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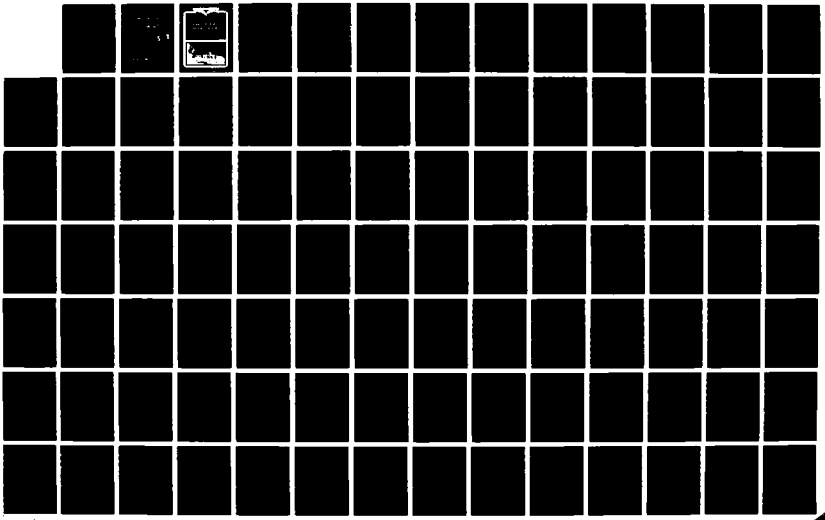

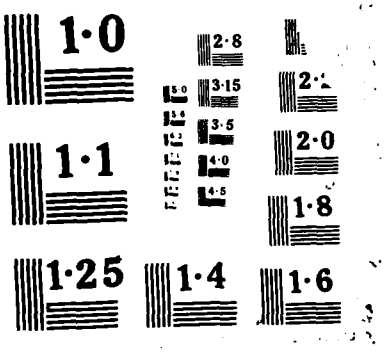
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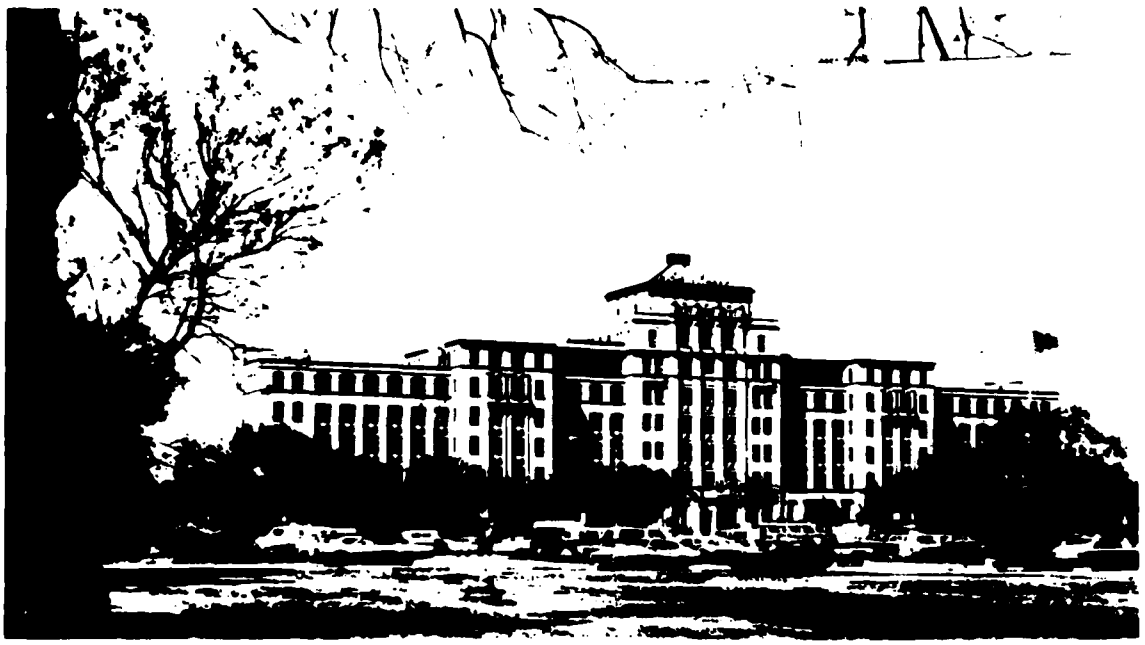
DEPARTMENT OF CLINICAL INVESTIGATION

ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1987

VOLUME I

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234



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The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

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Clinical Investigations, all medical specialties
Publications, presentations
Detail Summary Sheets (Study Objective; Technical Approach; Progress; Status)

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

Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1986. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The researhc protocols described were

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Block 20. Abstract

conducted under the provisions of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reprots; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the edical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.

FOREWORD

The Department of Clinical Investigation at Brooke Army Medical Center has completed another outstanding year. The number of protocols, as well as the general quality of work, has continued to improve year by year. This work could not be accomplished without the continued superior expertise and support of the assigned personnel, both technical and administrative.

A major effort of our department over this past year has been the challenging integration of our resources and efforts with those of Wilford Hall USAF Medical Center under the Joint Military Medical Command, San Antonio. This has proven difficult in a number of areas, primarily regarding the protocol approval process which differs in many ways between the Army and the Air Force system. Despite these differences, the cooperation and efforts from all parties concerned have been very gratifying and much progress has been made. Indeed, the resulting system should be quite efficient and allow the investigator access to expert critical review of his research proposal in a timely manner. Overall, the potential for clinical investigation under the new arrangements is virtually limitless and quite exciting. The facilities and expertise available between our two facilities rival those of many university centers. When combined with other research opportunities available within the San Antonio area, the local military investigator should be able to look forward to outstanding support. Such potential is already being recognized by outside sources, in particular the U.S. Army Medical Research and Development Command as well as private industry. In the latter area, projects are already underway in the general area of orthopaedic research with promise of expansion in additional areas as well.

The number of protocols continues to increase and this past year was no exception. Given the above opportunities, the breadth of projects has widened to include numerous areas of laboratory and animal projects in addition to clinical areas. The Commander's Award continues to be an incentive for young investigators. The winners this year were: 1st Place - CPT Michael F. Sugg, Department of Emergency Medicine - Potentiation of Glucagon by Theophylline in Reversing Propranolol Toxicity; 2d Place - CPT Martin E. Weisse, Department of Pediatrics - Fever Response to Antipyretics Correlated with Etiology of Fever; 3d Place - CPT Henry G. Chambers, Department of Surgery - Effects of Continuous Passive Motion on Muscle Biochemistry and Histology.

There appear to be some clouds on the horizon, particularly regarding resources, both monitary and personnel. There will definitely be a requirement for "belt tightening." This will require more critical analysis of priorities but I am confident that excellent support will continue to be provided by this department to investigators.

I congratulate all of those members of this department who have provided such excellent service over the past year as well as the physician staff of the hospital in general who have worked so hard on their ideas and projects. I am looking forward to an even more successful year in 1988!

F. Goldner

FRED GOLDNER
Colonel, MC
Chief, Dept of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1987

A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.

2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.

3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.

4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.

5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.

6. To maintain a high professional standard and accreditation of advanced health programs.

7. To assure the highest level of professional standards in the conduct of human research and animal research.

B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. Staffing

Name	Rank	MOS	Title
Goldner, Fred H.	COL	60G	Chief, Gastroenterologist
Peace, Theopolis*	COL	64B	Veterinary Lab Animal Officer
Danley, David L.*	MAJ	68E	Immunologist
Gelston, Hugh M., Jr.	MAJ	68A	Microbiologist
Krikorian, Debra J.**	CPT	68C	Biochemist
Diaz, Noel	SSG	92B2	NCOIC
Bretthauer, Ricky W.**	SSG	92B2	Med Lab Specialist
Hinds, Johnny W.*	SSG	92B	Med Lab Spec
Jones, Sheila	SSG	92B2	Med Lab Specialist

* Assigned 10 Jul 87; 3 Dec 86; 13 Apr 87
** Reassigned 1 Jan 87; 11 Aug 87

C. Staffing (continued)

Name	Rank	MOS	Title
Blomgren, Wendy**	SGT	91T	Animal Care Specialist
Hicks, Jeninne M.***	SGT	92B	Med Lab Specialist
Gaines, Marlene	SP4	91T	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Grassel, Janice	GS11	00404	Biological Laboratory Technician
Posch, John	GS11	00644	Medical Technologist
Reeb, Barbara	GS9	00644	Medical Technologist
Peek, Michael W.****	GS9	01320	Chemist
Marshall, Regina****	GS9	00610	Clinical Nurse
Chapa, Isidoro	GS7	00645	Medical Technician
Rios, Roberto	GS9	01020	Medical Scientific Illustrator
Bratten, Dodie	GS9	00301	Clin Research Protocol Coord
Smith, Helen J.	GS6	01087	Editorial Assistant

** Reassigned 17 Dec 86, 19 Sep 86
*** REFRAD 27 Dec 86
****Resigned 3 Jul 87; 3 Jul 87

D. Funding

Type	Fiscal Year 86	Fiscal Year 87
Civilian personnel to include benefits	452,565.00	439,220.00
Consumable supplies	123,000.00	121,000.00
Civilian contracts to include consultants	36,318.00	50,124.00
TDY	4,208.00	2,865.00
Publications	9,125.00	13,653.00
Noninvestment equipment (Minor MEDCASE)	--------	--------
Other OMA		
OMA Total	618,184.00	645,252.00
MEDCASE	196,362.71	63,815.70
Other		
Military	463,136.00	546,511.00
TOTAL	1,277,682.71	1,255,578.70

Protocol Disposition FY 87

	Terminated	Transferred	Completed	Ongoing to FY 88
FY 77	-		0	1
FY 78	0		0	1
FY 81	2		1	0
FY 82	1		1	0
FY 83	1		4	2
FY 84	5		4	7
FY 85	15	1	7	12*
FY 86	30		18	48*
FY 87	11	1	10	88
	64	2	46	159

*Two protocols (C-59-85 and C-9-86) reopened in FY 87.

Training Protocols

	Terminated	Completed	Ongoing to FY 88
FY 82			2
FY 85			1
FY 86	2	2	9
FY 87	0	0	7
	2	2	19

Group Protocol Disposition FY 87*

	Terminated	Completed	Ongoing to FY 88
SWOG	2	32	68
GOG	0	6	29
POG	0	9	45
	2	47	142

*In the annual report, FY 86, there were two less protocols ongoing to FY 87 in each of the Oncology Groups; i.e. SWOG - 74, GOG - 28, and POG - 28.

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O - Ongoing PR - Presentation

T - Terminated

TR- Transferred

DEPARTMENT OF THE ARMY
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DEPARTMENT OF CLINICAL INVESTIGATION

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Peripheral Vascular Surgery Service

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DEPARTMENT OF THE ARMY
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DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

Ayala, E., Krikorian, D. Recovery of herpes simplex virus type I strain (KOS) from guinea pig dorsal root ganglia after topical applications of lysine. 1987 Annual American Society of Microbiology, Atlanta, GA., 1-6 Mar 87. (C)

Danley, D. The Joint Military Medical Command - new opportunities for medical research. Seminar, U.S. Army Biomedical Research and Development Laboratory, Fort Detrick, MD, 24 Sep 87.

Peek, M.W. Statistics in medical research. Hospital Research Series, Darnall Army Community Hospital, Fort Hood, TX, 9 Oct 86.

DEPARTMENT OF EMERGENCY MEDICINE

Guiffre, Y. Heat injuries. University of Texas at San Antonio, San Antonio, TX, 20 Jan 87.

Coleridge, S.T. Venomous snake bites in U.S. Trinity University, San Antonio, TX, 5 Mar 87.

Morgan, A. Insect and spider bites. Trinity University, San Antonio, TX, 5 Mar 87.

Coleridge, S.T. Admiral Eshe scientific session. AMOPS, Colorado Springs, CO, 6 Mar 87.

Coleridge, S.T. Moderator, Introduction to research and abstract. AMOPS, Colorado Springs, CO, 26-29 Mar 87.

Coleridge, S.T. Career development and hospital triage. Tri Service Symposium, San Antonio, TX, 27 Apr-1 May 87.

Norris, R. Venomous snake bites in the U.S. Tri Service Symposium, San Antonio, TX, 30 Apr 87. (C)

Chisholm, C.D. Blast injuries. Tri Service Symposium, San Antonio, TX, 1 May 87.

Norris, R. Snake bite management. Tri Service Symposium, San Antonio, TX, 1 May 87.

