indicates that diabetes mellitus can be effectively treated in animals. For this treatment approach to become practical in humans it appears obligatory to achieve effective animal allograft islet transplants. This goal has not been realized and thus the current protocol directly attempts to perform allogeneic islet transplantation in diabetic animals.

(16) *Technical Approach:

Pancreatic islets are isolated and purified from donor strain rats and under various conditions are transplanted to Lewis recipient rats. The assessment of transplantation success is made by measurement of daily urine volumes and 24 hr urine glucose excretion in addition to serum glucose values.

(17) *Progress:

Isograph transplantations are approximately 95% successful. Allografts have been unsuccessful. Culturing the islets for 7 days may help to alleviate this problem by destroying the lymphocytes. An Isograft transplantation of frozen islets in a glycerol medium was partially successful since the animal was partially cured before reverting back to diabetic.

**This study was inadvertently shown as completed in the last FY report.

FAMC WU No (Prot No) 76/301

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Biochemistry DEPARTMENT of Clinical Investigation

(1) Charles, A., Noble, S., Ownbey, J., Brown, G.L., and O'Barr, T.P.: Mechanisms of Islet Allograft Rejection. (Abst.) Journal of the American Diabetes Association, 1979.

(2) Charles, M.A.: Islet Allograft Transplantation in Diabetic Rats. Diabetes 26: 1978.

Presentations:

(1) Charles, M.A.: Islet Allograft Transplartation in Diabetic Rats. Presented: American Diabetes Association National Meeting, 1978.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults: I. Correlation of Immune Functions in the Immunodeficiency State. II. Correlation(cont'd)

(5) Start Date: 1 October 1977 (6) Est Comp Date: Open ended

(7) Principal Investigator
G. L. Brown, Ph.D., COL, MSC (8) Facility: FAMC

(9) Dept/Sec: Clinical Investigation (10) Assoc Investigators:
Donald G. Corby, M.D., COL, MC
R. Stephen Whiteaker, Ph.D., CPT, MSC

(11) Key Words:
Immunologic Disorders

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic Review Results: continue 4/80

(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,

(17) *Progress:
A total of 267 patients were evaluated on consultative basis for immunologic disorders. During this period ten physician housestaff personnel were also trained in laboratory clinical immunology procedures (humoral and cellular). Patients studied: 159 in the area of serum protein gammapathies and 108 for special studies of cellular immunologic problems. Subjects with indicated major findings were as follows: 1) Humoral immunologic disorders-serum protein profile

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 77/300

(4) continued - of Immune Functions of Leukemia and other Childhood Malignancies.

(16) continued -

clinical immunodeficiency state, lack of response to medical management and availability of clinical investigation service for laboratory evaluations for patient care.

(17) continued -

evaluations: 13 cryoglobulinemias, 89 serum protein gammapathies, 39 immunoglobulin disorders (heavy and light chain and benign spike), 18 hypogammaglobulinermias, 18 hypergammaglobulinemias, 4 C' complement abnormalities; II) Cellular immunologic disorders-lymphocyte evaluations: 108 lymphocyte blast transformations (PHA, Con A, Pokeweed Mitogen), 101 T-lymphocyte enumeratives, of these 20, 10, and 6 patients were recorded suppressed post PHA, PWM and candida stimulations, respectively. III) Miscellaneous evaluations: 20 B-cell flourescent taggings, 26 NBT evaluations, 13 neutrophil chemotactic studies, 7 monocyte chemiluminescence evaluations.

Publications: None

Presentations:

(1) Brown, G.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.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/301 (3) Status: Completed

(4) Title: Radiometric Methods for the Rapid Detection, identification and Susceptibility Testing of Mycobacterium Species.

(5) Start Date: 1978 (6) Est Comp Date: Aug 1980

(7) Principal Investigator
J.J. Damato, MAJ, MSC (cont'd)

(8) Facility: FAMC

(9) Dept/Sect: of Clinical Investigation

(10) Assoc Investigators:
Mary V. Rothlauf, M.S., DAC
Kenneth McClatchy, Ph.D., NJH

(11) Key Words:
Mycobacteria
Radiometric testing

(12) Accumulative Research Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results:

(15) *Study Objective:
To develop radiometric methodology for rapid detection, identification and susceptibility testing of mycobacteria isolate from patients' specimens.

(16) *Technical Approach:
C^{14} substrates are employed to detect the early growth of mycobacteria in various medium bases. In addition, various chemical agents are being evaluated and incorporated in these bases in order to attempt to differentiate the various mycobacterial species and provide early susceptibility data.

(17) *Progress:
Eighty nine smear positive sputum specimens were evaluated using radiometric and standard plate isolation procedures to determine the methodology which would provide the earliest detection and maximum sensitivity. Rapid detection and maximum recovery may be expected by inoculating a combination of radiometric broth and plate media.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/301

(7) continued -

G.L. Brown, Ph.D., COL, MSC

Publications: None

Presentations:

(1) Damato, J.J. Rapid Methods for Differentiating Mycobacterium Species. Presented: University of Northern Colorado, Greely, CO, October 1979.

(2) Damato, J.J., Rothlauf, M.V., and McClatchy, J.K.: Differentiation of Tubercle Bacilli and Nontuberculous Mycobacteria by a Radiometric Method. Presented: Annual Meeting of The American Society for Microbiology, Miami Beach, FL, May 1980.

(3) Damato, J.J., Rothlauf, M.V., and McClatchy, J.K.: Differentiation of Tubercle Bacilli and Nontuberculous Mycobacteria by a Radiometric Method. Presented: National Jewish Hospital and Research Center, Denver, CO, June 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/302 (3) Status: Completed
(4) Title: Adsorbtion of Propoxyphene by Activated Charcoal

(5) Start Date: Jan 1978	(6) Est Comp Date: 1 July 1980
(7) Principal Investigator W.Nicholas Glab, SP6, B.S.	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation	(10) Assoc Investigators: Donald G. Corby, M.D., COL, MC Walter J. Decker, Ph.D. Virginia R. Coldiron, M.S.
(11) Key Words: Propoxyphene Activated Charcoal Toxicity	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 11/79

(15) *Study Objective: To determine the efficacy of activated charcoal in the emergency management of propoxyphene overdosage.

(16) *Technical Approach: Holtzman rats (100-150 g) were administered propoxyphene hydrochloride (P-HCl, 350 mg/Kg) or propoxyphene naysylate (P-N, 825 mg/Kg) dissolved or suspended in 5% acacia in H_2O. After 30 minutes, the rats were administered either AC at 10 times the drug dose or water. Surviving rats were sacrificed at 1,2,4,8, 12 and 24 hr; the brain, liver and both kidneys were removed intact, weighed, and stored at -70°C. After lyophilization, the tissues were

(17) *Progress: There were significantly less deaths in rats who received P-HCl+AC or P-N + AC than rats who received either P-HCl or P-N alone (9vs19, p 0.01 and 5vs10, p 0.05 respectively). Tissue levels of propoxyphene and norpropoxyphene were similarly significantly reduced. These studies provide further evidence of the efficacy of AC in propoxyphene overdosage.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/302

(16) continued-
analyzed for propoxyphene and its metabolite, norpropoxyphene by GLC.

(To all C's, Depts/Svcs)

PUBLICATIONS occuring during FY 80

SERVICE Surgical Research Laboratories DEPARTMENT of Clinical Investigation

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(1) Glab, W.N., Corby, D.G., Decker, W.J., and Coldiron, V.R.: Prevention of Propoxyphene Absorption by Activated Charcoal in Rats: Clinical and Pharmacological Correlations. Vet & Human Toxicol (in press).

(2) Glab, W.N., Corby, D.G., Decker, W.J. and Coldiron, V.R.: Decreased Absorption of Propoxyphene by Activated Charcoal. Submitted for publication to J of Fundamental and Applied Toxicology.

PRESENTATIONS:

(1) Glab, W.N., Corby. D.G., Decker, W.J., and Coldiron, V.R.: Prevention of Propoxyphene Absorption by Activated Charcoal in Rats: Clinical and Pharmacological Correlations. Presented: AACT/AAPCC/CACAT Meeting "Clinical Toxicology '80", Minneapolis, Minnesota, 6 Aug 1980.

[illegible] ARMY MEDICAL [illegible]
[illegible], Colorado [illegible]

[illegible]
(HSCR 40-23, [illegible] Summary Sheet)

(1) Date: [illegible] Proj No.: 78/30[illegible] Status: Ongoing
(4) Title: Evaluation of Humic Substances [illegible] Gastrointestinal Decontamination [illegible] Patient.
(5) Start Date: 1978 [illegible]
(7) Principal Investigator [illegible]
Donald G. Carl[illegible]
(9) [illegible]
(11) Key Words:
Humic Acid [illegible]
Gastrointe[illegible]
Poisons
(12) [illegible] continue
[illegible] Results: 12/79
(15) [illegible]
To [illegible] substances to bind [illegible] toxic drugs and household poisons.

(16) [illegible]
Humic [illegible] from Florida through [illegible] After obtaining a [illegible] determine the relative [illegible] substances to [illegible] diphenylhy-
amphetamine [illegible], meprobamate,
dantoin [illegible]

[illegible] than 0.3%.
Humic [illegible] Using gel
filtr[illegible] ugFe++/mg.
[illegible] with a LD_{50} of
24[illegible] acid/kg in
[illegible] compared to control rats
[illegible] equilibrium dialysis are

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/303

(7) continued -

T.P. O'Barr, Ph.D., DAC
Walter J. Decker, Ph.D., Department of Pharmacology/Toxicology, University of Texas Medical Branch, Galveston, TX

(16) continued -

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.