Sugg, M. Potentiation of glucagon canine model with complete beta adrenergic blockade by propranolol. University Association of Emergency Medicine (UAEM), Philadelphia, PA, 19 May 87. (C)

Singletary, E. Comparison of arterial and venous CoHb levels in a sheep model. UAEM, Philadelphia, PA, 21 May 87. (C)

Chisholm, C.D. Carboxyhemoglobin levels in patients with headache. UAEM, Philadelphia, PA, 21 May 87. (C)

Chisholm, C.D. Approach to toxicologic emergencies. Internal Medicine, Tripler Army Medical Center, HA, 1 Sep 87

Chisholm, C.D. Wound management. Emergency Medical Services, Tripler Army Medical Center, HA, 1 Sep 87.

Chisholm, C.D. Carbon monoxide poisoning. Department of Pediatrics, Tripler Army Medical Center, HA, 2 Sep 87.

Chisholm, C.D. Near drowning. Emergency Medical Services, Tripler Army Medical Center, HA, 2 Sep 87.

Chisholm, C. D. Diarrhea. Emergency Medical Services, Tripler Army Medical Center, HA, 4 Sep 87.

Norris, R. Snake bite emergencies. Department of Emergency Medicine, Darnall Army Community Hospital, Fort Hood, TX, 10 Sep 87.

Norris, R. Venomous snake bites. Department of Emergency Medicine, Darnall Army Community Hospital, Fort Hood, TX, 16 Sep 87.

Chisholm, C.D. MAST. Texas Tech University, Lubbock, TX, 19 Sep 87.

Chisholm, C.D. Blast. Texas Tech University, Lubbock, TX, 19 Sep 87.

Chisholm, C.D. Panel Member Aeromedical evaluation. Texas Tech University, Lubbock, TX, 19 Sep 87.

Olinger, M. Bicarbonate in ACLS. Department of Emergency Medicine, Fort Hood, TX, 30 Sep 87.

Chisholm, C.D. MAST 10-11. Department of Emergency Medicine, Fort Hood, TX, 30 Sep 87.

Chisholm, C.D. Co poisoning 11-12. Department of Emergency Medicine, Fort Hood, TX, 30 Sep 87.

DEPARTMENT OF MEDICINE

Allergy Immunology Service

Ortiz, A.A. Fire ants. Allergy Service, Fitzsimons Army Medical Center, Aurora, CO, 6 Feb 87.

Cardiology Service

Wrenn, R.C. Percutaneous transluminal coronary angioplasty in acute myocardial infarction at Brooke Army Medical Center, 3rd Annual U.S. Army Regional American College of Physicians Meeting, San Francisco, CA, Oct 86. (C)

Matthews, E.A. Retrograde systolic coronary artery flow in cardiac amyloidosis. 16th Annual Meeting, Association of Army Cardiology, San Francisco, CA, Oct 86.

Schatz, R.A. Mechanism of PTCA. PTCA Update Faculty Presentation USCI, New Orleans, LA, Oct 86. (C)

Latham, R.D. Hemodynamic effects of the Muller maneuver by simultaneous right and left heart micromanometry in man. 59th Scientific Sessions of the American Heart Association, Dallas, TX, Nov 86. (C)

Pasipoularides, A. External left ventricular load during Mueller and Valsalva maneuvers in man. 59th Scientific Sessions of the American Heart Association, Dallas, TX, Nov 86. (C)

Pasipoularides, A. The genesis of aortic root pressure waveform patterns in man. 59th Scientific Sessions of the American Heart Association, Dallas, TX, Nov 86.

Schatz, R.A. Balloon expandable intracoronary grafts in dogs. 59th Scientific Sessions of the American Heart Association, Dallas, TX, Nov 86.

Krouse, J.R., Pasipoularides, A., Bailey, S.R., et al. Right ventricular hemodynamic abnormalities in hypertrophic cardiomyopathy. 36th Scientific Sessions, American College of Cardiology, New Orleans, LA, Mar 87.

Latham, R.D., Thornton, J.R. Cardiovascular researve in idiopathic dilated cardiomyopathy. Poster presentation, 36th Annual Scientific Sessions, American College of Cardiology, New Orleans, LA, Mar 87. (C)

Latham, R.D., Mulrow, J.P. Efficacy of prednisone therapy for new onset idiopathic dilated cardiomyopathy. Poster presentation, 36th Annual Scientific Sessions, American College of Cardiology, New Orleans, LA, Mar 87. (C)

Rubal, B.J., Alamo, M.G., et al. Real-time data acquisition in an automated clinical laboratory. Texas Academy of Science, Sam Houston, State University, Huntsville, TX, 5-7 Mar 87.

Latham, R.D. Dilated cardiomyopathy, diagnosis and management. Cardiology Faculty, LSU School of Medicine, Shreveport, LA, Apr 87.

Pasipoularides, A., Mirsky, I. Models and concepts ofdiastolic mechanics: Pitfalls in their misapplication. Sixth International Conference on Mathematical Modelling, Session on Mathematical Modelling in Cardiology, St. Louis, MO, Aug 87.

Dermatology Service

Salasche, S.J. Patterns of tumor spread in the skin - surgical anatomy. Tufts University, Oct 86.

Salasche, S.J. Surgical anatomy and surgery complication. University of Ohio, Oct 86.

Kraus, E.A. South American blastomyocosis. Southern Medical Meeting, Atlanta. GA, Nov 86.

Kraus, E.A., Clemons, D.E. Interesting cases from BAMC. Central American Congress of Dermatology, Tegucigalpa, Honduras, Nov 86.

Kraus, E.A. Antifungal therapy. Central American Congress of Dermatology, Tegucigalpa, Honduras, Nov 86.

Blaskis, M. Three cases of sclerosing sweat duct carcinoma in prior scar sites. American Association of Dermatology (AAD), New Orleans, LA, 6 Dec 86.

Speelman, P. Dowling Degos disease as the presenting sign of leukemia. AAD, New Orleans, LA, 6 Dec 86.

Salasche, S.J. Acute surgical complications. AAD, New Orleans, LA, Dec 86.

Salasche, S.J. Basic surgery course - Surgical Anatomy. AAD, New Orleans, LA, Dec 86.

Salasche, S.J. Advanced surgery Course - Rotation Flap. AAD, New Orleans, LA, Dec 86.

Salasche, S.J. Seminar on cutaneous tumors - limitation of curettage in the treatment of basal cell carcinoma. AAD, New Orleans, LA, Dec 86. (C)

Clemons, D.E. Basic dermatopathology - tumor polosebaceous differentiation. AAD, New Orleans, LA, Dec 86.

Feldman, A. Perforating calunosis cutis - a cutaneous manifestation of atrial myxoma. AAD, New Orleans, LA, Dec 86.

Radentz, W. Waldenstrom's macroglobulinemia and Merkel cell carcinoma and bullous pemphigoid. AAD, New Orleans, LA, Dec 86.

General Medicine Service

Kroenke, K. A prospective study of fatigue. Army ACP meeting, San Francisco, CA, 25 Oct 86. (C)

Omori, D. The adverse effects of hospitalization on drug regimens. Army ACP meeting, San Francisco, CA, 25 Oct 86.

Wood, D. Syncope in mitral valve prolapse. Army ACP meeting, San Francisco, 25 Oct 86.

Simmons, J. The effect of physician review of peripheral blood smears on the work-up of anemia. Army ACP meeting, San Francisco, CA, 25 Oct 86.

Simmons, J. Critical reading of the medical literature. Army ACP meeting, San Francisco, CA, 25 Oct 86.

Simmons, J. Panel "Future of general internal medicine in the Army." Army ACP meeting, San Francisco, CA, 25 Oct 86.

Simmons, J. Panel "Getting started in research." Army ACP meeting, San Francisco, CA, 25 Oct 86.

Pinholt, E.M. Reducing polypharmacy in the elderly. American Geriatrics Society, 6-19 Nov 86, Chicago, IL. (C)

Kroenke, K. Getting started in research. Grand Rounds, Madigan Army Medical Center, Tacoma, WA, 27-28 Mar 87.

Kroenke, K. Preoperative evaluation. Grand Rounds, Madigan Army Medical Center, Tacoma, WA, 27-28 Mar 87.

Kroenke, K. Fatigue in primary care. Society of General Internal Medicine, San Diego, CA, 30 Apr 87. (C)

Kroenke, K. Do diuretics cause hypomagnesemia. American Federation of Clinical Research, San Diego, CA, 2 May 87.

Kroenke, K. Fatigue in primary care. Mental Health in Primary Care Conference, National Institute of Mental Health, Seattle, WA, 25 Jun 87. (C)

Kroenke, K. Nutritional assessment by clinical examination. SGO Postgraduate Short Course, 15 Jun 87.

Kroenke, K. Management of hyperlipidemias. SGO Postgraduate Short Course, 15 Jun 87.

Simmons, J. Ethical and legal issues in critical care nutrition. Nutritional Assessment Postgraduate Short Course, 25 Jun 87.

Hanley, J. Automatic blood pressure machines: Utilization, accuracy, and physician attitudes. National High Blood Pressure Conference, Las Vegas, NV, Apr 87.

Omori, D. The adverse effects of hospitalization on drug regimens. Society of General Internal Medicine, San Diego, 30 Apr 87.

Hematology Oncology Service

Zaloznik, A.J. Smoking cessation program at Fitzsimons Army Medical Center. 3rd Annual US Army Regional American College of Physicians, San Francisco, CA, 24-26 Oct 86.

Levey, I.L. Acute lymphoblastic leukemia following meyodysplastic syndrome. 3rd Annual US Army Regional American College of Physicians, San Francisco, CA, 24-26 Oct 86.

Levey, I.L. Antiemetic efficacy of haloperidol. 3rd Annual US Army Regional American College of Physicians, San Francisco, CA, 24-26 Oct 86 . (C)

Harvey, W.H. Role of chemotherapy for locally advanced breast cancer. American College of Osteopathic Surgeons Oncology Update, Dallas, TX, 31 Jan 87.

Harvey, W.H. Curent status of adjuvant chemotherapy for primary breast cancer. American College of Osteopathic Surgeons Oncology Update, Dallas, TX, 31 Jan 87.

Gee, A.P., Pick, T., Harvey, W.H. et al. Transplantation for neuroblastoma using immunomagnetically-purged autologous bone marrow - factors influencing engraftment. Third International Symposium on Autologous Bone Marrow Transplantation, Houston, TX, Dec 86. (C)

Graham-Pole, J., Gee, A., Harvey, W.H. et al. Autologous BMT using immunomagnetically purged marrow for metastatic neuroblastoma: A Pediatric Oncology Group Study. First International Workshop on Bone Marrow Purging. Orlando, FL, Feb 87. (C)

Gee, A.P., Pick, T., Harvey, W.H. et al. Immunomagnetic purging and autologous transplantation in stage D neuroblastoma. First International Workshop on Bone Marrow Purging, Orlando, FL, Feb 87.

Harvey, W.H. Transplantation for neuroblastoma using immunomagnetically-purged autologous bone marrow - factors influencing engraftment. Third Internal Conference on Autologous BMT, Houston, TX, Dec 86. (C)

Nephrology Service

Cushner, H.M. Calcium citrate a new phosphate binder. Concepts in Internal Medicine, ACP Regional Nephrology Meeting, San Francisco, CA, Oct 86. (C)

Wortham, W. HTLV-III in the dialysis unit. Concepts in Internal Medicine, ACP Regional Nephrology Meeting, San Francisco, CA, Oct 86. (C)

Melton, K. Clearance of immune complexes in experimental glomerulonephritis. Concepts in Internal Medicine, ACP Regional Nephrology Meeting, San Francisco, CA, Oct 86.

Lindberg, J.S. Interference of digoxin like immunoreactive substances in cardiac patients. American Heart Association, Dallas, TX, Nov 86.

Kennerly, G., Koger, D., Cushner, H., Copley, J.B. Ultrafiltration at the initiation of peritoneal diaglysis. 7th National Conference on CAPD, Kansas City, KA, Feb 87.

Pulmonary Disease Service

Richey, H.M. The mortality rates of ventilator dependent patients in the MICU at Brooke Army Medical Center. 3rd Army Regional American College of Physicians, San Francisco, CA, Oct 86.

Morales, F.M. Predictive values of bronchoalveolar lavage (BAL) in patients with pulmonary sarcoidosis. 3rd Army Regional American College of Physicians, San Francisco, CA, Oct 86. (C)

Johnson, J.E. Diagnostic significance of hemosiderin laden macrophages in bronchoalveolar lavage fluid. 3rd Army Regional American College of Physicians, San Francisco, CA, Oct 86. (C)

Goya, D.S. A randomized prospective study of the percutaneous J-wire exchange technique for safety and efficacy. 3rd Army Regional American College of Physicians, San Francisco, CA, Oct 86. (C)

Anders G.T. Transbronchial biopsy without fluoroscopy: A seven year perspective. Texas Thoracic Society Annual Meeting, San Antonio, TX, Apr 87. (C)

Johnson, J.E. Predictive value of hemosiderin-laden macrophages in bronchoalveolar lavage fluid for clinical alveolar hemorrhage syndrome. Texas Thoracic Society Annual Meeting, San Antonio, TX, Apr 87. (C)

Goya, D.S. The safety and efficacy of the guide-wire exchange technique for central venous catheters in the ICU. Texas Thoracic Society Annual Meeting, San Antonio, TX, Apr 87. (C)

Matthews, J.I. Lung cancer in former tobacco users. American Thoracic Society, New Orleans, LA, 10 May 87. (C)

Anders, G.T. Transbronchial biopsy without fluoroscopy: A seven year perspective. American Thoracic Society, New Orleans, LA, 10 May 87. (C)

Rheumatology Service

Melton, G.B. Approach to low back pain. National Medical Association, New Orleans, LA, 2 Aug 87.

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Simon, F.A., Jr. Leiomyomata in Pregnancy. Armed Forces District, American College of Obstetrics and Gynecology (AFD-ACOG), San Diego, CA, Oct 86.

Burke, T.W. Calyceal rupture with perineal uninoma in a patient with cervical cancer. AFD-ACOG, San Diego, CA, Oct 86.

Burke, T.W. The treatment of retroperitoneal fibromatosis with medroxyprogesterone acetate. AFD-ACOG, San Diego, CA, Oct 86.

Burke, T.W. Pathologic criteria for the evaluation of the ECC in endometrial carcinoma. AFD-ACOG, San Diego, CA, Oct 86.

Burke, T.W. Widespread lymph node metastases in a patient with microinvasive squmous cell carcinoma of the cervix. AFD-ACOG, San Diego, CA, Oct 86.

Burke, T.W. Retroperitoneal hematoma presenting as an abdominal-pelvic mass. AFD-ACOG, San Diego, CA, Oct 86.

Burke, T.W. Complications of total parenteral nutrition in pregnancy: A case report. AFD-ACOG, San Diego, CA, Oct 86.

Burke, T.W. End colostomy using the end-to-end anastomosis (EEA) instrument. Scientific Exhibit, AFD-ACOG, San Diego, CA, Oct 86.

Schipul, A.H., Jr. Fetal tobacco syndrome. 2nd Annual Pediatric Respiratory Disease Conference, San Antonio, TX, Mar 87.

DEPARTMENT OF PATHOLOGY AND ALS

Farr, W.D. Army anthropometric standards for the rotary wing aviator in the light obsevation helicopters. 15th Scientific Session of the Joint Committee on Aviation Pathology, RAF Halton, England, 10 Oct 86.

DEPARTMENT OF PEDIATRICS

Brien, J.H. Infectious diseases - emergencies. Emergency Medicine, Madigan Army Medical Center, Tacoma, WA, 9 Sep 87.

Brien, J.H. Croup syndrome. Emergency Medicine, Madigan Army Medical Center, Tacoma, WA, 9 Sep 87.

Brien, J.H. Communicable diseases in emergency medicine. Emergency Medicine, Madigan Army Medical Center, Tacoma, WA, 9 Sep 87.

Potter, A. Hemangioendothelioma. Grand Rounds, University of Texas Health Science Center at San Antonio, 27 Sep 87.

DEPARTMENT OF PSYCHIATRY

Gillooly, D.H. Outpatient workload sample of AMEDD settings providing psychological services: An epidemiologic and management tool. 1986 AMEDD Clinical Psychoogy Short Course, Tripler, Army Medical Center, HI, 6 Nov 86.

Brenz, R.W. Forensic psychiatry. Region IV US Army Trial Defense Service Conference, San Antonio, TX, 6 Dec 86.

Powell, J.B. Evaluation of a comprehensive biofeedback/stress management program. 1987 AMEDD Psychology Short Course, San Francisco, CA, 11 Mar 87. (C)

Powell, J.B. Psychological assessment of fatigue in a medical setting. 1987 AMEDD Psychology Short Course, San Francisco, CA, 11 Mar 87. (C)

Randle, C.D. Women in divisions. Symposium for Military Psychiatry, AMEDD Division and Combat Psychiatry Course, 12-16 Jan 87.

Brenz, R.W. Medical Treatment Issues (Presentor/Moderator). RTFs, Staff for HSC, 18 Mar 87.

DEPARTMENT OF RADIOLOGY

Hartshorne, M.F. Decontamination of radiation accident and victims workshop. Radiations Accidents Management Course, University of New Mexico. Albuquerque, NM, 3 Oct 86.

Bauman, J.F. In WBC's clinical applications. University of Texas Health Science Center, San Antonio, TX, 24 Oct 86.

Hartshorne, M.F. New fangled mUGAS. Texas Association of Nuclear Medicine, 18 Oct 86.

Hartshorne, M.F. Radionuclide ventriculograms. Radiology Department, Fitzsimons Army Medical Center, Aurora, CO, 28 Oct 86.

Hartshorne, M.F. Radiology oral boards stratety and preparation. Radiology Department, Fitzsimons Army Medical Center, Aurora, CO, 30 Oct 86.

Hartshorne, M.F. Emergency medicine in radiation fields. South Central Management Association, 5 Dec 86.

Redd, R.A. Imaging of renal masses. Keller Army Community Hospital, West Point, NY, 6 Nov 86.

Hartshorne, M.F. Medical effects of radiation orientation. Kirtland, AFB, NY, 12 Feb 87.

Hartshorne, M.F. Nuclear radiology review. Letterman Army Medical Center, Presidio of San Francisco, CA, 20 Feb 87.

Hartshorne, M.F. Bone scans in benign disease. Advanced Physical Therapy Course, Academy of Health Sciences, 11 Mar 87.

Byrd, B. Gated xenon right ventricular scans. SNM Chapter, Houston, TX, 26 Mar 87.

Hartshorne, M.F. GI bleeding review. SNM Chapter, Houston, TX, 27 Mar 87.

Bauman, J.M. Update on Indium labeled leukocytes. SNM Chapter, Houston, TX, 27 Mar 87. (C)

Grabowski, W.S. Residency curriculum. 35th Annual Meeting of the Association of University Radiologists, Charleston, SC, Mar 87.

Byrd, B. Conference on post-graduate medical education. West Texas State University, Apr 87.

Hartshorne, M.F. Reactive bone disease. University of Texas Health Science Center at San Antonio, May 87.

Byrd, B. Bone mineral analysis. University of Texas Health Science Center at San Antonio, May 87.

Hartshorne, M.F. Bone part II. University of Texas Health Science Center at San Antonio, May 87.

Hartshorne, M.F. Myocardial SPECT. Texas Medical Meeting, Houston, TX, May 87.

Stull, M.A. Rickets. M.D. Anderson Hospital, Houston, TX, May 87.

Hartshorne, M.F. Bone scans for the physical therapist. Physical Therapy Course, Academy of Health Sciences, 21 Jul 87.

Hartshorne, M.F. Radiation effects seminar. Nuclear Hazards Training Course, Kirtland AFB, NM, 8 Jul 87.

Hartshorne, M.F. Bone scans for physics/therapist. Air Force Physical Therapy Course, Academy of Health Sciences, Sep 87.

DEPARTMENT OF SURGERY

Office of the Chief

Rosenthal, D. Workshop - Nutrition in the critically ill patient. Present Concepts in Internal Medicine, San Francisco, CA, 24 Oct 86.

Rosenthal, D. Management of recurrent groin hernias. Annual Arizona Surgical Society Symposium, Phoenix, AZ, Jan 87.

Rosenthal, D. Management of diverticulitis and its complications. Annual Arizona Surgical Society Symposium, Phoenix, AZ, Jan 87.

Rosenthal, D. Stoma complications diagnosis and management. Annual Arizona Surgical Society Symposium, Phoenix, AZ, Jan 87.

Rosenthal, D. Management of colonic injuries. Sansun Clinic Annual Colorectal Course, Santa Barbara, CA, Feb 87.

Rosenthal, D. Felix et Ano Regis. Sansun Clinic Annual Colorectal Course, Santa Barbara, CA, Feb 87.

Rosenthal, D. Modern advanced in burn care. Military Surgical Congress, El Salvador, Mar 87.

Rosentahl, D. Early management of abdominal injuries. Anuual USAREUR Surgical Meeting, Heidelberg, Germany, Mar 87.

Rosenthal, D. Management of rectal trauma. USAREUR Surgical Meeting, Heidelberg, Germany, Mar 87.

Rosenthal, D. Common ano rectal problems. USAREUR Surgical Meeting, Heidelberg, German, Mar 87.

Rosenthal, D. Management of common anal problems. Fort Riley, KS, 13 Aug 87.

Rosenthal, D. Managing the "difficult" stoma. Fort Riley, KS, 13 Aug 87.

Anesthesia and Operative Service

Kingsley, C.P. Mega code. Village Oaks Hospital, San Antonio, TX, 4 Oct 86.

Menk, E.J. A technique for studying the flow and distribution of regional anesthetic agents. Poster presentation at American Society of Anesthesiology, Las Vegas, 16-21 Oct 86.

Kingsley, C.P. Mega code. McKenna Hospital, New Braunfels, TX, 18 Nov 86.

Middaugh, R.E., Menk, E.J. In vivo documentation of the spread of large anesthetic volumes for intercostal nerve blocks. Poster presentation at Post Graduate Assembly in Anesthesiology of the New York State Society of Anesthesiologists, 12-17 Dec 86.

Middaugh, R.E. Anesthesia for laser surgery. Northwest Anesthesia Associates, 5-9 Jan 87.

Middaugh, R.E. Capnography and pulse oximetry in the operating room. Northwest Anesthesia Associates, 5-9 Jan 87.

Middaugh, R.E. CPR update. Northwest Anesthesia Associates, 5-9 Jan 87.

Middaugh, R.E. What's new in anesthesia 1986. NOrthwest Anesthesia Associates, 5-9 Jan 87.

Current, J.D. Drug interactions in obstetrical anesthesia. University of Texas Health Science Center at San Antonio, 12 Feb 87.

Middaugh, R.E. Preparation of the pediatric patient for anesthesia. Northwest Anesthesia Associates, New Orleans, LA, 26 Feb 87.

Middaugh, R.E. Intraoperative fluid management for the pediatric patient. Northwest Anesthesia Associates, New Orleans, LA, 26 Feb 87.

Middaugh, R.E. Verbal induction techniques for pediatric anesthesia. Northwest Anesthesia Associates, New Orleans, LA, 26 Feb 87.

Middaugh, R.E. ACLS clinical update. Dannemiller Education Foundation, 6 Apr 87.

Middaugh, R.E. Verbal induction techniques for pediatric patients. Dannemiller Education Foundation, 6 Apr 87.

Middaugh, R.E. Nitrous oxide a balance clinical perspective. Northwest Anesthesia Seminars, 26-28 May 87.

Middaugh, R.E. IV drug distribution in the pediatric patient. Northwest Anesthesia Seminars, 26-28 May 87.

Middaugh, R.E. Respiratory depression - a practical management approach. Northwest Anesthesia Seminars, 26-28 May 87.

Middaugh, R.E. Lasers and anesthesia. Northwest Anesthesia Seminars, 23-26 Jun 87.

Middaugh, R.E. New aspects of BLS training. Northwest Anesthesia Seminars, 23-26 Jun 87.

Middaugh, R.E. New considerations for ACLS algorithms. Northwest Anesthesia Seminars, 23-26 Jun 87.

Middaugh, R.E. Geriatrics and anesthesia. Northwest Anesthesia Seminars, 23-26 Jun 87.

Middaugh, R.E. What's new in anesthesia in 1987. Northwest Anesthesia Seminars, 23-26 Jun 87.

Middaugh, R.E. Capnography and pulse oximetry for the practitioner. Northwest Anesthesia Seminars, 23-26 Jun 87.

Middaugh, R.E. Airway management. ATLS Instructor at Fort Bragg, NC, 25-29 Jul 87.

Menk, E.J. Combat anesthesia. 2d Annual West Point Medical Association, West Point, NY, 11 Sep 87.

Cardiothoracic Surgery Service

Cohen, A.J., Helsel, R.A., Griskin, B.A. The use of the IMA for life threatening coronary anomalies. Army Regional ACP Meeting, San Francisco, CA, 23-26 Oct 86.

Helsel, R.A., Grishkin, B.A., Briggs, R.M. Trans-hiatal esophagectomy: The initial BAMC experience. Gary P. Wratten Surgical Symposium, William Beaumong Army Medical Center, El Paso, TX, 6-8 Apr 87.

Helsel, R.A. LV-RA fistula. Summit Cardio-vascular Sympsoium, Siverthorne, CO, Mar 87.

General Surgery Service

Otchy, D. The malpositioned greenfield filter. 14th Annual Vascular Surgery Symposium of the Society of Military Vascular Surgeons, Washington, D.C., Dec 86.

Black, C.P., Jr. Comparison of Indium labelled WBC scans in the diagnosis of intraabdominal abscesses. Southeastern Surgical Congress, Atlanta, GA, 15 Mar 87.