(17) continued -

being conducted in order to determine the optimum conditions for binding of iron and other harmful drugs to humic acid.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/304 (3) Status: Ongoing

(4) Title: Treatment of Iron-deficiency Anemia I: Comparison of Hematologic Parameters following Treatment with Carbonyl Iron of Ferrous Sulfate(cont'd)

(5) Start Date: 1978 (6) Est Comp Date: 1981

(7) Principal Investigator
Donald G. Corby, M.D., COL, MC

(8) Facility: FAMC

(9) Dept/Sec: Clinical Investigation

(10) Assoc Investigators:
Walter J. Decker, Ph.D.
Director, Dept. of Pharmacology/ Toxicology, Univ. of Texas Med. Br., Galveston, TX.

(11) Key Words:
Iron-deficiency Anemia
Carbonyl Iron, Ferrous Sulfate
hematocrit values

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic continue Review Results: 12/79

(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 CBS indices, serum iron, unsaturated iron-binding capacity, free erythrocyte protoporphyrin levels, ferritin levels, 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

(17) *Progress:
Delays in initiating this project have occurred because of requirements for animal housing for other registered research projects. Carbonyl iron and iron-free diets have been received. Animals are on order; study expected to begin within the next month.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/304

(4) continued - in Wistar Rats.

(10) continued -

Penelope Rich Giese, B.S., SSG
Lawrence E. Jones, M.T., DAC
Troy Engle, SFC

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: On going
(7) Principal Investigator John W. Harbell PhD, Cpt, MSC		(8) Facility: FAMC
(9) Dept/Sec: DCI/SRLS		(10) Assoc Investigators: Donald Mercill, BS, DAC Lesie Kramer, BS, Sp5
(11) Key Words: Breast Tumors		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 3/80

(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 pituitary 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 in-

sensitive 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. 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 that DNA synthesis was the most sensitive to the insulin concentration with the other parameters markedly less so.

FAMC WU No (Prot No) 79/300

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Surgical Research Lab's DEPARTMENT of Clinical Investigation

1. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Strain Mouse Mammary Tissues. (Abst) Ann Tissue Culture Assoc, 1980.

2. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Strain Mouse Mammary Tissues. In Vitro 16(3):247, 1980.

FAMC WU No (Prot No) 79/300

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Surgical Research Lab's DEPARTMENT of Clinical Investigation

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

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/301	(3) Status: Ongoing
(4) Title: Basic Studies to Hasten Recovery from or Help Prevent Bone Injury		
(5) Start Date: February 1979		(6) Est Comp Date: October 1982
(7) Principal Investigator David T. Zolock, Ph.D., CPT(P), MSC		(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation		(10) Assoc Investigators: Daniel D. Bikle, M.D., Ph.D. Veterans Administration Med.Ctr. San Francisco, CA
(11) Key Words: Vitamin D, Caicium, Bone, Intestine, Calcium Binding Protein		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 3/80

(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 measures, 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:

The initial vitamin D mediated calcium transport across the lumen and the mediated mucosal calcium accumulation in 1,25-dihydroxycholeciferol repleted rachitic chicks do not depend on the synthesis of the vitamin D dependent intestinal calcium binding protein or other protein synthesis. However, protein synthesis is necessary for the vitamin D mediated calcium uptake in bone. The homogeneous purification of calcium binding protein is almost complete. This preparation will be used to determine

(17) continued -

if calcium binding protein, injected intraveneously, will affect calcium uptake in the bone and calcium transport and accumulation in the intestine in rachitic and vitamin D repleted chicks which have blocked protein synthesis.

FAMC WU No (Prot No) 79/301

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Biochemistry DEPARTMENT of Clinical Investigation

(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 in Vitamin D; Biochemical, Chemical and Clinical Aspects Related to Calcium Metabolism. Walter DeGruyter, Inc., New York, 1979.

(2) Bikle, D.D., Morrissey, R.L., Zolock, D.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, D.D., Morrissey, R.L., and Zolock, D.T. The Mechanism of Action of Vitamin D in the Intestine. Am J Clin Nutr 32:2322-2338, 1979.

(4) Morrissey, R.L., Zolock, D.T., Mellick, P.W., and Bikle, D.D.: Influence of Cycloheximide and 1,25-dihydroxyvitamin D_3 on Mitochondrial and Vesicle Mineralization in the Intestine. Cell Calcium 1:69-79, 1980.

(5) Bikle, D.D., Askew, E.W., Zolock, D.T., Morrissey, R.H. and Herman, R.H.: Calcium Accumulation by Chick Intestinal Mitochondria: Regulation by Vitamin D_3 and 1,25-dihydroxyvitamin D_3. Biochem, Biophys Acta 598: 561-574, 1980.

Presentations:

(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. Presented: Berlin (West), Germany, February 1979.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/304 (3) Status: Ongoing		
(4) Title: Quantitation of Steroid Hormone Receptors in Tissue Sections Using Quantitative Autoradiography		
(5) Start Date: 1979		(6) Est Comp Date: ongoing
(7) Principal Investigator John W. Harbell PhD,Cpt, MSC		(8) Facility: FAMC
(9) Dept/Sec: DCI/SRLS		(10) Assoc Investigators:
(11) Key Words: Steroid Receptors		none
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 12/79

(15) *Study Objective:
To provide a means to quantify cellular steroid receptors (estrogen, progesterone and glucocorticoids)on a cell by cell basis in both normal and transformed tissue samples.

(16) *Technical Approach:
Viable tissue samples are pulse-labelled, in vitro, with ^{3}H-labelled steroids, extensively washed with culture medium and quick frozen. Frozen sections are placed on emulsion-coated slides and exposed at -15C. Microscope quantitation of specific(total-background) silver grain number over the cell nucleus is used to indicate a responsive cell.

(17) *Progress:
The basic steroid autoradiography technique using in vitro steroid exposure is now available and is used:1) to provide nuclear translocation controls for more rapid but nonquantitative fluorescent steroid receptor localizing techniques especially applicable for very small clinical samples and 2)to study steroid receptors in cells of the growing murine and human mammary end-buds and mesenchyme.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/305 (3) Status: Terminated

(4) Title: Field Trial of New Techniques for Isolation, Identification and Susceptibility Testing of Mycobacteria.

(5) Start Date: 1979 (6) Est Comp Date: Nov 1980

(7) Principal Investigator
James L. Owmby, MAJ, MSC (cont'd)

(8) Facility: FAMC

(9) Dept/Sec: Clinical Investigation

(10) Assoc Investigators:
J.J. Damato, MAJ, MSC
J. Kenneth McClatchy, Ph.D.,NJH

(11) Key Words:
Mycobacteria
Isolation, Identification
Susceptibility testing

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(15) *Study Objective:

1. To set up a field trial of Mitchison's selective medium.
2. To develop and evaluate the use of a transport medium for clinical specimens for mycobacteriology sent to reference laboratories for processing.
3. To determine primary antituberculosis drug resistance of TB infected personnel stationed in Korea.

(16) *Technical Approach:
The 121st Evacuation Hospital, Korea, will collect TB sputum specimens, prepare smears, inoculate S7H10 directly and split remaining specimens. They will process on aliquot as usual and, after adding an equal volume to holding medium to the remaining portion, send that portion to Mycobacteriology, Department of Clinical Investigation, FAMC, for isolation and susceptibility testing. Drug susceptibility of M. tuberculosis

(17) *Progress:
No progress during FY 80. Therefore, this protocol has been administratively terminated.

Publications and Presentations: None

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/305

(7) continued-

Mary V. Rothlauf, M.S., DAC
James D. Hakes, DAC

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/306 (3) Status: Ongoing
(4) Title: Adenohypophyseal-thyroid Interrelationships in Dehydration.

(5) Start Date: June 1979 | (6) Est Comp Date: December 1980
(7) Principal Investigator: W. Nicholas Glab, B.S., SP6 | (8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation | (10) Assoc Investigators: John W. Harbell, Ph.D., CPT, MSC
(11) Key Words: Adenohypophysis, Thyroid, Dehydration

(12) Accumulative MEDCASE Cost: | (13) Est Accumulative OMA Cost: | (14) Periodic Review Results: continue 6/80

(15) *Study Objective:
To examine the activity of the thyroid and thyroid stimulating hormone (TSH) producing cells of the anterior pituitary gland during dehydration, utilizing light and electron microscopy.

(16) *Technical Approach:
Sacrifice periods, totaling 8 days, will include members of two groups of rats: controlled and water-deprived, and body weights and urine output monitered. Upon pituitary, thyroid, and adrenals will be processed for light and electron microscopy. Cell morphology, counts of both TSH cell numbers, and secretion granule size versus number per cell will be evaluated.

(17) *Progress:
The animal phase has been completed and samples collected. Tissues are being evaluated, with preliminary results showing a decrease in thyroid cell height in dehydration.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/308		(3) Status: Terminated
(4) Title: Quantification of Alpha Adrenergic Receptors (Alpha AR) and Platelets of Adults Demonstrating Decreased Response to Epinephrine.		
(5) Start Date: 1979		(6) Est Comp Date: 1980
(7) Principal Investigator Donald G. Corby, M.D., COL, MC		(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation		(10) Assoc Investigators: Judy Barber, M.T., DAC Pat Rush, M.T., DAC Ellen Swanson, B.S., DAC T.P. O'Barr, Ph.D., DAC
(11) Key Words: platelet aggregation epinephrine		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 10/79

(15) *Study Objective:
To determine whether adults who demonstrate decreased platelet aggregation in response to the inducing agent, epinephrine, have decreased numbers of platelet Alpha AR.

(16) *Technical Approach:
Patients who have previously been evaluated in the Coagulation Section of the Department of Pathology for minor bleeding disorders as well as some normal adults known to have decreased secondary aggregation responses to epirephrine will be studied. All patients will abstain from aspirin and other drugs known to affect secondary aggregation and release (i.e., aspirin) for ten days prior to study. Approximately

(17) *Progress:
During the year since this study was initiated, no patients have been found that fit the criteria for evaluation, i e.. Their platelets failed to undergo secondary phase of aggregation in response to epinephrine. The reasons for this are unclear but may be relative to the acquisition of new equipment for measuring <u>in vitro</u> platelet aggregation. The study will be terminated, however, if patients fitting study criteria become available they will be evaluated for adrenergic

(16) continued -

10 to 15 patients in each group will be studied. The following studies will be performed.