Harrison, D.L. Liver trauma: Mortality and morbidity in review. Gary P. Wratten Surgical Symposium, William Beaumont Army Medical Center, El Paso, TX, 6-8 Apr 87.

Simmang, C.L. Acute acalculus cholecystitis in the critically ill surgical patient. Gary P. Wartten Surgical Symposium, El Paso, TX, 6-8 Apr 87.

Pinkerton, S.F. Needle directed biopsy for clinically occult breast malignancies. Gary P. Wratten Surgical Symposium, El Paso, TX, 6-8 Apr 87.

Mozingo, D.W. Candida infection and colonization in critically ill surgical patients. Gary P. Wratten Surgical Symposium, El Paso, TX, 6-8 Apr 87.

Black, C.P., Jr. Non-occlusive mesenteric infarction - a report of five cases. Southwestern Surgical Congress, Coronado, CA, 26-29 Apr 87.

Cook, R.D. Timing of surgery in gallstone pancreatitis. Southwestern Surgical Congress, Coronado, CA, 26-29 Apr 87.

Walters, M.J. Grand Rounds, University of Texas Health Science Center at San Antonio, TX, 24 Apr 87.

Walters M.J. Grand Rounds, University of Texas Health Science Center at San Antonio, TX, 26 Jun 87.

Neurosurgery Service

Hodge, C.J. Correlating the degree of choroidal stenosis in cerebral ischemia. 12th International Joint Conference on Stroke and Cerebral Circulation, Tampa, FL, 26-28 Feb 87.

Ophthalmology Service

Glover, A.T. Lacrimal trauma. Ocular Trauma Symposium, Letterman Army Medical Center, San Francisco, CA, 11 Feb 87.

Mein, C.E. Sympathetic ophthalmia. Ocular Trauma, Symposium, Letterman Army Medical Center, San Francisco, CA, Jan 87.

Hansen, E.A. Magnetic resonance imaging findings. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Webster, G.B. Magnetic resonance imaging of choroidal melanoma. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Farris, S.R. Effect of caffeine on intention tremor. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Foster, M.S. HLA antigens in vital patients with ocular infection. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Speicher, P.J. Culture from whirlpools of area health spas. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Mazzoli, R.A. Congenital aminoceles of the nasolacrimal system. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Hammer, B.D. Intermittent exotropia. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Dirks, M.S. Creutzfeld-Jakob disease Heidenhain (cortical blindness) variant - a case report. Alamo City Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Woodcock, M.G. Posterior chamber intraocular lenses in the presence of capsular tears. Alamo Area Ophthalmology Residents Conference, San Antonio, TX, 4 Apr 87.

Glover, A.T. Plastics and reconstructive surgery. Air Force Surgeons Meeting, University of Texas Health Science Center at San Antonio, 28 Apr 87.

Mein, C.E. Antibiotic usage. Wilford Hall USAF Medical Center, Lackland AFB, TX, 13 Jul 87.

Mein, C.E. Retinal detachment. University of Texas Health Science Center at San Antonio, 30 Jul 87.

Optometry Section

Glenesk, N. Creative approach to low vision in the military. Annual Meeting of the Association of Military Surgeons of the United States, San Antonio, TX, 4 Nov 86.

Pinson, R.H. HSC consultant update. Field Optometry Course, Fitzsimons Army Medical Center, Aurora, CO, 23 Mar 87.

Pinson, R.H. Ambulatory care data base system. European Optometry Conference, Heidelberg, West Germany, 24 Apr 87.

Pinson, R.H. Army Optometry. European Optometry Conference, Heidelberg, West German, 24 Apr 87.

Orthopaedic Service

Bucknell, A.L. Cementless total hip and knee arthroplasty. Orthopaedic Hip and Knee Bioskills Course, San Antonio, TX, 4 Oct 86. (C)

Bucknell, A.L. Preliminary report on polysulfone coated titanium hip stem. Revision Total Hip Surgery Seminar, Grenelef, FL, 24-25 Oct 86. (C)

Bucknell, A.L Complicated intertrochanteric fractures of femur treated by primary cemented biopolar endoprosthesis and reconstruction of proximal femur. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Chambers, H.G. Osteonecrosis of the femoral head - diagnosis and management. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Chambers H.G. The effect of continuous passive motion on muscle: An experimental study in the rabbit. Society of Military Orthopaedic Surgeons, 17-23 Nov 86. (C)

Stratton, H.T. Avulsion of the tibial tuberosity. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Silver, S.M. Retrosternal dislocation of the clavicle. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Emery, S.F. Diagnostic ultrasound - a new technique for the evaluation of interdigital neuroma. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Christensen, K.P. Use of the Pavlik harness in a newborn proximal femur fracture. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Haak, M.H. The clenched fist syndrome. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Norwood, S.M. Calcitonin and osteoporosis - new mechanisms of pathophysiology. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Smith, J.R. Chondroblastoma of the clavicle: Report of a case in an unusual location with a review of the literature. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Milnor, W.H. The multidisciplinary hand therapy clinic in a military setting: A model for integrated patient care and for education of health care providers. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Silver, S.M. Tank turret injuries to the foot. Society of Military Orthopaedic Surgeons, 17-23 Nov 86.

Bucknell, A.L. Principles of total joint replacement arthroplasty. A.O.R.N., Methodist Hospital, San Antonio, TX, 17 Apr 87.

Peters, V. Surgery of hallux valgus. Texas Podiatry Association, Hill Country Podiatry Seminar, 23-25 Apr 87.

Peters, V. Surgery of hallux valgus. University of Texas Health Science Center at San Antonio, 16 May 87.

Chambers, H.G. The effect of continuous possive motion on skeletal muscle - A laboratory study in the rabbit. Southern Orthopaedic Association, Hamilton, Bermuda, 23 May 87. (C)

Chambers, H.G. Osteonecrosis of the femur. Southern Orthopaedic Association, Hamilton, Bermuda, 23 May 87.

Bucknell, A.L. Techniques of uncemented total knee replacement arthroplasty. University of Arizona Orthopaedic Program, Tucson, AZ, 13 Jun 87. (C)

.....Evaluation of soft tissue masses. University of Texas Health Science Center at San Antonio Grand Rounds, 11 May 87.

Bucknell, AL. Uncemented total knee replacement. San Antonio Orthopaedic Society, San Antonio, TX, 10 Aug 87. (C)

Bucknell, A.L. Uncemented acetabular reconstruction using threaded, nonporous metallic implants. Memphis TN, 28 Aug 87. (C)

Greenfield, G.Q. Bulbocavernosus reflex. Munich S.I.C.O.T., Aug 87.

Otolaryngology Service

Jarchow, R.C. Soft tissue workshop. Annual Otolaryngology Basic Science Course, Armed Forces Institut of Pathology, Washington, D.C., 20-21 Apr 87.

Moss, J., Jr., Ortiz, J. Complication of shotgun wound to the face. Annual Meeting of Military Plastic Surgeons, Denver, CO, 27 Apr 87.

Moss, J., Jr., Ortiz, J. Complication of shotgun wound to the face. Annual Meeting of the Society of Air Force Clinical Surgeons, San Antonio, TX, 30 Apr 87.

Moss, J., Jr. Temporal bone and soft tissue injury of the head and neck. Military Emergency Room Medicine Annual Conference, San Antonio, TX, 30 Apr 87.

Devine-Rust, M.J. Upper aerodigestive tact emergencies. Military Emergency Room Medicine Annual Conference, San Antonio, TX, 30 Apr 87.

Jarchow, R.C. Surgical techniques of rytidectomy. Biennial Symposium on Plastic Surgery of the Aging Face, American Academy of Facial Plastic and Reconstructive Surgery, St. Louis, MO, 27 Jun 87.

Fraker, J.T. A case report of Burkitt's lymphoma. American Academy of Otolaryngology-Head and Neck Surgery, Chicago, IL, 20-22 Sep 87.

Simpson, R.J. Parathyroid adenoma and non-medullary thyroid carcinoma syndrome - A new multiple endocrine neoplasti syndrome? American Academy of Otolaryngology-Head and Neck Surgery, Chicago, IL, 20-22 Sep 87.

Peterson, T.T. Facial paralysis resulting from cat-scratch disease. American Academy of Otolaryngology-Head and Neck Surgery, Chicago, IL, 20-22 Sep 87.

Jarchow, R.C. Moderator, Scientific Program. American Academy of Facial Plastic and Reconstructive Surgery, Chicago, IL, 16-19 Sep 87.

Jarchow, R.C. Surgical principles in facelift. American Academy of Otolaryngology-Head and Neck Surgery, Chicago, IL, 20-22 Spe 87.

Peripheral Vascular Surgery Service

Ramirez, M. El Salvador experience. Vascular Conference, Bethesda, MD, 7-9 Dec 86.

Olson, D. Blunt traumatic rupture abdominal aorta. Vascular Conference, Bethesda, MD, 7-9 Dec 86.

Olson, D.R. Acute acalculus cholecystitis in the critically ill surgical patient. Gary P. Wratten Surgical Symposium, El Paso, TX, 6-8 Apr 87.

Olson, D.R. Blunt trauma abdominal aorta. Vascular Surgical Symposium, San Antonio, TX, 21 May 87.

Plastic Surgery Service

Ortiz, J.E. Tissue expansion throughout the body. South Texas Chapter of the American College of Surgeons, Houston, TX, 30 Jan 87.

Young, R.N. Scalp reconstruction. University of Texas Health Science Center at San Antonio, 21 Feb 87.

Young R.N. Breast reconstruction. American CAncer Society, 11 Apr 87.

Ortiz, J.E. Nasal reconstruction. Annual Symposium of Military Plastic Surgery, Fitzsimons Army Medical Center, Aurora, CO, 27 Apr 87.

Ortiz, J.E. Vascular complications of gunshot injuries to the face. Air Force Clinical Society, 29 Apr 87.

Young, R.N. Nasal reconstruction. Air Force Clinical Society, 29 Apr 87.

Urology Service

Rodriguez, F. Are frozen sections really necessary in all patients undergoing radical prostatectomy? South Central Section, American Urological Association, 2 Oct 86.

Rodriguez, F. Are frozen sections really necessary in all patients undergoing radical prostatectomy? Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Rodriguez, F. Is pelvic lymph node status a predictor of capsular penetration in prostatic cancer? Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Thompson, I.M. Bioluminescence assay of ATP concentration as an objective measurement of sperm motility. South Central Section, American Urological Association, San Antonio, TX, 2 Oct 86. (C)

Thompson, I.M. Treatment of intactable hematuria secondary to carcinoma of the prostate with alum irrigation. South Central Section, American Urological Association, San Antonio, TX, 3 Oct 86.

Thompson, I.M. Intravesical alum irigation for intractable bleeding secondary to adenocarcinoma of the prostate. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Thompson, I.M. Impact of cigarette smoking on stage, grade, and number of recurrences of transitional cell carcinoma of the urinary bladder. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86. (C)

Thompson, I.M. Incidental renal cell carcinoma. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Thompson, I.M. Impact on stage distribution of screening for carcinoma of the prostate. Poster presentation, Association of Military Surgeons of the U.S., San Antonio, TX, 2-5 Nov 86.

Thompson, I.M. Treatment of renal cell carcinoma. Professional Staff Conference, Keller Army Hospital, West Point, NY, 7 Nov 86.

Thompson, I.M. Impact of cigarette smoking on stage, grade, and number of recurrences of transitional cell carcinoma of the urinary bladder. Urology Staff Conference, Walson Army Community Hospital, Fort Dix, NJ, 10 Nov 86. (C)

Thompson, I.M. Incidental renal cell carcinoma. Urology Staff Conference, Walson Army Community Hospital, Fort Dix, NJ, 10 Nov 86.

Thompson, I.M. Importance of early diagnosis for testis tumor surveillance protocols. Urology Staff Conference, Walson Army Community Hospital, Fort Dix, NJ, 10 Nov 86.

Thompson, I.M. Treatment of intractable hematuria secondary to carcinoma of the prostate with alum irrigation. Urology Staff Conference, Walson Army Community Hospital, Fort Dix, NJ, 10 Nov 86.

Thompson, I.M. Salvage radical prostatectomy. Urology Staff Conference, Walson Army Community Hospital, Fort Dix, NJ, 10 Nov 86.

Thompson, I.M. Screening for genitourinary malignancies. Professional Staff Conference and Commander's Grand Rounds, Walso Army Community Hospital, Fort Dix, NJ, 10 Nov 86. (C)

Thompson, I.M. The early diagnosis of genitourinary malignancies. Urology Grand Rounds, University of Michigan Medical Center, Ann Arbor, MI, 15 Nov 86.