Platelet aggregation studies will be performed by standard photometric techniques in response to epinephrine, (2 and 20 uM) soluble collagen, epinephrine (5.5 and 55 uM), thrombin and ristocetin at standard concentrations.

Thromboxan (TxB_2) levels will be obtained on samples of platelet-rich plasma clotted with 0.5 units of thrombin. Patients with decreased thromboxane B_2 levels will be presumed to have taken aspirin and will be excluded from the study.

Other studies to be performed will be: Platelet count, PT, PTT, and fibrinogen. Coagulation studies such as bleeding time as well as other more sophisticated studies will be done as needed.

(17) continued -

receptor deficiency as part of their clinical workup.

Publications and Presentations: None

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 *through* 17)

Proto No. 80/300

(17) continued -

parameters (i.e. pH, time, and temperature). An assay has been developed which is able to differentiate between normal serum and normal serum with 12.5 ug/ml AHG.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 80/300	(3) Status: Ongoing
(4) Title: Evaluation of Laser Nephelometry for Detecting and Quantitating Circulating Immune-complexes in Cancer Patients.		
(5) Start Date: 1 March 1980		(6) Est Comp Date: 1 March 1982
(7) Principal Investigator George L. Brown, Ph.D., COL, MSC		(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation		(10) Assoc Investigators: Nicholas J. DiBella, M.D., COL,MC Wilson C. Bourg, M.D., MAJ,MC
(11) Key Words: Laser Nephelometry Circulating Immune Complexes Cancer Patients		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 3/80

(15) *Study Objective:
To evaluate laser nephelometry as a means of efficient and rapid detection and quantitation of circulating immune complexes in cancer patients. To correlate the levels of circulating immune complexes with disease status.

(16) *Technical Approach:
The known ability of polyethylene glycol to precipitate immune complexes will be combined with the ability of laser nephelometry to detect small quantities of precipitates to produce a rapid, simple, efficient assay for detecting circulating immune complexes (CIC). This assay will then be used to quantitate the levels of CIC in the serum from cancer patients and determine the correlation between CIC levels and disease status.

(17) *Progress:
The initial laser nephelometry assay conditions (i.e. 4% polyethylene glycol, 60 min incubation at room temp.) were able to differentiate between normal serum and normal serum containing 125 ug/ml heat aggregated IgG (AHG). This failure to achieve greater sensitivity was eventually found to be due to a concentration of polyethylene glycol which precipitated monomeric IgG in addition to AHG. By lowering the polyethylene glycol concentration and changing the other incubation

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FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/301 (3) Status: Ongoing
(4) Title: Microbiological Research in Tuberculosis

(5) Start Date: June 1980
(6) Est Comp Date: 1982
(7) Principal Investigator
J.J. Damato, MAJ, MSC (cont'd)
(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation
(10) Assoc Investigators:
Donald D. Paine, B.S., DAC
J. Kenneth McClatchy, Ph.D., NJH
Philip J. Kessens, SP5, USA
James D. Hakes, DAC
(11) Key Words:
Tuberculosis Research
(12) Accumulative MEDCASE Cost:
(13) Est Accumulative OMA Cost:
(14) Periodic continue Review Results: 6/80

(15) *Study Objective:
To evaluate and/or design new methods for improving diagnostic laboratory procedures in mycobacteriology and to maintain an in-depth data base and reference cultures on all patient isolates for future correlation with patient data, treatment results and laboratory quality control.

(16) *Technical Approach:
1. Evaluation and comparison of mucolytic agents.
2. Evaluation and comparison of growth media.
3. Tests for identification of Mycobacterial species.
4. Evaluation of drug susceptibility test media.
5. Characterization of Mycobacteria other than Tuberculosis (MOTT) isolated from experimental media. (cont'd)

(17) *Progress:
"SPUTOLYSIN" has been evaluated and has been found to be an effective mucolytic agent. No further evaluation or formal report of these studies is contemplated. Bi-phasic chromogenicity, arylsulfatase, niacin, nitrate reductase, and pyrazinamide studies have been successfully completed and the results are being written by MAJ James J. Damato, MSC. Evaluation of Mitchison's selective OA medium (S7H10) has been completed, and a paper has been accepted by the Journal of Clinical (cont'd)

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 80/301

(7) continued - Mary V. Rothlauf, M.S., DAC

(16) continued-

6. Comparison of smears before and after decontamination to determine possible loss of staining characteristics and viability.

(17) continued-

Microbiology. Evaluation of S7H10 medium for direct susceptibility testing is continuing, as are studies indicating the frequency with which casual isolates of mycobacteria are recovered from undecontaminated specimens. Studies concerning a simplified method for determining growth temperature range or mycobacteria have been completed and is currently being written.

PUBLICATIONS (80 Annual Progress Report (2nd Part of Detail Summary Sheet)

SERVICE MICROBIOLOGY DEPARTMENT DCI

(1) Rothlauf, M.V., Brown, G.L., and Blair, E.B.: Isolation of Mycobacteria from Undecontaminated Specimens With Selective 7H10 Medium. Accepted for publication in the Journal of Clinical Microbiology. (In Press)

FAMC WU No (Prot No) 80/301

PRESENTATIONS for FY 8[illegible] nual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE MICROBIOLOGY DEPARTMENT DCI

(1) Damato,J.J.: Biochemical Methods for Differentiating Mycobacteria. Presented: Colorado State University, Ft. Collins, Colorado, May 1980.

DEPARTMENT OF CLINICAL INVESTIGATION

Surgical Research Laboratories Service

Training Support Summary

During the year, 109 students received training in suturing techniques. Seventy-two were students in the practical nurse (91C) course; 12 were personnel assigned to Emergency Treatment Service, FAMC, eight were Colorado Air National Guardsmen from the 140th TAC Hospital; 12 were reservists from the 361st Med Lab and 5502 US Army Hospital; and five were from the US Air Force Clinic, Lowry. Training was conducted on 27 days, using 27 dogs, and consisted of a slide lecture and movie, introduction to the operating room, including aseptic technique, scrub, gowning and gloving, and hands-on experience in the dry and wet labs. Three hundred and twenty-four hours was expended by Surgical Research Labs personnel in providing this training.

The Department of Pediatrics trained 64 nurses and medical students in the placement of endotracheal and chest tubes, using 20 cats in eight visits of approximately three hours duration. Sixty-four hours was required of Surgical Research Labs personnel for initial anesthetic induction, maintenance and monitoring.

Orthopedic Service, Department of Surgery, utilized 32 rabbits and seven rats in 39 visits to train one staff surgeon and seven residents in microvascular surgery using the operation microscope. A total of 117 hours was spent to accomplish this training, requiring 195 hours of support by Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring, post-operative recovery and angiography.

Neurosurgery Service, Department of Surgery, used five rabbits in eight visits to train one staff surgeon and one resident in microvascular surgery techniques using the operation microscope. Twenty-four hours was spent in this training, requiring 40 hours of support by Surgical Research Labs personnel.

Thoracic Surgery Service, Department of Surgery, used six dogs in the training and evaluation of cardiopulmonary bypass methods. Two staff surgeons spent 66 hours in training, requiring 72 hours of support by Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring and pump operation.

General Surgery Service, Department of Surgery, used four dogs in training 16 surgeons in the use of staple guns. A total of 80 hours of training was received, requiring 24 hours of support by Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring, circulating and clean-up.

Urology Service, Department of Surgery, used two dogs in training three staff surgeons, four residents and two interns in the use of staple guns. Forty-five hours of training was received, requiring 12 hours of support by Surgical Research Labs personnel.

DCI-SRLS Training Support Summary - continued

In addition, two high school seniors from Aurora Public Schools Technical Center received on-the-job vocational training as veterinary aides and one senior was given training as a clincial laboratory aide under Memorandum of Agreement. A total of 358 hours of training was received, requiring 537 hours of supervision and instruction by personnel of the Surgical Research Labs.

Cost of Training

Suturing Techniques:	$90.64/session	x	27 sessions	=	$2,447.28
Pediatric Nurses:	14.35/animal	x	20 cats	=	287.00
Rabbit Microsurgery:	79.19/session	x	40 sessions	=	3,167.60
Rat Microsurgery:	61.94/animal	x	7 rats	=	433.58
Thoracic Surgery:	143.75/case	x	6 cases	=	862.50
Staple Gun Exercises:	76.11/animal	x	6 dogs	=	456.66
					($7,654.62)

OB-GYN

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FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 76/350 (3) Status: Terminated

(4) Title: Evaluation of Ibuprofen (Motrin) in treatment of dysmenorrhea

(5) Start Date: September 1979	(6) Est Comp Date: June 1980
(7) Principal Investigator Gordon S. Park, M.D., CPT, MC	(8) Facility: FAMC Department of Obstetrics&Gynecology
(9) Dept/Sec: GYN Section	(10) Assoc Investigators: None
(11) Key Words: Treatment of dysmenorrhea	

(12) Accumulative MEDCASE Cost: None	(13) Est Accumulative OMA Cost: None	(14) Periodic Review Results: continue 5/80

(15) *Study Objective:
To compare the effectiveness of Ibuprofen (Motrin) in the treatment of primary dysmenorrhea.

(16) *Technical Aproach:
Patients to be randomly treated with either aspirin, placebo, or Motrin for three consecutive cycles and comparison of subjective relief.

(17) *Progress:
Study terminated as of June 1980. No presentations or plans for publication have been formulated at this time.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/350	(3) Status: Terminated
(4) Title: Inhibition of Premature Labor With Terbutaline		
(5) Start Date:		(6) Est Comp Date: June 1979-terminated
(7) Principal Investigator J.R. Bobitt, MD, Col, MC		(8) Facility: FAMC
(9) Dept/Sec: OB-GYN - OB Service		(10) Assoc Investigators: D.D. Riston, MD;CPT,MC
(11) Key Words: Inhibition of Premature Labor with Terbutaline		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic terminate Review Results: 5/80

(15) *Study Objective:

To study inhibitory effects of Terbutaline on premature labor.

(16) *Technical Approach:

Patients at less than 35 weeks of gestation, with no contraindicating condition such as ruptured BOW, intrauterine sepsis, or abruptio placentis, will be treated for premature labor with either Terbutaline or a placebo. The presence of labor and absence of fetal distress will be confirmed by electronic monitor. Entrance to the study will be approved by a member of the attending staff prior to obtaining permission from the hospital.

(17) *Progress:

The project was terminated in June 1979 as ordered by the Office of the Surgeon General who ordered discontinuance of the I.V. administration of Terbutaline.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/351	(3) Status: Completed
(4) Title: An Evaluation of the Effect of Suction Drainage on Infectious Morbidity in Patients Undergoing Cesarean Section.		
(5) Start Date:		(6) Est Comp Date: Terminated
(7) Principal Investigator Bobitt, J.R., M.D., Col, MC		(8) Facility: FAMC
(9) Dept/Sec: OB-GYN - OB Service		(10) Assoc Investigators:
(11) Key Words: Effect of suction drainage on cesarean section patients.		W.D. Smith, M.D., Cpt, MC J.J. Mancuso, M.D., Cpt, MC
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 5/80

(15) *Study Objective:
To determine if the incidence and severity of pelvic infections in patients undergoing cesarean section is significantly decreased through the use of retroperitoneal suction drainage of the uterine operative site.

(16) *Technical Approach:
We plan to compare the frequency and severity of pelvic infections among 50 patients undergoing cesarean section with suction drainage of the operative site, with a similar group of 50 patients without drainage. Patients considered infected at the time of cesarean section will not be included in the study. Patients on antibiotic medications will also be excluded. Any patient who will have had to hours of labor at the time of cesarean section or has ruptured

(17) *Progress: (Cont'd)
This study was completed after 100 patients had been studied. There was found to be no difference in infectious morbidity among the two groups of patients. It has therefore been concluded that the routine use of suction drainage to decrease infectious morbidity in patients undergoing cesarean section is not indicated.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 78/351

Cont'd from #(16)
membranes at the time of cesarean section is a candidate for the study. The study group will be drained by a hemovac suction apparatus whereas this technique will not be available to those patients in the control group. The suction catheter will be placed beneath the vesico-uterine fold and brought out through the lower abdomen remaining extra-peritoneal. Study and control patients will be selected by a table of random numbers prepared prior to the study.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/352	(3) Status: Completed
(4) Title: Amniotic Fluid Infection in Premature Labor Patients with Intact Membranes: As Determined by Transabdominal Amniocentesis		
(5) Start Date:		(6) Est Comp Date: Completed
(7) Principal Investigator Bobitt, J.R., M.D., Col, MC		(8) Facility: FAMC
(9) Dept/Sec: OB-GYN - OB Service		(10) Assoc Investigators: Clifford C. Hayslip, CPT, MC James J. Damato, MAJ, MSC
(11) Key Words: Amniotic Fluid Infection transabdominal amniocentesis		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic complete Review Results: 8/80

(15) *Study Objective:

To determine the presence, number and frequency of bacteria in the amniotic fluid of patients in premature labor with intact membranes.

(16) *Technical Approach:

Patients in premature labor with intact membranes will have an amniocentesis if they consent to participate in the study. Amniotic fluid will be analyzed for the following infectious parameters: 1) Quantative cultures, 2) Viral cultures, 3) Polymorphonuclear count, 4) Lactic dehydrogenase, and 5) Gram stain.

(17) *Progress:

Project completed.

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet.)

SERVICE Obstetrics DEPARTMENT OB-GYN

Bobitt, J.R., Damato, J.J., Hayslip, C.C.: Amniotic Fluid Infection in Premature Labor Patients with Intact Membranes: As Determined by Transabdominal Amniocentesis. Submitted for publication. (C)

Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/353	(3) Status: Ongoing
(4) Title: Prenatal Evaluation of Quantitative Cervical and Vaginal Cultures for the Group B Streptococcus and Their Relationship to Maternal & Neonatal		
(5) Start Date:		(6) Est Comp Date: Mar 80-terminated
(7) Principal Investigator J.R. Bobitt, M.D., Col, MC		(8) Facility: FAMC
(9) Dept/Sec: OB-GYN - OB Service		(10) Assoc Investigators: G.L. Brown, Ph.D., Col, MSC J.J. Damato, MAJ, MSC
(11) Key Words: Prenatal Evaluation for Group B Streptococcus		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Result: continue 12/79

(15) *Study Objective:

To determine the incidence and clinical significance of Group B Streptococcus colonization in the cervix and vagina of prenatal women after 24 weeks gestation.

(16) *Technical Approach:

Antepartum vaginal cultures are collected by the clinical personnel in the Department of OB-GYN at weekly intervals and at delivery. Plates are streaked and growth quantitated by the Clinical investigation Service, Department of Microbiology. Results are blinded. Mother and newborn records are reviewed for infectious morbidity.

(17) *Progress:

This study was completed in March 1980 after approximately 700 patients had been studied. Maternal and Neonatal clinical charts are currently being reviewed to establish the infectious morbidity among the entire population. No data presently available for evaluation. Microbiologic cultures and antepartum evaluation - completed Compiling data - ongoing.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 78/350

#4 Infectious Morbidity.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(SCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79-350 (3) Status:Ongoing		
(4) Title: A prospective study of endometrial changes with exogenous hormonal therapy		
(5) Start Date: June 1979		(6) Est Comp Date: June 1981
(7) Principal Investigator Steven R. Shirts, M.D., CPT, MC		(8) Facility: FAMC
(9) Dept/Sec: OB/GYN		(10) Assoc Investigators:
(11) Key Words: Exogenous hormore use in postmenopausal females.		Donald A. Simsen, M.D., COL, MC
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 11/79

(15) *Study Objective:

To determine by tissue diagnosis, the incidence of various forms of endometrial pathologic changes in women who use exogenous hormonal therapy in relief of perimenopausal and postmenopausal symptoms.

(16) *Technical Approach:

We do yearly endometrial sampling on unopposed postmenopausal estrogen users, either by in office endometrial biopsies or formal D&C. The rate of abnormal biopsy results was tabulated.

(17) *Progress:

Our results have been tabulated and prepared for publication. The attached article has been accepted for print in The Journal of Gynecologic Oncology.

It has been reported that women on both estrogen and progesterone postmenopausally have a decreased incidence of atypical endometrial pathologic changes. We will now look at the incidence of hyperplasia in this group of patients.

(To all C's, Depts/Svcs)

PUBLICATIONS occuring during FY 80

SERVICE Obstetrics DEPARTMENT Obstetrics/Gynocology

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(1) Simsen, D.A., Shirts, S.R., Howard, F.M., Sims, J., Hill, J.M.,: Endometrial Findings in Asymptomatic Postmenopausal Women on Exogenous Estrogens - A Preliminary Report. (Submitted to Journal of Gynecological Oncology for publication - In Press)

Presentations: None

PEDIATRICS

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 75/401	(3) Status: Ongoing
(4) Title: Effect of Prophylactic Antibiotic Therapy on Gravid Group B Beta Hemolytic Streptococcus Carriers.		
(5) Start Date: September 1975		(6) Est Comp Date: 1982
(7) Principal Investigator Gerald B. Merenstein, Col, MC		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn		(10) Assoc Investigators: John R. Pierce, LTC, MC
(11) Key Words: Group B Strep, Prophylactic Penicillin		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 8/80

(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 presecne 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) *Progress:

We are currently reviewing the literature and otherwise evaluating methods of more rapidly identifying GBHS carriers. The rapid identification will then permit random evaluation of preterm deliveries.

FAMC W/U No (Prot No) 75/401

PUBLICATIONS for FY 80 Annual Progress Report (2nd Part of Detail Summary Sheet)

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. Clin Res. 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.

FAMC WU No (Prot No) 75/401

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

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 fro Microbiology, Atlantic City, N. J. 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.

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 75/402 (3) Status: Ongoing

(4) Title: Early Digitalization in Premature Infants with Idiopathic Respiratory Distress (IRDS) Who Have Echocardiographic Evidence of Left Atrial Enlargement

(5) Start Date: January, 1976	(6) Est Comp Date: July, 1981
(7) Principal Investigator *Gerald L. Way, M.D., MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: Gerald B. Merenstein, M.D., COL, MC John R. Pierce, M.D., LTC, MC
(11) Key Words: Digitalization, infants, idiopathic respiratory distress, echocardiographic, left atrial enlargement.	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 6/80

(15) *Study Objective: To determine the usefulness of early digitalization in altering the progression of congestive heart failure and left-to-right shunting through the PDA in premature infants with IRDS.

(16) *Technical Approach: Infants with RDS and left atrial aortic diameter ratio of greater than 1.0 by echocardiograph will be included in the two study groups. The two study groups will be Group A-infants who will be digitalized with 40 mcg/kg dose of digoxin and maintained at 10 mcg/kg/day. Group B-infants who will not receive digoxin unless they clinically demonstrate overt congestive heart failure. Echocardiogram will be repeated every other day throughout the respirator course, and

(17) *Progress: There have been no new patients added to this study during the past year; however, the data is being evaluated to determine if we achieved any meaningful results. It is anticipated that more patients may be added to this study this year.

*Deceased

16. Technical Approach (Continued): subsequently only if abnormal findings remain. Additional echocardiograms will be obtained if the clinical situation deteriorates. Echocardiograms will be evaluated with coinciding arterial blood gases, chest x-rays, EKG's, and laboratory data which will be done as needed for clinical management.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

(HSCR 40-23, App. C.) ANNUAL PROGRESS REPORT (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: December 1981
(7) Principal Investigator Carl Gumbiner, Maj, MC		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn		(10) Assoc Investigators: Patrick Glasow, Cpt, MC
(11) Key Words: Newborn, Asphyxia, Heart		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 2/80

(15) *Study Objective:

To serially measure left ventricular in newborns with asphyxia neonatorum .