Brizzolara, J.P. Salvage radical prostatectomy for adenocarcinoma of the prostate. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86. (C)

Brizzolara, J.P. Perineal recurrence of adenocarcinoma of the prostate following radiation therapy. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Corrie, D. Utility of follow-up bone scans in carcinoma of the prostate. South Central Section, American Urological Seminar, San Antonio, TX, 3 Oct 86.

Corrie, D. Periurethral teflon injection for post-prostatectomy incontinence. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Corrie D. False positive testicular ultrasound. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Legate, A.H. Correlation of class and severity of pelvic fracture with urologic injury. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Hansberry, K.L. Improved survival in testis tumors associated with early detection. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Hansberry, K.L. Outpatient therapy of resistant urinary tract infection with Amikacin. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Boykin, W.H., Jr. Sarcoidosis with diffuse involvement of the intrascrotal contents: Case report. Kimbrough Urological Seminar, San Antonio, TX, 12-16 Oct 86.

Legate, A.H. Amikacin-based outpatient therapy of resistant urinary tract infections. 1987 Southern Section of American Federation for Clinical Research/Society for Clinical Investigation, New Orleans, LA, 28-31 Jan 87.

Legate, A.H. The impact of incidentally noted renal cell carcinoma. 1987 Southern Section of American Federation for Clinical Research/Society for Clinical Investigation, New Orleans, LA, 28-31 Jan 87.

Legate, A.H. Salvage radical prostatectomy for recurrent adenocarcinoma of the prostate. 1987 Southern Section of American Federation for Clinical Research/ Society for Clinical Investigation, New Orleans, LA, 28-31 Jan 87.

Thompson, I.M. Adjuvant therapy for surgical stage C carcinoma of the prostate. Southwest Oncology Group, San Antonio, TX, 4 Mar 87.

Zeidman, E.S. Principals of urodynamics. Urology Conference, Wilford Hall USAF Medical Center, Lackland AFB, TX, 16 Jul 87.

DEPARTMENT OF MINISTRY AND PASTORAL CARE

Anderson, L.J. The human-animal bond in the Department of Defense. Technology Assessment seminar, National Institute of Health on the Health Benefits of Pets, 10 Sep 87. (C)

NUTRITIONAL CARE DIVISION

Phelan, J.A., Turcotte, J.M., Miller, C. Clinical dietetics, education and training, and quality assurance. Daisy Francisco, Nutrition Consultant, Wichita Falls, TX, Nov 86.

Hemingway, M.M. Nutrition. A vital part of atheltic performance. FSH Master Fitness Trainers, Fort Sam Houston, TX, 13 Nov 86.

Walton, ... Nutrition: Infancy - childhood. FSH Youth Center, Fort Sam Houston, TX, 3 Dec 86.

Hemingway, M.M. Dental nutrition. FSH Elementary School, Fort Sam Houston, TX, 5 Feb 87.

Hemingway, M.M. Basic nutrition. U.S. Navy Reserve Center, San Antonio, TX, 12 Feb 87.

Guinn, E. Basic nutrients and a guide to good eating. Thousan Oaks Elementary School, San Antonio, TX, 13 Feb 87.

Garrigan, ..., Ragsdale, ... Sugar in your food. FSH Elementary School, Fort Sam Houston, TX, 2, 4, and 5 Mar 87.

Garrigan, ... Question and Answer Session on "Good nutrition - your personal choice." PX patrons, Main Exchange, Fort Sam Houston, TX, 9 Mar 87.

Ragsdale, ... Question and Answer Session on "Good nutrition - your personal choice." PX patrons, Main Exchange, Fort Sam Houston, TX, 11 Mar 97.

Yu, ... Question and Answer Session on "Good nutrition - your personal choice." PX patrons, Main Exchange, Fort Sam Houston, TX, 12 Mar 87.

Rodriguez and Manship. Question and Answer Session. National Nutrition Month Display, HEB Supermarket, San Antonio, TX, 14 Mar 87.

Garrigan, ...The high fiber connection. School Lunch Program, FSH Schools, San Antonio, TX, 21 Apr 87.

Hemingway, M.M. Master fitness. FSH Master Fitness Trainers, Fort Sam Houston, TX, 11 Jun 87.

Hemingway, M.M. Nutrition in the later years. MacArthur Church of Christ, San Antonio, TX, 7 May 87.

Brandenburg, J.W. Health booth with question and answer session. Randolph AFB Air Show, 17 May 87.

Hemingway, M.M. Height and weight measurements in 10 year olds. Fort Sam Houston Elementary School, 14 and 16 Jul 87.

Hemingway, M.M. Weight control principles. Federally Employed Women's Chapter, Fort Sam Houston, TX, 15 Sep 87.

ACADEMY OF HEALTH SCIENCES

Underwood, F.B. Electroanalgesia as it relates to electrically induced quadriceps femoris muscle contraction. Texas Physical Therapy Association Annual Conference, Austin, TX, 5 May 87. (C)

REYNOLDS ARMY COMMUNITY HOSPITAL

Calder, R.A. Tine Test versus Mono-vacc screening for tuberculosis. Preventive Medicine Symposium, Walter Reed Army Institute of Research, Washington, D.C., 20 May 87. (C)

DETAIL SUMMARY SHEETS

Detail Summary Sheet

Date: 6 Nov 87	Proj No: C-4-81	Status: Completed

Title: Chemiluminescence (CL) in Populations of Immunocompetent Cells.

Start Date 4 Feb 81	Est Comp Date:
Principal Investigator David G. Burleson, Ph.D., LTC, MS	Facility Institute of Surgical Research
Dept/Svc Biochemistry Section	Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC Karen M. Wolcott, DAC Janice M. Grassel
Key Words: Chemiluminescence Immunocompetent cells	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____
Total Number of Subjects Enrolled to Date:_____
Date of Periodic Review n/a Results_____

Objective(s): 1) To quantitate the oxidative metabolic response of stimulated populations of immunocompetent cells isolated from mouse or guinea pig spleen, thymus, liver, and lymph nodes using chemiluminigenic probes.

2) To quantitate and characterize the chemiluminescent response from various populations of immunocompetent cells in the presence of cyanide, superoxide dismutase, and catalase.

3) To characterize the lymphoid cell subpopulations in animal models of inflammation, infection and trauma.

Technical Approach: Several methods are employed to analyze immunocompetent cells from animal models of inflammation, infection and trauma. Sterile inflammation is induced by IP injection of sodium casienate. Trauma is induced by application of a 30% scald burn with or without infection induced by seeding with *P. aeruginosa*. Phagocyte respiratory burst activity is analyzed by chemiluminescence and flow cytometry using oxidation sensitive molecular probes. Lymphoid cells from various tissues are analyzed for ability to be stimulated by mitogen stimulation and flow cytometry analysis. Cell populations are characterized by morphological analysis by light microscopy after Wright's stain and surface marker analysis by flow cytometry after staining with chromophore labeled monoclonal antibodies.

Progress: A technique for measuring oxidative activity of phagocytes by flow cytometry was developed. Polymorphonuclear leukocytes (PMNL) were analyzed for oxygenation activity by chemiluminescence using luminol and lucigenin as molecular probes. PMNLs were also analyzed by flow cytometry using dichlorofluoroscein diacetate (DCF) as a molecular probe. The kinetics of the oxidative responses to these probes, the relative magnitude of the response to different stimuli and the ability of azie or superoxide dismutase (SOD) to inhibit or

stimulate the response were compared for all three molecular probes. The results show that the oxidative response of PMNLs after stimulation with phorbol myristate acetate (PMA) or opsonified zymosan (OZ) is a complex process. PMA stimulates a greater total oxidative response than OZ in all three molecular probes. The response reaches maximum more quickly with DCF as a probe than luminol or lucigenin. Luminol and DBA reach maximum response at much lower concentrations of PMA than with DCF. Luminol oxygenation by OZ stimulated PMNLs is much more reduced in the presence of azide than is DCF oxidation while lucigenin is increased after the addition of azide. Lucigenin and luminol oxygenation by PMA stimulated PMNL is decreased in the presence of azide but DCF oxidation is increased. SOD does not affect DCF oxidation by PMA stimulated PMNL but decreases the lucigenin oxidation drastically and luminol oxidation only slightly.

These three molecular probes measure a different aspect of the stimulation process. A new protocol will be prepared in which this technique will be used to quantify phagocyte function.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-45-83	Status: Completed

Title: Development of a Chemiluminescent Enzyme Linked Immunoassay (CELIA) System for Detection of Antigens of Medical Importance in Serum and Tissue Fluids.

Start Date 17 May 83	Est Comp Date:
Principal Investigator Gerald A. Merrill, DAC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators Ricky D. Bretthauer, SSG Jeninne Hicks, SGT
Key Words: Antibody system	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 20,234.18

Number of Subjects Enrolled During Reporting Period:_____
Total Number of Subjects Enrolled to Date:_____
Date of Periodic Review n/a Results_____

Objective(s): To develop an enzyme-linked antibody system for antigen-specific detection of fungi, bacteria, viral agents, hormones, and immune complexes.

Technical Approach: This study was designed to be conducted in three phases: 1) isolation of haloperoxidases, 2) kinetic analysis of enzymes, and 3) assay development. Haloperoxidase isolation from granulocytes by several techniques was to be examined. The study of the microbicidal function of animal granulocytes in relation to the haloperoxidase activity of these cells is a secondary objective of this study. Isolated enzymes will be used for analysis of substate dependence to determine optimal enzyme conditions for both halogenation activity and chemiluminescent activity. Investigaiton of inhibitors of the haloperoxidases will permit selection of suitable methods of collection of biological samples which may ultimately be assayed by this immunoassay system. Once optimal conditions have been determined, the enzymes can be covalently bound to antibodies of choice, and correlations between chemiluminescence and antigen concentration can be determined.

Progress: Myeloperoxidase (MPO) has been linked to goat antirabbit antibody by use of a hetero bifunctional cross linking agent. Attempts to isolate cross linked MPO-antibody complex free of either free antibody or free MPO has not been satisfactorily accomplished. Use of protein A and antigoat immunoaffinity columns for this purpose has successfully adsorbed the MPO-antibody complex with elution of free enzyme with good activity. However, subsequent elution of the complex by use of glycine HCl at pH2 has resulted in elution of immunoglobulin which shows evidence of MPO being bound (characteristic absorbtion of 428 nm light by MPO), although little enzyme activity is recovered. Although both

antibody and MPO alone are not irreversibly denatured by this elution technique, it appears that this pH change results in inactivation of bound MPO. Use of size exclusion HPLC did not provide sufficient resolution to separate antibody-MPO complex from free MPO. Use of sephadex chromatography resulted in unacceptable yields. Alternate methods of cross linking antibody to MPO using biotin labelled disulfide heterobifunctional reagents and Avidin affinity columns to adsorb noncomplexed MPO and antibody are planned.

A model CELIA has been developed using horseradish peroxidase (HRPO) labelled antibody to mouse immunoglobulins. Mouse immunoglobulins to immobilized antigens are readily detected via this assay. The assay involves several modifications of standard HRPO ELISA techniques which improve sensitivity. These modifications include use of luminol as the chemiluminogenic substrate, and use of urea peroxide as a replacement of hydrogen peroxide. When urea peroxide is used at 1mM concentrations at pH 6.8, the HRPO catalyzed chemiluminescence rapidly reaches a plateau which remains elevated far in excess of 10 minutes. Integrals of these responses are proportional to quantities of bound mouse immunoglobulins. Use of slightly acidic conditions lowers total chemiluminescent responses significantly, but greatly reduces nonspecific chemiluminescence resulting in a highly reproducible assay with signal to noise ratios (sensitivity) equal to or slightly greater than an ELISA performed using orthophenylene diamin as substrate. This assay is useful for screening mouse monoclonal antibody production from hybridoma cells. Additional modifications to allow for quantitation of antigen antibody binding affinities using an indirect CELIA under conditions where neither antigen or primary antibody are modified are currently being evaluated.

The goals of this protocol have been achieved. Future development of specific CELIA immunoassays will be submitted as separate protocols.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-73-83	Status: Completed

Title: The Effect of Lysine on Herpex Simplex Virus (HSV) Infection.

Start Date 30 Sep 83	Est Comp Date:
Principal Investigator Eleanor Ayala, MT, DAC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words: Herpes simplex virus L-lysine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 9,645.66

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): To evaluate the in vitro effect of L-lysine on HSV infected cells and the in vivo effect of topical applications of L-lysine in treatment of HSV skin infections in laboratory animals.