(16) *Technical Approach:

All infants with the diagnosis of asphyxia neonatorum are candidates for this study. Study infants will be serially evaluated with echocardiograph.

(17) *Progress:

The addition of a pediatric cardiologist to our staff will permit the resumption of this study that was temporarily suspended with the medical retirement of our previous pediatric cardiologist.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 77/403	(3) Status: Ongoing
(4) Title: Determination of Pulmonary Vascular Resistance in Newborn Infants at 5280 feet using Right-sided systolic time intervals.	
(5) Start Date: September 1977	(6) Est Comp Date: December 1981
(7) Principal Investigator H. Philip Stalker, Cpt, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: Carl Gumbiner, Maj, MC
(11) Key Words: Newborn, Pulmonary Vascular Resistance Echocardiogram, Electrocardiogram	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 2/80

(15) *Study Objective:

To determine the normal range of pulmonary vascular resistance and electrocardiograms at 5280 feet.

(16) *Technical Approach:

All normal infants admitted to the normal nursery will have echo-and/or electro-cardiograms in the first 24 hours of life.

(17) *Progress:

Due to the medical retirement of the original principal investigator little progress has been made in FY 80. The new investigators have added electrocardiograms to the study and it is anticipated that FY 81 will be productive.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/402	(3) Status: Ongoing
(4) Title: The Influence of Body Positioning on Gastric Residuals in Premature Infants		
(5) Start Date: July, 1978		(6) Est Comp Date: July, 1981
(7) Principal Investigator Barbara S. Turner, MAJ, ANC		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn		(10) Assoc Investigators: None.
(11) Key Words: Body position, gastric residuals, premature infants		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 5/80

(15) *Study Objective: To compare the amount of gastric residuals in the premature infant's stomach three hours after feeding in relation to the body position of the infant.

(16) *Technical Approach: Premature infants requiring gavage feedings who were less than 35 weeks gestation were examined. Infants meeting outlined criteria were fed the same formula, at the same time and in the same manner as previously used. Gastric residuals were measured and recorded with body position. Positions used are right side, left side and stomach.

(17) *Progress: Data collection began in July, 1978. To date, 20 subjects have been studied. Data have been recorded on gastric residuals, body positions as well as the extraneous variables of gestational age, sex, race and type of formula. Data analysis will begin on 1 Jan 1981.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT
(USCP 40-25, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/403	(3) Status: Ongoing
(4) Title: The Influence of Body Positioning on Gastric Residuals in Premature Infants Requiring Ventilatory Assistance		
(5) Start Date: July, 1978		(6) Est Comp Date: July, 1981
(7) Principal Investigator Barbara S. Turner, MAJ, ANC, RN,MS,MA		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn		(10) Assoc Investigators:
(11) Key Words: Gastric residuals, premature infants, body positioning		None.
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic review Results: continue 5/80

(15) *Study Objective: To compare the amount of gastric residuals in the premature infant's stomach three hours after feeding in relation to the body position of the infant.

(16) *Technical Approach: Premature infants requiring ventilatory assistance and gavage feedings who were less than 35 weeks gestation were examined. Infants meeting outlined criteria were fed the same formula, at the same time, and in the same manner as previously used. Gastric residuals were measured and recorded with body position. Positions used are left side, right side and and back.

(17) *Progress: Data collection began in July, 1978. To date 20 subjects have been studied. Data have been recorded on gastric residuals, body positions as well as the extraneous variables of gestational age, sex, race, and type of formula. Data analysis will begin on 1 Jan 1981.

Publications and Presentations: None

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/404 (3) Status: Terminated

(4) Title: Assessment of the Relationship of Serum Amino Acid Levels to Episodes of Apparent Sepsis.

(5) Start Date: July, 1978	(6) Est Comp Date:
(7) Principal Investigator John R. Pierce, M.D., LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: Thomas P. O'Barr, Ph.D., DAC
(11) Key Words: Serum amino acid, levels, sepsis.	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic terminate Review Results: 3/80

(15) *Study Objective: To determine the relationship between possible abnormal serum amino acid levels and clinical episodes of apparent sepsis in premature infants.

(16) *Technical Approach: Blood samples will be taken from each premature infant (26-36 weeks gestation) who is suspected of having sepsis. These samples will be examined by thin-layer chromatography for the amino acids: tyrosine, phenylalanine, cystine and methionine. A relationship between elevated levels of these amino acids and episodes of clinical sepsis (signs consistent with sepsis but negative cultures) is being sought.

(17) *Progress: Since no patients have been enrolled in the study and interest and attention have been placed on other projects, it is requested that this project be terminated.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/407 (3) Status: Terminated

(4) Title: Evaluation of New Criteria in the Diagnosis of Acute Renal Failure in the Full-term and Premature Newborn.

(5) Start Date: July 1979 (6) Est Comp Date: July 1980

(7) Principal Investigator
John Moore, Cpt, MC

(8) Facility: FAMC

(9) Dept/Sec: Pediatrics

(10) Assoc Investigators:
Gerald B. Merenstein, Col, MC

(11) Key words:
Renal Failure, Full Term Newborn, Premature Newborn

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic terminate Review Results: 3/80

(15) *Study Objective:

To determine the normal values of urine and serum urea nitrogen, creatinine, sodium, potassium, and chloride in full-term and premature infants of various gestational ages on a fixed oral or I.V. sodium load. Using these normal vlaues, the usefulness of the urine-to-plasma urea, urine-to-plasma creatinine ratios, and the fractional excretion of sodium in the differential diagnosis of pre-renal versus renal failiure in the newborn can be determined.

(16) *Technical Approach:

Randomly selected newborns of consenting parents have been studied.

(17) *Progress:

Due to the publication, by other authors, of a similar study meeting our objectives, the study has been terminated.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT
(USCF 82-23, Apr. 81) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/408 (3) Status: Completed

(4) Title: The Tired Adolescent: An Analysis of Etiology

(5) Start Date: January 1979	(6) Est Comp Date: Completed
(7) Principal Investigator: Dr. Alan R. Figelman	(8) Facility: FAMC
(9) Dept/Sec: Pediatric/Adolescent Med Svc	(10) Assoc Investigators: Dr. Gentry W. Yeatman
(11) Key Words: adolescent fatigue, clinical correlation	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 11/79

(15) *Study Objective:

a. To examine the conditions that may cause the adolescent to present to an outpatient clinic with the chief complaint of tiredness.

b. To determine the clinical correlation, if any, of age, sex, growth and maturation, diet, and exercise with the complaint of tiredness.

c. To determine the clinical correlation, if any, of social, sexual, psychological and medical history with tiredness.

(16) *Technical Approach:

A lengthy history and physical was performed along with an extensive laboratory evaluation was performed.

17. *Progress:

The patients and controls have been seen and evaluated. At present Dr. Figelman is in the process of analyzing the data and preparing it for publication.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT Proto No: 78/408
(Blocks 1 through 17)
Continuation:

15. Study Objective:

d. To determine the clinical correlation, if any, of subclinical mononucleosis, anicteric hepatitis, hypo or hyperthyroidism, urinary tract infection, or nephritis with fatigue.

e. To determine laboratory correlation, if any, of tiredness with minerals (Fe, Zn), enzymes (CPK, GGT, Alkphos), hemogram, or uric acid.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/400	(3) Status: Ongoing
(4) Title: Effect of Adriamycin in Platelet Function		
(5) Start Date: November 1978		(6) Est Comp Date: June 1981
(7) Principal Investigator: Askold D. Mosijczuk, M.D.		(8) Facility: FAMC
(9) Dept/Sec: 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 Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 5/80

(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 percent aggregation compared in the two samples. Aliquots of PRP are removed at certain times to measure the amount of tromboxane released.

(17) *Progress: To date, 23 donors have been studied; in five of these a slight to moderate degree of inhibition of platelet aggregation has been found, which was also reflected by decreased levels of thromboxane.

Additional donors are planned to be tested, as well as attempts to determine the possible mechanism by which adriamycin decreases platelet function. This is being done by reacting the platelets with thrombin and measuring the intermediate products of platelet phosphalipid metabolism on a column.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/401 (3) Status: Terminated

(4) Title: An Investigation of the Effects of Aminoglycosides and Lasix upon the Inner Ear of the Guinea Pig

(5) Start Date: June 79 (6) Est Comp Date: May 80

(7) Principal Investigator
John D. Daigh, Jr., CPT, MC

(8) Facility: FAMC

(9) Dept/Sec: Pediatrics

(10) Assoc Investigators:
Patrick Glasow, CPT, MC
John W. Harbell, Ph.D.,CPT,MSC
W. Nicholas Glab, B.S., SP6

(11) Key Words:
Aminoglycosides
Lasix
Inner Ear

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic terminate Review Results: 8/80

(15) *Study Objective:
The objective is to establish the effect upon the cochlea of the Guinea pig of aminoglycosides and lasix.

(16) *Technical Approach:
Guinea pigs were given various amounts of aminoglycosides and lasix. The animals have been sacrificed and their cochlea examined under light and electron microscopy.

(17) *Progress:
The study was terminated due to the unanticipated, early PCS of the Principal Investigator to enter Pediatric Sub-specialty training.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/402 (3) Status: Terminated

(4) Title: An Analysis of the Health Care Needs of Teenagers Living in Single Parent or Reconstituted Families.

(5) Start Date: Has not been started	(6) Est Comp Date: Is not being done.
(7) Principal Investigator Dr. Alan R. Figelman	(8) Facility: FAMC Fitzsimons Army Medical Center
(9) Dept/Sec: Dept of Pediatrics, FAMC	(10) Assoc Investigators: Dr. David W. Wells, and Dr. Richard T. Takao.
(11) Key Words: Health Care; Teenagers; Single Parent; Reconstituted Families	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 11/79

(15) *Study Objective.