Technical Approach: In vivo studies were performed on male, white Dunken-Hartley guinea pigs (g.p.) inoculated with 20 l of HSV-1 (KOS) (titer 5 x 10^6 + TCI D_{50}/ml) at each of 8-10 sites/animal. Topical applications of pulvarized crystalline lysine or leucine (amino acid control) (40 mg/site) or Zovirax ointment 5% (acyclovir), 1 cm strip/25 mg Acyclovir and covered with Tegaderm transparent dressing for 3 or 6 days. Applications were made 30-60 minutes post inoculation (p.i.) when sites were dry. In some studies mouse interferon (alpha and beta globulin), which has been reported to display activity in guinea pig cell lines, was also used with a polyclonal antisera neutralizing mouse interferon as a control. Treated or untreated animals were sacrificed 3 or 6 days post inoculation, appearance of skin noted, skin biopsies of inoculated areas collected for extract cultures on primry rabbit kidney cells (PRK), secitons taken for electron microscopy (EM) studies and for tissue examination by fluorescent antibody (FA) technique. Individual dorsal root ganglia (DRG) (C1-S3) were collected from treated and control animals 3 or 6 days post inoculation and co-cultivated on PRK cells. All cultures were passaged at least twice. All isolates from DRGs or epidermis were identified by immunofluorescence testing.

Progress: L-lysine enhanced healing of HSV-1 inoculated skin. L-leucine and untreated controls manifested clinical symptoms up to 3 days p.i. No infective HSV-1 was recovered from DRGs of untreated controls, but infective HSB-1 was recovered from DRGs T10 (leucine Rx) and from T12,T13, and L1 at 3 days p.i. in the lysine treated group. Acyclovir also enhanced healing of HSV-1 inoculated

skin in 24-48 hours. HSV-1 was recovered from biopsy cultures of the Acyclovir treated sites only after first passage when Acyclovir lost activity. 18/20 tissue biopsy cultures were positive. The DRGs collected from Acyclovir treated guinea pigs were negative in one case when the DRGs were cultured 3 months, frozen at -20°C for 2 months, and cultured again for 1 month. In another case, the DRGs were maintained in culture up to 1 year by transferring the DRGs to fresh RKC's about every 3-4 weeks. The DRGs were never stored at -20°C during that time. After 10 months in culture DRGs: C7(1),T3(1), T6(1), T8(1), T12(2) and T13(2) were positive for HSV-1. The next month DRGs: C7(2), T3(1), T5(1), T6(1), T7(1), T8(1), T9(1), T12(2), T13(2), L3(1), and L4(1) were positive. Prior to this DRGs had not been maintained in culture for longer than 6 months. Pilot studies did not indicate that mouse interferon applied to a few HSB-1 inoculated sites had any effect on guinea pig skin. Skin biopsies collected on days 3 or 6 p.i. never revealed HSV-1 by EM. No HSV would be seen if latency was already established. The present findings suggest areas for further study:

1. To investigate how amino acids such as lysine and leucine may affect the immunological and biochemical basis of HSV-1 neurovirulence.

2. How variations in aminoacid utilization may influence susceptibility to HSV infections.

3. How lysine may be affecting the activity of some biochemicals associated with neurogenic inflammation.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-11-85	Status: Terminated

Title: Assessment of Immunocompetence in Patients with Lymphomas and Solid Tumors Prior to and During Therapy.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator (vice Lance) David G. Burleson, LTC, MS	Facility Institute of Surgical Research
Dept/Svc Biochemistry	Associate Investigator : Janice Grassel, GS-11
Key Words: Immunocompetence	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 12 Mar 87 Results Continue

Objective(s): To evaluate immunocompetence in tumor patients receiving chemotherapy or radiation therapy before and after therapy is begun by (1) assess severl accepted in vitro measures of immunocompetence and (b) identify and quantitate the various mononuclear cell subpopulations present in peripheral blood.

Technical Approach: Peripheral blood cells from patients will be analyzed by several immunological function tests and surface analysis by flow cytometry after staining with monoclonal antibodies. Functional tests include mitogen stimulation, mixed lymphocyte culture, antibody production by pokeweed mitogen stimulated cells and induction of surface stimulation antigens by lectins. Surface marker analysis will include all currently accepted clinically significant markers.

Progress: This study was terminated due to inability to obtain the assistance of Oncology in accruing patients.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-46-85	Status: Ongoing

Title: Isolation and Characterization of the Chlorinating Moiety of *Aspergillus sp.* and *Penicillium sp.*

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Jeninne Hicks, SGT Paul M. Horowitz, Ph.D. Ricky D. Bretthauer, SSG
Key Words: *Aspergillus sp.* *Penicillium sp.*	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review n/a Results _____

Objective(s): 1) To isolate a haloperoxidase from a readily available source which has characteristics that would enable it to be utilized in a chemiluminescent immunoassay system currently being developed under protocol C-45-83.

2) To gain understanding of the mechanism of action of haloperoxidase, so insight into the physiological roles of this class of enzymes (i.e., the microbicidal action) in various cell types (granulocytes, plants, fungi, etc.) can be gained.

Technical Approach: Selected fungi (*Aspergillus sp.* and *Penicillium sp.*) would be cultured in Czapek Dox media and homogenized. Following centrifugation, both supernatant and pellet would be assayed for haloperoxidase activity at various chloride/HOOH ratios at a series of pH's using a standard assay for halogenating activity employing monochlorodimedon. If a significant halogenating activity is detected furthur purification of the responsible enzyme would be initiated. The methods employed for purification would depend on gross charcteristics of the enzyme such as pI, carbohydrate content, molecular weight, etc. The purified enzyme would then be tested for optimum conditions for HOOH dependent halogenation and for its ability to catalyze the chemiluminogenic dioxygenation of cyclic hydrazides (luminol derivatives) at various pH's and halide/HOOH ratios in an attempt to achieve a practical enzyme for use in development of a chemiluminogenic enzyme linked immunoassay system. Proposal of an enzyme mechanism of action would involve use of methods designed to show conformational changes in substrates and enzyme during catalysis, to include fluorescent techniques.

Progress: Very little time has been devoted to this project during FY 87. Initial cultures of *Aspergillus terreus* and *A. fumigatus* were contaminated with bacteria before sufficient quantities of fungi were obtained for evaluation of haloperoxidase activity. Chloroperoxidase (CPO), a haloperoxidase of *Caldariomyces sp.*, was examined for conformational changes which result as

substrates are bound by this enzyme. A fluorescent technique was employed to evaluate changes in the hydrophobic sites exposed. The dual substrate haloperoxidase operates via a ping pong (double displacement) mechanism and thus can be evaluated as free enzyme and with either of its substrates bound. Bis anilonapthalene sulfonate (Bis ANS), an agent which becomes fluorescent only when immobilized to hydrophobic sites, was added to free enzyme to determine the number of hydrophobic sites available on the surface of CPO. No significant fluorescence was observed indicating there are no significant hydrophobic areas exposed on this highly glycosylated haloperoxidase when no substrates are bound. Addition of either halide or peroxide did not increase the binding of Bis ANS to CPO suggesting that binding of either substrate does not produce conformational changes which result in increased hydrophobic exposure of the enzyme. As the enzyme acts primarily as a haloperoxidase at pH 2.75 but as a peroxidase at more neutral pHs, the exposure of hydrophobic sites as a function of pH was evaluated using Bis ANS. No increased fluorescence due to bound Bis ANS was observed at pH 2 through pH 7.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-16-87	Status: Ongoing

Title: A Study on the Specificity of Phospholipase Associated with the Cell Wall of *Candida albicans*

Start Date 29 Jan 87	Est Comp Date:
Principal Investigator David L. Danley, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Johnny W. Hinds, SSG
Key Words: *Candida albicans*	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To determine the susceptibilities of various phospholipid substrates to degradation by phospholipoase(s) associated with the cell wall of *C. albicans*.

2) To isolate and purify a soluble form of the active enzyme(s) which can be tested for cytotoxicity against human monocytes.

Technical Approach: To determine the susceptibility of various phospholipids to degradation to fungal cell phospholipases, we incubated radiolabeled phospholipids with viable yeast cells, extracted total lipids with chloroform:methanol, and separated components by thin layer chromatography.

Progress: We have tested six different phospholipids radiolabeled with either arachidonic acid or palmitic acid at the C2 position and with different moities: choline, inositol, or ethanolamine, attached to the phosphate at C3. The only phospholipid degraded by viable yeast cells within one hour was lysophosphotidylcholine (LPC). This capability of *C. albicans* to degrade LPC, which reflects phospholipase B activity, has been reported by others and is a characteristic shared with other fungi including *Saccharomyces cerevisiae* and *Penicillium notatum*.

C-16-87 (continued)

We have measured phospholipase B activity in culture supernatants of C. albicans yeast cells grown overnight at 37°C. The enzyme has been purified by precipitation with ammonium sulfate and chromatography over DEAE Sephadex. We are currently developing an affinity chromatography support for a final purification step.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-30-87	Status: Ongoing

Title: An Investigation on the Significance of Monocyte Lysis by Candida Albicans Yeast Cells

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator David L. Danley, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words: Candida albicans	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $457.00

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review_____ Results_____

Objective(s): We have recently determined that human monocytes are uniquely susceptible to lysis by yeast cells of Candida albicans in vitro. The objective of this proposal is to dtermine whether or not this finding has any applicability to our understanding of host immunity to this opportunistic fungus and to determine if this finding can be integrated into an assay that will help clinicians define the patient at risk from infection by Candida albicans.

Technical Approach: Peripheral blood was drawn from volunteers, and the mononuclear leukocyte fraction was isolated by density gradient centrifugation. Afterwards, these cells were labeled with 51-chromium and incubated with yeast cells of C. albicans or soluble extracts from this fungus. Monocyte killing was measured by determining the amount of radioisotope released into the culture supernatant after one hour.

Progress: In previous studies we determined that monocyte killing by C. albicans could be inhibited with chemicals that block phospholipase activity. At the present time, we are purifying the most predominant phospholipase, phospholipase B, from yeast cells, and we are evaluating the purified material for cytotoxic activity against monocytes. We have determined that the culture supernatant from yeast cells grown overnight at 37°C contains a soluble cytotoxic factor. This factor copurifies with phospholipase B; i.e., both are present following purification by ammonium sulfate fractionation and chromatography on DEAE Sephadex. Further purification processes are being examined to determine if the cytotoxic factor is phospholipase B or another enzyme.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-15-86	Status: Ongoing

Title: Penicillin and Erythromycin Levels after Oral Administration in the Preoperative Oral and Maxillofacial Surgery Patients.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator Michael E. Lessin, COL, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators: Hugh M. Gelston, Jr., MAJ, MS Sheila Jones, SSG
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 29

Total Number of Subjects Enrolled to Date: 29

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To establish whether adequate serum levels of penicillin or erythromycin are obtained after oral administration following current American Heart Association guidelines for the prevention of SBE in the patient undergoing elective or emergency removal of impacted teeth or infected teeth with associated periapical abscess, pericoronitis and/or associated space abscesses.

Technical Approach: Subjects in the study will not ordinarily need penicillin or erythromycin prophylaxis for the prevention of SBE. Dosages will be administered orally in the Oral Surgery Clinic according to the schema outlined in the study protocol.

Progress: Two more patients are needed to complete the study. Data will be analyzed at that time.

Detail Summary Sheet

Date: 15 September 1987	Proj No: C-74-87	Status: Ongoing

Title: Short Term High Dose Steroids in Orthognathic Surgery

Start Date 12 Aug 87	Est Comp Date:
Principal Investigator (vice Bussell) John McLaughlin, LTC, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators:
Key Words: Steroids Surgery, Orthognathic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review n/a Results

Objective(s): To determine the effects of high dose steroids on serum cortisol levels in oral surgery patients.

Technical Approach: Fifteen patients undergoing orthognathic and preprosthetic surgery will receive 20 mg of Decadron at the beginning of surgery and then 20 mg every two hours while they are in surgery. Postoperatively they will receive 8 mg of Decadron every six hours for 24 hours and then two intramuscular injections of 80 mg of Depo-Medrol on the morning after surgery and the following morning. Serum cortisol levels will be checked at the time of admission, immediately postoperatively on the day of surgery, postoperative day three which would correspond to maximum suppression, postoperative day frou which is after the delayed release steroid, then on a weekly basis until serum cortisol level returns to baseline.

Progress: This is a new study. It is too early to report any meaningful data.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-17-86	Status: Completed

Title: A Simple Approach to Scalp Laceration Repair.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator James A. Morgan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: John M. Howell, CPT, USAF MC
Key Words: Laceration, scalp	
Accumulative MEDCASE Number	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 68

Total Number of Subjects Enrolled to Date: 68

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To compare the complication rates of simple scalp lacerations when utilizing two methods of wound preparation.

Technical Approach: Patients agreeing to participate were assigned to one of two groups. One group will have the scalp hair removed about ½ inch on either side of the laceration prior to repair. The second group will undergo repair without hair removal. All patients will return for evaluation in five days unless complications arise.

Progress: Sixty-eight scalp lacerations were repaired without hair removal and examined prospectively for infection. No infections were noted at 5 day follow-up. The mean patient age was 21.8 years and the mean laceration length was 2.5 cm. The mean time from injury to repair of laceration was 2.2 hours. Sixty three lacerations were repaired within 3 hours of injury.