N/A due to the termination of the study.

(16) *Technical Approach:

N/A due to the termination of this study.

(17) *Progress:
We have decided not to do this study at the present time.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

(HSCR 40-23, App. C.) ANNUAL PROGRESS REPORT (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/403 (3) Status: On going

(4) Title: Evaluation of Transcutaneous Oxygen Monitoring in the Acute Management of Infants with RDS

(5) Start Date: January 1980	(6) Est Comp Date: July 1981
(7) Principal Investigator Gerald B. Merenstein, MD, Col, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/ Newborn	(10) Assoc Investigators: Howard Kilbride, MD, Maj, MC Gilbert Frank, MD, Maj, MC
(11) Key Words: Transcutaneous Oxygen Monitoring	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 10/79

(15) *Study Objective:

To determine the efficacy of continuous 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) *Progress:

To date 17 infants have been studied. The study will have sufficient infants by July 1981.

Publications: None

FAMC WU No (Prot No) 79/403

PRESENTATIONS for FY 80 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE Newborn DEPARTMENT Pediatrics

Kilbride, H. Transcutaneous oxygen monitoring. Presented: Aspen Conference on Perinatal Research, July 1980. (Aspen, CO)

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/404	(3) Status: Ongoing
(4) Title: The Effect of Early Meconium Evacuation on Bilirubin Levels in Breast-Fed and Formula-Fed Healthy Full-term Infants		
(5) Start Date: February 1981		(6) Est Comp Date: January 1982
(7) Principal Investigator Gerald B. Merenstein, MD, Col, MC		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn		(10) Assoc Investigators: Marilyn DiGirol, LTC, ANC Jan Collins, Cpt, ANC Leonard Weisman, Maj, MC
(11) Key Words: Bilirubin, Meconium, Breast Fed, Bottle Fed		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 12/79

(15) *Study Objective:

a. To determine the effect of glycerine suppositories on peak bililrubin levels in breast and formula fed infants.

b. To compare peak bilirubin levels in breast and formula fed full term infants.

(16) *Technical Approach:

500 Healthy fullterm infants will be randomly assigned to one of four groups including suppository or control and breast or bottle fed. Bilirubins will be measured serially by a bilirubinometer.

(17) *Progress:

Funds have been obtained from the March of Dimes to purchase the Bilirubinometer by early 1981.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/405 (3) Status: Ongoing

(4) Title: Assessment of Maternal Fever in the Immediate Prenatal Period as a Predictor of Perinatal Newborn Infections

(5) Start Date: January, 1981 (6) Est Comp Date: July, 1982

(7) Principal Investigator
Howard Kilbride, M.D., MAJ, MC

(8) Facility: FAMC

(9) Dept/Sec: Pediatrics/Newborn

(10) Assoc Investigators:
Gil Frank, M.D., MAJ, MC
John Steenbarger, M.D., LCDR, MC, USN

(11) Key Words: Maternal fever, re: perinatal infections

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 12/79

(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: Due to the PCS move of the principal investigator, no patients have as yet been enrolled in the study. The associate investigators will assume responsibility for the protocol and the study will be begun in the immediate future There have also been some delays as HSC has asked for some clarifications of the volunteer agreement.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/405

6. Technical Approach (Continued): CSF will be obtained on each infant treated with antibiotics or as clinically indicated. Specimens for viral cultures will also be obtained. A data collection sheet will be maintained on each mother and infant pair. At the end of the study period, the data will be analyzed to determine the clinical course of infants born to febrile mothers and the incidence of bacterial and viral infection in those infants compared to control infants.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/406		(3) Status: Ongoing
(4) Title: Intergroup Ewing's Sarcoma of Pelvic and Sacral Bones		
(5) Start Date: 27 March 1980		(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D.		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics		(10) Assoc Investigators: None
(11) Key Words: Intergroup Ewing's Sarcoma of Pelvic and Sacral Bones		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 5/80

(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 protocol guidelines and tumor survival and response are measured.

(17) *Progress:

To date, no FAMC patients have been entered on this study. Nationally, the study is progressing satisfactorily and is open to new entries.

(15) 3. Determine the effectiveness of surgical resection to control local disease.

4. Determine the effectiveness of a uniform radiation therapy regimen to control local disease.

5. Identify, determine and compare the degree of early and late toxicity and sequelae of therapy.

6. Evaluate and confirm the prognostic characteristics with respect to the tumor and the host.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/407	(3) Status: Ongoing
(4) Title: Intergroup Ewing's Sarcoma Pelvic and Sacral Sites Excluded		
(5) Start Date: 27 March 1980		(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D.		(8) Facility: FAMC
(9) Dept/Sec: General Pediatrics		(10) Assoc Investigators: None
(11) Key Words: Intergroup Ewing's Sarcoma; Pelvic and Sacral Sites Excluded		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 5/80

(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 and is open to new entries.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 79/407

(15)

3. Determine the effectiveness of a uniform radiation therapy regimen to control local disease.
4. Determine the effectiveness of surgical resection to control local disease.
5. Identify, determine and compare the degree of early and late toxicity and sequelae of therapy.
6. Evaluate and confirm the prognostic characteristics with respect to tumor and host.

Publications and Presentations: None

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(See AR 40-38, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/408 (3) Status: Ongoing

(4) Title:

Intergroup Rhabdomyosarcoma Study II

(5) Start Date: 27 Mar 80	(6) Est Comp Date: 1982
(7) Principal Investigator: Askold S. Mosijczuk, M.D.	(8) Facility: FAMC
(9) Dept/Svc: General Pediatrics	(10) Assoc Investigators:
(11) Key Words: Intergroup Rhabdomyosarcoma Study II	None

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 5/80

(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 jeopardizing 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 reported.

(17) *Progress:

To date, no FAMC patients have been enrolled on this study. Nationally, the study is progressing satisfactorily and is open to receive entries.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17)

Proto No: 79/408

(15) cont'd:

achievable for microscopic residual disease with cyclic-sequential vincristine and dactinomycin, all patients receiving post-operative radiation to the tumor bed. In Clinical Group III and IV Disease, it is to determine if adriamycin, if given in pulse combination with vincristine and cyclophosphamide ("pulse" VADRC), improves the complete remission and survival beyond that now achievable with "pulse" VAC, all patients receiving radiation to the tumor bed and sites of metastases. It is also to determine if two years of repetitive pulse therapy is superior to the non-repetitive pulse regimens previously employed in IRS-1 for Groups III and IV disease (Regimens E and F). In the case of "Extremity Rhabdomyosarcoma Requiring Primary Amputation", it is to determine if two years of repetitive "pulse" VAC will improve the duration of remission and survival in patients subjected to primary major amputation for primary tumors localized in the extremity. In the case of "Rhabdomyosarcoma Localized in the Nasopharynx-Nasal Cavity, Middle Ear and Paranasal Sinus" the objective is to determine if the "prophylactic" local meningeal radiation with or without intrathecal chemotherapy can prevent direct meningeal extension of disease and improve the duration of remission and survival in these patients. In "Rhabdomyosarcoma Localized to the Pelvis (vagina, uterus, bladder, prostrate)" it is to determine if a primary chemotherapeutic and radiotherapeutic approach can avoid the disability associated with radical surgery without jeopardizing local disease control and survival. In "lymphatic Involvement in Rhabdomyosarcoma" it is to determine what the frequency and significance is of regional lymph node involvement in relation to primary site of tumor origin. In relation to "Pathology" it is to determine the relationships between the special and undifferentitated cell types I and II (Ewing's tumor of soft tissue) and classical rhabdomyosarcomas in terms of biological behavior, ultrastructural features, and response to therapy.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/409 (3) Status: Ongoing

(4) Title:
National Wilm's Tumor Study

(5) Start Date: 27 March 1980	(6) Est Comp Date: 1982
(7) Principal Investigator Askold D. Mosijczuk, M.D.	(8) Facility: FAMC
(9) Dept/Sec: General Pediatrics	(10) Associate Investigators:
(11) Key Words: National Wilm's Tumor Study	None

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 5/80

(15) Study Objective:

To gain a better understanding of the Wilms' 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 adverse effects of unnecessary treatment in patients requiring minimal therapy. To test treatment hypotheses by randomized, prospective clinical trials.

(16) Technical Approach:

Patients with Wilm's tumor receive treatment with surgery, radiation, and chemotherapy according to protocol guidelines and their tumor response and survival are measured.

(17) Progress:

To date, no patients at FAMC have been enrolled in this study. Nationally, the study is progressing satisfactorily and is open to new entries.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 79/409

(15) 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 Wilms' tumor.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 79/410	(3) Status: ongoing
(4) Title: Non-Hodgkin's Lymphoma		
(5) Start Date: 27 March 1980		(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D.		(8) Facility: FAMC
(9) Dept/Sec: Pediatrics		(10) Assoc Investigators:
(11) Key Words: Non-Hodgkin's Lymphoma		None
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue review Results: 6/80

(15) *Study Objective:

To study the classification and biology of that group of childhood neoplasms included in the "Non-Hodgkin's Lymphomas." To compare the effectiveness of two combination chemotherapy programs in the control of all forms of childhood Non-Hodgkin's Lymphoma. Pulsed High Dose Cyclophosphamide, Moderate Dose Methotrexate, Vincristine and Prednisone (COMP). Regimen I. The Memorial Hospital LSA$_2$-L$_2$ Protocol (Modified). Regimen II. To determine for each [illegible]

(16) Technical Approach:

Patients with non-Hodgkin's lymphoma receive one of two chemotherapeutic regimens as per protocol guidelines, and their survival and their ability to enter [illegible] are measured.

(17) *Progress:

To date, one patient has been enrolled at FAMC in this study. At a national level, [illegible] patients have been enrolled showing that LSA$_2$-L$_2$ is superior for patients with lymphoblastic lymphoma and two year survival is in excess of 70%, whereas COMP is superior in all other subtypes of non-Hodgkin's lymphoma, also with about 70% 2 year survival.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT Proto No: 79/410
(Blocks 1 through 17)

(15) the two treatment regimens the effectiveness of standardized IT MTX without radiation for the control of occult CNS disease. To determine for each of the treatment regimens the effectiveness of standardized irradiation of bulk disease.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/400 (3) Status: Ongoing

(4) Title: Evaluation of Lymphocyte Blast Transformation in Breast Milk and Peripheral Blood Lymphocytes.

(5) Start Date: 1 April 80 (6) Est Comp Date: 30 Sept. 83

(7) Principal Investigator
Leonard E. Weisman MD MAJ, M.C.

(8) Facility: FAMC

(9) Dept/Sec: Pediatrics/Newborn

(10) Assoc Investigators:
R. Stephen Whiteaker, Ph.D., CPT, MSC

(11) Key Words:
Breast Milk
Lymphocyte
Blast Transformation

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic continue Review Results: 4/80

(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 micro-technique after: 1) utilizing various isolation procedures or 2) utilizing various selected patient populations or 3) utilizing various laboratory storage conditions.

(17) Progress: 1) Ten paired samples were collected, at various days post-partum from term uncomplicated post-partum women, for absolute lymphocyte counts. Optimum time for sample collection was thus determined. 2) 23 paired samples were collected from term uncomplicated post-partum women for comparative lymphocyte evaluation of E- rosetting. Normal breast milk T-cell populations were established and found smaller than peripheral blood.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT (Blocks 1 through 17) Proto No: 80/400

(17) 3) 37 paired samples were collected from term uncomplicated post-partum women for comparative evaluation of lymphocyte blast transformation. Normal values for lymphocyte blast transformation were established and breast milk lymphocytes were found hyporeactive when compared to peripheral blood lymphocytes. 4) 6 paired samples were collected from term uncomplicated post-partum women for comparative evaluation of lymphocyte blast transformation after isolation of E-rosetting population. 5) 14 paired samples were collected from term uncomplicated post-partum women for comparative evaluation of viability after storage at -196°C. 6) 3 paired samples were collected from term uncomplicated post-partum women for comparative evaluation of viability after storage at -20°C.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/401 (3) Status: Ongoing

(4) Title: Investigation of Heparin Induced Platelet Aggregation Secondary to Prostacyclin Interference in the Rabbit Model

(5) Start Date: June 1980 | (6) Est Comp Date: July 1981

(7) Principal Investigator
Larry G. Maden, MD, Maj, USAF, MC | (8) Facility: FAMC

(9) Dept/Sec: Pediatrics/Newborn | (10) Assoc Investigators:
John Harbell, PhD, Cpt, MSC,
Donald G. Corby, MD, PhD, Col, MC
Peter W. Blue, MD, LTC, MC
Gerald B. Merenstein, MD, Col, MC

(11) Key Words:
Heparin, Prostacyclin, Platelet Aggregation

(12) Accumulative MEDCASE Cost: | (13) Est Accumulative OMA Cost: | (14) Periodic continue Review Results: 6/80

(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 4 rabbits from each group will have an autocardiograph of the aorta. The remaining 2 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 is being retrieved from computer storage and will be analyzed.

Publications and Presentations: None

PATHOLOGY

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/450 (3) Status: Ongoing

(4) Title: The Role of Complement Activation in the Pathogenesis of Juvenile Onset Diabetes and Its Subsequent Effects on the Coagulation Status and Peripheral Vascular Complications in Diabetic Patients

(5) Start Date: Sep 79 (6) Est Comp Date: Sep 81

(7) Principal Investigator
Patricia L. Stranahan, MC

(8) Facility: FAMC

(9) Dept/Sec: Dept of Pathology

(10) Assoc Investigators:
Paul Nakane, Ph.D.
Judy Barber, MT (ASCP)
Patricia Rush, MT (ASCP)

(11) Key Words: Complement Activation; Juvenile Onset Diabetes Mellitus; Coagulation Abnormalities in Juvenile Onset Diabetes Mellitus; Peripheral Vascular Complications of Juvenile Onset Diabetes Mellitus

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 3/80

(15) *Study Objective:

Clq is present on human platelets. 1) It is known that Clq displaces collagen with respect to collagen dependent platelet aggregation. 2) It is also known that Clq specifically binds to Beta cell membranes. 3) The objective of this study is to compare the levels of Clq in normal patients with juvenile onset diabetes mellitus.

(16) *Technical Approach:

We have developed a rocket immunoelectrophoresis procedure for quantitation of Clq. Previous methods used for determining Clq levels take up to 10 days. With our procedure, overnight results are obtained. Presently we are reporting our results in % of normal as we currently have no purified Clq to quantitate ug levels.

(17) *Progress:

In the past 18 months we have continued to run serum samples on several normal patients and diabetic patients as well as patients with known auto-immune disease. Our problem at this time is procuring a pure Clq antibody substrate. Many of the results have been exciting; however, due to the inability to produce a specific antihuman Clq, the results have not, to date, been confirmed.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/451 (3) Status: Ongoing

(4) Title: Efficacy of Freeze Preservation of Platelets for Human Utilization - In Vitro and In Vivo Functional Capabilities After Freeze Preservation with Hydroxyetheystarch (HES).

(5) Start Date: 30 Sep 80	(6) Est Comp Date: 30 Sep 81
(7) Principal Investigator Patricia L. Stranahan, MC	(8) Facility: FAMC
(9) Dept/Sec: Dept of Pathology	(10) Assoc Investigators: Rick Martinez, MT (ASCP) Judy Barber, MT (ASCP)
(11) Key Words: Freeze Preservation of Human Platelets Freeze Preservation of These Platelets Utilizing HES	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(15) *Study Objective:
To compare the differences between fresh platelets and freeze preserved (HES) platelets for use in thrombocytopenic leukemic patients.

(16) *Technical Approach:
In the past six months, platelets have been frozen in HES and tested for in vitro function. These studies have been carried out both before freezing and after thawing. Suitable controls with room temperature incubation have also been studied.

(17) *Progress:
We have manipulated the platelets using various techniques which as to date, have not included the technique utilized by the British Study which freezes the platelets at a constant temperature with liquid nitrogen. Work is underway to begin study utilizing liquid nitrogen.

Publications and Presentations: None

PSYCHIATRY

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 80/500	(3) Status: Ongoing
(4) Title: **Health Expectancy Styles for Patients and Physicians and Their Perceptions of a Referral Process**		
(5) Start Date: **July 1980**		(6) Est Comp Date: **Sept 81**
(7) Principal Investigator **CPT ROBERT R, ROLAND, MC**		(8) Facility: FAMC
(9) Dept/Sec: **DEPT OF PSYCH**		(10) Assoc Investigators: Paul G. Longobardi, CPT, MC
(11) Key Words: **Health Styles, Patient/Physician Perception of Referral**		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue review Results: 5/80

(15) *Study Objective:

The purpose of this study is to demonstrate that reliable similarities and differences between patients and their referring physicians in the degree to which their perceived health behavior is under one's control or as a result of luck, chance, or fate will affect the satisfaction of each with specific aspects of their interactions and contribute to differing numbers of referrals for psychological evaluations

(16) *Technical Approach:

Survey data compiled from both referring physician and subject patients will be compared and evaluated to establish any significant connections between Health expectancy styles for these two groups and the referral process.

(17) *Progress:

Thus far, data has been collected on 14 patient/physician pairs. It is expected that a sufficient number of responses will have been compiled by fall 1981 to allow analysis of these data.

Publications and Presentations: None

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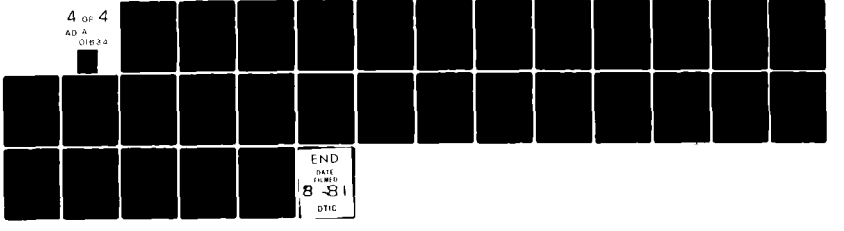

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 80/501 (3) Status: Terminated
(4) Title: Physical Anhedonia and Perceptual Aberration in Acute Psychosis.

(5) Start Date: 1980 (6) Est Comp Date: 1980
(7) Principal Investigator
Paul G. Longoberdi, CPT, MS (8) Facility: FAMC
(9) Dept/Sec: Psyciatry (10) Assoc Investigators:
(11) Key Words:
psychosis
schizophrenia
Loren J. Chapman, Ph.D.
Jean P. Chapman, Ph.D.
both with the Univ. of Wisconsin

(12) Accumulative MEDCASE Cost: (13) Est Accumulative OMA Cost: (14) Periodic Review Results: terminate 6/80

(15) *Study Objective: Using scales of psychosis proneness in college students that were developed on samples of chronic schizophrenics we will determine if the scales identify all early schizophrenics and/or other psychotics as deviant and, it not, what percent are so identified. Further, using other scales, we will seek to specify characteristics of the early schizophrenics and/or other psychotics who score deviantly high on each of the two main scales.

(16) *Technical Approach:
Participating patients will undergo the following procedures: Physical Anhedonia Scale, Perceptical Aberration Scale, NonConformity Scale, Magical Ideation Scale, Beck Depression Inventory and the Phillips Scale. Coded interviews and scale results will be forwarded to the Chapmans at the University of Wisconsin at Madison for analysis using computer programing and comparison with data from other groups.

(17) *Progress:
This protocol has been terminated due to the ETS of the Principal Investigator.