A prospective, randomized study to look at the effect of scalp hair removal on infection rate will be submitted.

Detail Summary Sheet

Date: 17 Sep 87	Proj No: C-51-86	Status: Ongoing

Title: Puncture Wounds of the Foot: A Randomized Prospective Study of Superficial Cleansing vs Epidermal Debridement in the Treatment of Superficial Puncture Wounds.

Start Date 9 Jun 86	Est Comp Date:
Principal Investigator (vice Sugg) John F. Schlesser, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Daniel J. Boyle, MAJ, MC Vern Peters, D.P.M.
Key Words: Wounds, puncture	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 9

Total Number of Subjects Enrolled to Date: 9

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To evaluate two methods of wound care for superficial puncture wounds of the foot and to determine if there is a difference between superficial cleansing and epidermal debridement in the treatment of these plantar injuries in a prospective, randomized study.

Technical Approach: Patients eligible for this study will be assigned to one of two treatment groups. Both groups will have an x-ray to insure no boney involvement and will receive tetanus prophylaxis if indicated. The first group will receive local anesthesia and have the wound cleansed. The second group will also receive anesthesia and debridement of the skin around the puncture wound. They will be re-evaluated in three days and again at the end of two weeks to see how well the wound is healing and to determine if there is any infection.

Progress: Patient accrual has been slow. No reportable data are available at this time.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-66-86	Status: Ongoing

Title: The Antimicrobial Spectrum of Fresh Water Contaminated Wounds and the Incidence of Wound Infections Associated with These Injuries

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator Eunice M. Singletary, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Carey Chisholm, MAJ, MC
Key Words: Wound, contaminated Wound, infection	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 30

Total Number of Subjects Enrolled to Date: 48

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To identify common fresh waterborn human pathogens involved in wounds acquired in or around fresh water bodies within the state of Texas.

2) To determine the incidence of wound infectins in wounds contaminated by fresh water.

3) To make recommendations for initial choice of antibiotics for wound infections caused by fresh water bacteria.

Technical Approach: Patients presenting for care to the BAMC Emergency Department with an acutely acquired (less than 24 hours) or infected wound that had been contaminated by fresh water will be studied. All wounds will be swabbed and culture swab sent for culture and antibiotic sensitivities.

Progress: This study has been expanded to include the Naval Hospital in San Diego and DDEAMC in Georgia. Ongoing enrollment is necessary in order to obtain statistically significant samples.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-67-86	Status: Ongoing

Title: The Choice of Antibiotics for Marine Acquired Wound Infections

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator Eunice M. Singletary, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Carey D. Chisholm, MAJ, MC
Key Words: Infection, marine acquired	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 12

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To identify the organisms responsible for infections of salt water contaminated wounds from the Texas/Gulf Coast region.

2) To determine antibiotic sensitivities for the pathogens involved in salt water exposed wound infections.

3) To make recommendations for the initial choice of antimicrobials to be utilized in treating salt water contaminated wounds pending culture results.

Technical Approach: All patients with an acutely acquired or infected wound with a history of salt water contamination will be initially eligible to participate in the study. All wounds will be swabbed for culture and sent for culture and sensitivity. If clinically indicated, debridement and/or suturing will e performed. Tetanus prophylaxis will be administered if indicated.

Progress: The project has been expanded to include the Naval Hospital in San Diego and DDEAMC in Georgia. Plans for inclusion of TAMC and MAMC are being made.

A paper was recnetly published in AEM documenting culture results from the mouths of several biting marine animals - the organisms obtained were pathogens which would not normally be covered by antibiotics given for soft tissue infections.

Detail Summary Sheet

Date: 15 Dec 86	Proj No: C-5-87	Status: Completed

Title: Third Shift in the Emergency Room An Ethnography of Stress

Start Date 19 Nov 86	Est Comp Date:
Principal Investigator Jeffery A. Huebner	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Emergency Room	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To write an ethnography with the third shift Emergency Room staff as the study group. Tehnography is a principal method of description used by anthropologists in the study of cultural groups. For this study, the ethnological problem to be undertaken is the effect of third shift on workers in the emergency room.

Technical Approach: The subject study group was all emergency room personnel on the third shift at BAMC. The principal investigator served as Red Cross volunteer which allowed him to make observations and to interview the personnel.

Progress: Most emergency room staff members agreed that third shift was different from the other shifts, and a number of features were identified. Once the differences were identified, they were broken down into two categories. There are those that promote stress such as reversed schedule, lack of sleep, adjustment of social and dietary habits, and age of worker. Among the things mentioned as relieving stress were decreased number of administrative personnel, night shift is more informal, and the closing of one side of the emergency room during slow periods.

Conclusion: Further studies are needed to explore more deeply the cultural patterns and environment of emergency room work.

Detail Summary Sheet

Date: 17 Sep 87	Proj No: C-6-87	Status: Completed

Title: Prevalence of Elevated Carboxyhemoglobin Levels in Patients Presenting to the Emergency Room for the Evaluation of Headache

Start Date 11 Dec 86	Est Comp Date:
Principal Investigator Carey D. Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Carboxyhemoglobin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To determine the prevalence of elevated carboxyhemoglobin levels in patients presenting to the Emergency Room with the chief complaint of headache.

2) To determine the accuracy of clinical suspicion in identifying patients with elevated carboxyhemoglobin levels.

Technical Approach: All adult patients (>18 years old) presenting to the emergency room with the chief complaint of headache were eligible for inclusion in the study. Of the 345 patients presenting during the study period, 194 consented to participate. The examining physician was asked to complete a questionnaire during the history and physicial. Historical questions included time of onset of the current headache, prior history of headaches, smoking history (time of last cigarette), heating source, vehicular travel, place of employment and associated symtpoms. The patient's duration of symptoms was calculated in 6 hour increments up to 96 hours. The physician was then instructed to predict the COHb level, prior to its being drawn, as being <5%, between 5 and 10%, or >10%. All COHb determinations were on venous samples drawn into heparinized syringes and spectrophotometrically analyzed within 10 minutes.

Progress: Of the 194 patients consenting to participate, 3 were excluded due to incomplete data collection on the questionnaire. The average age of the entire study population was 38.3 years; the average for nonsmokers was 39.6 and for smokers 35.9. Smokers had a mean COHb level of 5.9% while the mean for nonsmokers was 1.8%. This was a statistically significant difference ($p < 0.01$, nonpaired T test). Physicians were inaccurate in their predicted COHb levels in 32 patients (17%) of which 30 were smokers and 2 were nonsmokers. Seventeen (9%) patients had their COHb levels underestimated while overestimations occurred in

C6-87 (continued)

fifteen (8%). Five patients (4 smokers, 1 nonsmoker) were identified with significantly elevated COHb levels (>10%). All of these patients had a past history of headache. None of the elevations were predicted by the examining physician. The duration of symptoms prior to seeking health care in the group with COHb levels >10% was 33.6 hours, compared to 44.7 hours in the group with COHb levels <10%. None of these differences were statistically significant ($p>0.1$ for all values).

Conclusion: Our results indicate that in this temperate geographic area there is a low incidence of significantly elevated COHb levels in patients presenting with the chief complaint of headache. Physicians are unable to prospectively to prospectively identify these patients based upon history or physical examination. Further studies in less temperate climates are needed to establish the potential benefit of routine carboxyhemoglobin screening in such a patient population. Smokers have significantly higher COHb levels than nonsmokers and may be at greater risk for subacute or occult carbon monoxide poisoning than nonsmokers.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-17-87	Status: Ongoing

Title: Comparison of Diphenhydramine, Promethazine, and Placebo in Patients with Abdominal Pain

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator Douglas B. Ferguson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Robert N. Norris, CPT, MC
Key Words: Pain, abdominal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 30

Total Number of Subjects Enrolled to Date: 30

Date of Periodic Review n/a Results

Objective(s): 1) To evaluate the relief of abdominal pain using Diphenhydramine and Promethazine.

2) To compare the efficacy of Diphenhydramine versus Promethazine in the treatment of abdominal pain.

Technical Approach: This is a prospective randomized, double blind study of patients between the ages of 18 and 60 years who are diagnosed as having gastroenteritis. Following evaluation, the patient will be asked to rate the severity of abdominal pain using the numerical scale 1 through 5. Patients will be randomized by the coding sequence - A, B, C. Diphenhydramine, Promethazine, and normal saline will be placed in letter coded vials whose contents will be unknown to the evaluators. The evaluator will obtain 1 cc from the corresponding vial which correlates Diphenhydramine, 50 mg; Promethazine, 25 mg: or normal saline. The fluid will be administered intravenously over two minutes. The patient will be asked to evaluate the severity of the abdominal pain at 15 minutes and 30 minutes using the same numerical scale.

Progress: Approximately 30 subjects have been enrolled. Initially we had a problem getting and keeping up to date vials at the pharmacy, but this has been resolved. No adverse affects noted to date.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-38-87	Status: Terminated

Title: Actual and Perceived Significance of Awakening from Sleep with Pain

Start Date 19 Mar 87	Est Comp Date:
Principal Investigator D. Yvonne Guiffre	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the percentage of patients undergoing hospitalization, and the duration of the hospitalization, for the study group (patients awakened from sleep with chest or abdominal pain) and its statistical significance compared to sex-age matched controls.

Technical Approach: None.

Progress: Three days after approval of this protocol, the principal investigator opted to terminate the study.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-63-87	Status: Ongoing

Title: Role of Routine Radiographs in the Evaluation of Acute Knee Complaints in the Emergency Department

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator CPT Robert L. Norris, Jr.	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Peter Curka, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 124

Total Number of Subjects Enrolled to Date: 124

Date of Periodic Review n/a Results

Objective(s): To develop a set of high-yield criteria based on a careful history and physical examination in patients with acute knee complaints that will guide Emergency Department physicians in the ordering of knee radiographs.

Technical Approach: All patients 15 years of age and older presenting to the Emergency Department with a chief complaint of acute knee pain or dysfunciton will be included in the study. A thorough history and orthopedic examination as outlined in the study form will be performed. The examining physician will then document whether or not he/she expects to find an abnormality on radiographic examination and what he/she expects that abnormality to be. Then in a retrospective manner, each case will be reviewed, comparing the examining physician's expectationsand findings to the findings from the official radiologic report to determine whether the x-rays made any difference in the patient's diagnosis or management.

Progress: This study has progressed quite well. All of the data received is being placed in a spreadsheet computer program for analysis.

No patient complications have been reported.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-73-87	Status: Ongoing

Title: The availability of Antivenin (Crotilidae) Polyvalent and Antivenin (Micrurus fulvius) in Texas Hospitals Providing Emergency Medical Care

Start Date 12 Aug 87	Est Comp Date:
Principal Investigator William W. Collier, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Robert L. Norris, CPT, MC
Key Words: Antivenin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To attempt to determine the actual supply and availability of antivenins against the venomous snakes indigenous to texas in hospitals providing emergency medical care in the State.

Technical Approach: A questionnaire will be sent to all pharmacy directors of hospitals in the State of Texas. The pharmacy director will be asked to quantitate his/her faciliti's antivenin supply curently in stock. Simultaneously, a questionnaire will be mailed to all directors of Emergency Departments/Emergency Rooms of hospitals in the State. They will be asked several pertinent questions regarding their facility's approach to the management of snakebite victims.

Progress: Questionnaires have been mailed, and responses are being tabulated. However, it is too early to report any meaningful results.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-78-87	Status: Ongoing

Title: Maximal Inspiratory Pressure and Serum CPK in the Evaluation of Obstructive Airway Disease.

Start Date 13 Aug 87	Est Comp Date:
Principal Investigator Patrick Jordan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Mark Larsen, COL, MC
Key Words: Obstructive airway disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review_____ Results_____

Objective(s): To discover if the measurement of maximal inspiratory pressure (MIP) and serum CPK serve as prognostic factors in the evaluation of patients with obstructive airway disease (asthma and COPD).

Technical Approach: Subjects presenting to the Emergency Department with an acute exacerbation of their asthma or COPD will be included in the study. A MIP gauge reading will be performed on each patient before and after treatment. A Wright's spirometer will be utilized to obtain expiratory flow before and after treatment. Pulsus paradoxus will be recorded time of initial evaluation and post treatment.

Progress: Seven patients have been entered without report of complications. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-89-87	Status: Ongoing

Title: Prognostic Predictive Value of the Clinical/Hemodynamic Classification Schema of Left Ventricular Performance in Acute Myocardial Infarction Determined at the Time of Presentation and 72 Hours Post-Admission

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Brenda A. Gowesky, CPT, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Ricky D. Latham, MAJ, MC Lawrence Pupa, MAJ, MC
Key Words: Infarction, myocardial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To determine the predictive value of the Killip classification in acute myocardial infarction for short term prognosis.