Publications and Presentations: None

RADIOLOGY

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 74/600 (3) Status: Ongoing

(4) Title: Bone Marrow Scintigraphy and Scintigraphic Localization of Soft Tissue Tumors by Use of Indium-111 Chloride

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

(7) Principal Investigator
Peter W. Blue LTC, MC (8) Facility: FAMC

(9) Dept/Sec: Nuclear Medicine Service (10) Assoc Investigators:
Nasser Ghaed, COL, MC

(11) Key Words:
Indium 111 Chloride
Bone Marrow

(12) Accumulative MEDCASE Cost:

(13) Est Accumulative OMA Cost:

(14) Periodic continue Review Results: 6/80

(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) *Progress:
Only one study (normal) was performed during the previous year. It is anticipated that several of these studies will be done in the coming year.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 74/602	(3) Status: Ongoing
(4) Title: The Use of Indium 111 DTPA for the Study of Cerebrospinal Fluid Pathways.		
(5) Start Date: 1974		(6) Est Comp Date: Indefinite
(7) Principal Investigator Peter W. Blue LTC, MC		(8) Facility: FAMC
(9) Dept/Sec: Nuclear Medicine Service		(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Indium 111 DTPA Cerebrospinal Fluid		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 6/80

(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) *Progress:
Thirteen studies using Indium 111 DTPA for evaluation of patients with cerebral spinal fluid pathways pathology have been done in the last year since 1 October 1979. The radiopharmaceutical proved adequate for the intended diagnostic purpose, and again no detectable side effects were observed.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 79/600 (3) Status: Ongoing

(4) Title: Non-Invasive Realtime Ultrasonic Evaluation of Carotid Occlusive Vascular Disease

(5) Start Date: 1979 (6) Est Comp Date: indefinite

(7) Principal Investigator
Stanley F. Smazal, Jr., M.D., DAC

(8) Facility: FAMC

(9) Dept/Sec: Radiology/Ultrasound

(10) Assoc Investigators:
Lewis Mologne, COL
John Buscemi, LTC
John Eielson, LTC
Nasser Ghaed, COL

(11) Key Words:
Carotid Artery
Thrombus
Ulcerative plaque

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 6/80

(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 artery; and to employ a full pulsed doppler to measure bi-directional flow in the carotid artery.

(16) *Technical Approach:

Approximately 120 patients will be evaluated. Patients will be divided into 4 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 carotids bruits; 4) Patients who have experienced a previous stroke within the last 12 months. This entire patient population will be evaluated

(17) *Progress: 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.

(16) by a non-invasive real-time technique.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 80/600	(3) Status: Ongoing
(4) Title: Tc99m - PIPIDA for diagnosis of Hepatobilary disease		
(5) Start Date: 1980		(6) Est Comp Date: indefinite
(7) Principal Investigator Peter W. Blue, LTC, MC		(8) Facility: FAMC
(9) Dept/Sec: Nuclear Medicine Service		(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Tc-99m-PIPIDA, diagnostic hepatobiliary, Dignostic Isotopes		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 9/80

(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) *Progress:
Not yet begun.

Publications and Presentations: None

HOSPITAL CLINICS

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: Indefinite
(7) Principal Investigator Nicholas C. Bethlenfalvay, MD., DAC		(8) Facility: FAMC
(9) Dept/Sec: DPCCM		(10) Assoc Investigators: Joseph Lima, DAC, GS-11
(11) Key Words: Abnormal Hemoglobins Techniques on Identification		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 12/79

(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) *Progress: 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.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT
(USCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78-650 (3) Status: Ongoing

(4) Title: Evaluation of Thalassemia as Cause of Hypochromic Microcytic Anemia in Interaction with Hemoglobin Variants

(5) Start Date: March 1978 (6) Est Comp Date: Indefinite

(7) Principal Investigator D.G Corby,COL MC (8) Facility: FAMC
Nicholas C. Bethlenfalvay,MD,DAC

(9) Dept/Sec: DPCCM (10) Assoc Investigators:

(11) Key Words: Congenital Anemia
Thalassemia

None

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 2/80

(15) *Study Objective:

Copy abbreviated version from 1979 resume

(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) *Progress: Since the inception of the study, 30 patients were evaluated resulting in the identification of the following conditions: HbC/alpha thalassemia; 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.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 78/651	(3) Status: Ongoing
(4) Title: Evaluation and Structural Identification of Unusual Human Hemoglobin Variants		
(5) Start Date: March 1978		(6) Est Comp Date: Indefinite
(7) Principal Investigator Nicholas C. Bethlenfalvay, MD, DAC		(8) Facility: FAMC
(9) Dept/Sec: DPCCM		(10) Assoc Investigators: Joseph E. Lima, MS, DAC, GS-11
(11) Key Words: Abnormal Hemoglobins		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic Review Results: continue 2/80

(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) *Progress: Since the inception of the study, four cases with unusual hemoglobins were identified. Two of these were shown to have Hb Lepore/Boston, one, having heterozygosity for the hereditary persistence of Hb F (Aganima G gamma variety); the last patient with erythrocytosis and an electrophoretically silent Hb was found to have a left shifted oxygen dissociation curve and an abnormal Hb band on isoelectric focusing. Having a beta 97 his→tyr substitution, this is a hitherto unreported high oxygen affinity variant. Report is in preparation.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/652 (3) Status: Terminated

(4) Title: Alpha Thalassemia: Evaluation of the Significance of Hemoglobin Bart's in the Black Neonate.

(5) Start Date: May 1978	(6) Est Comp Date:
(7) Principal Investigator Nicholas C. Bethlenfalvay, MD., DAC	(8) Facility: FAMC
(9) Dept/Sec: DPCCM	(10) Assoc Investigators: Thomas P. O'Barr, Ph.D., DAC Donald G. Corby, COL, MC
(11) Key Words: Alpha-Thalassemia Hemoglobin Bart's	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic terminate Review Results: 5/80

(15) *Study Objective:
To confirm the presence and assess the severity of alpha thalassemia in Black neonates who have Hemoglobin Bart's. Those cases who present with detectable amounts of Hemoglobin Bart's at birth will be again studied at one year of age by incubating their peripheral blood with ^{14}C leucine in vitro. At that time alpha/beta chain synthetic ratios will be determined.

(16) *Technical Approach: Black neonates will be screened by means of electrophoresis for the absence or presence of Hemoglobin Bart's. Those cases who present with detectable amounts of Hemoglobin Bart's at birth will be again studied at one year of age by incubating their peripheral blood with ^{14}C leucine in vitro. At that time alpha/beta chain synthetic ratios will be determined.

(17) *Progress: Since the inception of this protocol in FY 78, eighty Black neonates with Hemoglobin Bart's, ranging between 11 and 0%, were studied. Most of these neonates are now over one year of age. In late 79 and in 1980 there have been rapid advances in the chemical analysis of the human globin gene clusters by means of endonuclease restriction mapping of gene deletions, rendering the technical approach detailed in this study obsolete. Study terminated in May 1980.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80 (2) Prot No.: 78/653 (3) Status: Terminated

(4) Title:
Gamma Thalassemia in the Newborn.

(5) Start Date: March 1978	(6) Est Comp Date: 1980
(7) Principal Investigator Dr Mosijczuk & Dr Bethlenfalvay	(8) Facility: FAMC
(9) Dept/Sec: DPCCM	(10) Assoc Investigators: Thomas P. O'Barr, Ph.D., DAC Donald G. Corby, COL, MC
(11) Key Words: Congenital anemia Gamma - thalassemia	

(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic terminate Review Results: 5/80

(15) *Study Objective:
To demonstrate that suppression of gamma polypeptide chain synthesis is one of the mechanisms that causes microcytic-hyopchromic (hemolytic) anemia.

(16) *Technical Approach: Peripheral blood of newborn having microcytic-hypochromic anemia of unknown etiology will be incubated with ^{14}C leucine in vitro. Globin will be prepared and fractionated into alpha, beta and gamma chains. Radioactivity and specific activity ratios of gamma/alpha and gamma plus beta/alpha chains will be calculated.

(17) *Progress: Sine the inception of the study, no newborn met the selection criteria to enter into the study. Project terminated May 1980.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT
(USCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 80	(2) Prot No.: 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 Comp Date: June 1982
(7) Principal Investigator Nicholas C. Bethlenfalvay, M.D., DAC		(8) Facility: FAMC
(9) Dept/Sec: DPCCM		(10) Assoc Investigators: N/A
(11) Key Words: Opossum Hemoglobin Methemoglobin reduction		
(12) Accumulative MEDCASE Cost:	(13) Est Accumulative OMA Cost:	(14) Periodic continue Review Results: 4/80

(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.

(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) *Progress: When correlated to the only in-vivo human study on record opossums tolerated 10 times the amount of intravenous nitrite resulting in significantly less methemoglobineuria, and quicker reduction of oxidized iron.

In-vitro, under identical oxidant stress, opossum red cells were shown not to require external glucose as substrate for methemoglobin reduction.

CONTINUATION SHEET FOR FY 80 ANNUAL PROGRESS REPORT
(Blocks 1 through 17)

Proto No: 80/650

(17) Progress: (continued)

NADH dependent cytochrome b_5 methemoglobin reductase was quantitatively twice that seen in human red cells, and unlike the human enzyme by electrophoretic migration.

The NADPH dependent diaphorase readily coupled with methylene blue, reduced opossum methemoglobin faster than human methemoglobin, and was, on electrophoresis, strikingly different from the human enzyme.

Publications and Presentations: None

INVESTIGATORS INDEX

INVESTIGATORS INDEX

Name	Page
Takao, R.T.	
Tipton, W.R.	
Treece, G.L.	
Turner, B.S.	
Vaccaro, J.A.	
Wagner, C.	
Way, G.L.	
Weber, R.W.	
Weisman, L.E.	
Wells, D.W.	
Wershaw, R.L.	
Whiteaker, R.S.	
Zaloznik, A.J.	
Zimmerer, R.W.	
Zolock, D.T.	
Zwillich, C.	
Yeatman, G.W.	

KEY WORD INDEX

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