2) To correlate the Forrester classification documented by invasive measurements as well as noninvasive assessment of left ventricular function with the Killip classification and prognosis.

Technical Approach: Patients arriving in the Emergency Room at BAMC with a chief complaint of chest pain and/or shortness of breath will be entered into the study. It is the object of this study to correlate noninvasive Killip with the invasive monitoring of the Forrester classification and to correlate these with hospital mortality and prognosis. Residents will assess the patient and complete a questionnaire.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-92-87	Status: Ongoing

Title: A 12 Year Retrospective Analysis of MICU Experience at BAMC

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator David L. Glendening, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To evaluate the impact of population aging on MICU Services at BAMC.

2) To compare demographic trends in sex, mean annual age of admissions, and death for the MICU population and all adult admissions to BAMC and Department of Medicine during the 12 year period 1974-1985.

Technical Approach: This is a retrospective chart review of admissions to MICU.

Progress: Charts are being reviewed.

Detaile Summary Sheet

Date: 16 Oct 87	Proj No.: C-52-81	Status: Terminated

Title: Effect of Aspirin (ASA) on Airway Responses.

Start Date 7 Jul 81	Est Comp Date:
Principal Investigator Ana A. Ortiz, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy-Immuno.	Associate Investigators: Dane C. McBride, M.D., MAJ, MC Gabriel E. Gonzalez, MAJ, MC
Key Words: Airway responses	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Terminate

Objective(s): To investigate the effects of aspirin on airway responses in man. Specifically, the following questions will be answered: a. What effect does ASA have on upper and lower airway resistance in patients with non-allergic rhinitis with eosinophilia (NARES)? and b. Are patients with NARES - or any identifiable subset thereof - at particular risk of developing lower airway obstruction from aspirin?

Technical Approach: Subjects are to be challenged with 10 grains of aspirin and their nasal airway resistance and pulmonary functions will be measured and followed.

Progress: The study was terminated due to lack of progress.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-58-81	Status: Terminated

Title: The Specificity of Priming on the Nasal Mucous Membanes by Allergens and the Effect of Pharmacological Intervention.

Start Date 20 Aug 81	Est Comp Date:
Principal Investigator Ana A. Ortiz, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy-Immunol.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Terminate

Objective(s): To investigate further phenomena of mucous membrane priming by antigens. a) Does it occur in different aeroallergen systems; b) Is the priming effect on the nasal mucosa specific for the allergen that induces it? c) What is the effect, if any, of antihistamines, intranasal corticosteroids, and cromolyn sodium on nasal priming? d) Is the priming effect due to an increase in specific IgE?

Technical Approach: None.

Progress: This study was terminated due to lack of progress.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-13-82	Status: Ongoing

Title: Intracardiac Pressure and Flow Changes Following Amyl Nitrite Inhalation.

Start Date 8 Jan 82	Est Comp Date:
Principal Investigator Steven Bailey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D., DAC
Key Words: Intracardiac pressure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 8

Total Number of Subjects Enrolled to Date: 9

Date of Periodic Review 12 Mar 87 Results Continue

Objective(s): To better understand the hemodynamic events responsible for the auscultatory changes following amyl nitrite inhalation in normal man.

Technical Approach: Patients on no medical therapy who are felt to be probably normal are offered a chance to participate after a routine heart catheterization using a 3 sensor catheter in the right heart and a 2 sensor catheter in the left heart. They inhale amyl nitrite and the intracardiac pressure and flow response is recorded.

Progress: A total of nine complete studies have been performed. Study will be discontinued once data analysis performed to assure an acceptable number.

Detail Summary Sheet

Date: 25 Jun 86	Proj No: C-38-82	Status: Completed

Title: Autologous Bone Marrow Rescue in Resistant Neoplasms: A Phase I Study.

Start Date 7 Jul 82	Est Comp Date:
Principal Investigator Walter H. Harvey. D.O., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Bone marrow transplant	Glenn M. Mills, M.D., MAJ, MC Barbara Reeb, DAC John J. Posch, Jr., DAC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 24,737.08

Number of Subjects Enrolled During Reporting Period: n/a

Total Number of Subjects Enrolled to Date: n/a

Date of Periodic Review n/a Results

Objective(s): 1) To develop a bone marrow transplantation program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as part of the Southwest Oncology Group.

3) To establish a competent transplantation service for all eligible DOD patients for present clinical indications and future indications.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general or local anesthesia. The marrow will be prepared by accepted methods and either frozen for storage or returned to the patient after intensive chemotherapy.

Progress: The initial phase phase of the bone marrow rescue program has been completed. BAMC has been approved by the Southwest Oncology Group and Pediatric Oncology Group as a bone marrow transplant institution.

An updated protocol has been approved, and the study will be continued under protocol C-62-87.

Detail Summary Sheet

Date: 15 Mar 87	Proj No: C-26-83	Status: Terminated

Title: A Study of the Transmission of the Arterial Pulse Pressure Wave Form in the Descending Aorta of Man.

Start Date 16 Mar 83	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC Nico Westerhof, Ph.D.
Key Words: Arterial pulse pressure wave form	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To examine the changes in the arterial pulse pressure wave form throughout the descending aorta of man; to determine the pulse wave velocity at various sites in the descending aorta; to determine the significance of wave reflection sites in the descending aorta.

Technical Approach: Routine Sones procedure. 6-sensor catheter positioned by fluoro in descending aorta. Control, Valsalva, Muller and femoral artery occlusions performed.

Progress: The catheters utilized in this study have a maximal number of uses and are no longer certified for human use. Therefore, the study was terminated.

Detail Summary Sheet

Date: 17 Oct 87	Proj No: C-39-83	Status: Completed

Title: Mechanism of Exercise Limitation in Patients with Obstructive Lung Disease.

Start Date 6 May 83	Est Comp Date:
Principal Investigator (vice Matthews) Bruce A. Bush, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators:
Key Words: Obstructive lung disease	Frank W. Ewald, Jr., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 26

Date of Periodic Review 18 Jun 87 Results Continue to 1 Oct 87

Objective(s): 1) To determine the mechanism by which patients with obstructive lung disease are limited in their ability to perform exercise.

2) To examine ventilatory patterns in patients with obstructive lung disease during different types of exercise.

3) To determine if age matched control patients with reasonably normal lung function develop abnormal ventilatory patterns during similar modes of exercise.

Technical Approach: Ventilatory and cardiac responses to different types [illegible] exercise between 10 normal controls (NC) and 12 patients (PT) with mode[illegible] severe COPD were compared. All subjects underwent a maximal increme[illegible] (IC), a 6-minute state test (SST) at 75% of their maximal workload [illegible] 20-minute SSG at 50% of their maximal WL.

Progress: PT had a higher heart rate (HR) [illegible] level of WL-VO_2. Five of twelve PT with [illegible] however, their V_T was still less than N[illegible] WL, V_E, or MVO_2. Thus nonventilat[illegible] exercise limitations in some PT. [illegible] increased but does not lim[illegible]

AD-A190 939 ANNUAL RESEARCH PROGRESS REPORT FISCAL YEAR 1987 VOLUME 1(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX F H GOLDNER 01 OCT 87 2/4

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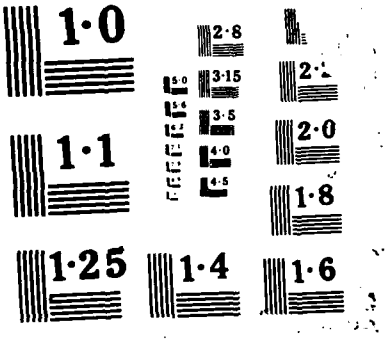
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Detail Summary Sheet

Date: 20 Oct 86	Proj No: C-51-83	Status: Ongoing

Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

Start Date 16 Jun 83	Est Comp Date:
Principal Investigator Stuart J. Salasche, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators:
Key Words: Basal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 84

Total Number of Subjects Enrolled to Date: 169

Date of Periodic Review 18 Jun 87 Results Continue

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

Technical Approach: Patients having at least two basal cell carcinomas in the last five years are contacted. If interested in participation, they are screened according to protocol. If all inclusion factors are met, they are randomized and begun on medication or placebo. After beginning medication, follow-up will occur at two weeks, three months, six months and every six months thereafter for the duration of the study. Patients are on medication for three years and have follow-up for two years afterward. Physical exams are done yearly. History, laboratory data, total skin exam, and necessary biopsies are done at each visit. Lateral cervical and thoracic spine films are done at 0 and 36 months on each patient and at 6, 12, or 18 months depending on entry date.

Progress: Patient enrollment has been completed. The total number of subjects randomized over eight clinical centers was 981. The study is now entering its next phase, patient follow-up.

Detail Summary Sheet

Date: 17 Jul 87	Proj No: C-77-83	Status: Completed

Title: High Dose Busulfan with Autologous Bone Marrow Rescue

Start Date 30 Sep 83	Est Comp Date:
Principal Investigator Walter H. Harvey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Paul J. Thomas, COL, MC Allan R. Potter, LTC, MC John J. Posch, Jr., MT Barbara Reeb, MT
Key Words: Bone marrow rescue Busulfan	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To study the response rate and toxicity of oral, high dose busulfan in malignancies refractory to standard therapy.

Technical Approach: Patients agreeing to participate were admitted to the hospital, and a Hickman catheter inserted into a large vein in the region of the should. Following insertion of the catheter, approximately 600-900 cc of marrow were drawn from the hip bones and stored for transfusion the next day. Approximately two hours following the marrow collection, busulfan was given orally, and the next morning they received a transfusion of their marrow. Marrow was cryopreserved when it was not reinfused within four days.

Progress: The initial phase of this study has been completed. An application to the FDA for an IND was approved, and this study will continue under protocol #C-70-87.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-2-84	Status: Completed

Title: Left Ventricular Systolic Dynamics in Normal Man.

Start Date 6 Dec 83	Est Comp Date:
Principal Investigator Ares Pasipoularides, M.D., Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC William E. Craig, M.D., LTC,.MC Jerry W. Miller, M.D., MAJ, MC
Key Words: Ventricular systolic dynamics	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review 11 Mar 87 Results Completed

Objective(s): To assess whether flow velocity-associate intraventricular pressure gradients represent a considerable intrinsic component of the total left ventricular systolic load when ejection is rapid, as in exercise.

Technical Approach: Simultaneous intraventricular pressure gradients and ejection flow patterns were measured by a multisensor catheter in 6patients with normal left ventricular function and no valve abnormalities, at rest and in exercise.

Progress: Peak measured intraventricular pressure gradients were attained very early in ejection, amounted to 6.7 $\pm$ 1.9 (SD) mm Hg at rest and were intensified to 13.0 $\pm$ 2.3 mm Hg during submaximal supine bicycle exercise. The augmentation of the gradients during exercise ws associated with a pronounced accentuation of the flow acceleration and flow at the instant of peak gradient. At peak flow, the intraventricular gradients amounted to 5.4 $\pm$ 1.7 mm Hg at rest, and 10.0 $\pm$ 1.8 mm Hg during submaximal exercise. The exercise-induced enhancement of the measured intraventricular pressure difference at the time of peak flow was underlain by an accentuation of the peak flow itself. A semiempirical fluid dynamic model for ejection was applied to the pressure gradient and simultaneous outflow rate and acceleration data to identify the contributions by local and convective acceleration effects to the instantaneous intraventricular gradient values.

C-2-84 (continued)

The peak intraventricular pressure gradient which is attained very early in ejection is mostly accounted for by local acceleration effects (85 $\pm$ 5% of the total). Conversely, at peak flow only convective acceleration effects are responsible for the measured pressure gradient. Thus, when inertial effects are augmentted, as in exercise and other hyperdynamic states, the intrinsic component of the total elft ventricular systolic load can be substantial, even with no outflow tract or valve abnormalities.

In view of the inverse force-velocity relationship of the myocardium, the preceind findings imply that the intrinsic component of the left ventricular load and the corresponding component of the left ventricular muscle load must be taken into account in exploring analytically the loading feedback between the total myocardial load and the acceleration, velocity and extent of shortening, which, along with end-diastolic dimensions, determine ejection flow waveforms. Further study/analysis of the ejection dynamic data is currently underway to develop a unified model of systolic cardiac performance in man.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-18-84	Status: Ongoing

Title: Congestive Cardiomyopathy: Evaluation of Transvenous Myocardial Biopsy and Treatment with an Anti-Inflammatory Regimen.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: John P. Mulrow, MAJ, MC Bernard J. Rubal, Ph.D. Renu Virmani, MAj, MC, AFIP Max Rabinowitz, M.D., AFIP James Baker, M.D., WRAMC Stephen Ramee, CPT, MC, LAMC
Key Words: Cardiomyopathy, congestive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2500.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 12 Mar 87 Results Continue

Objective(s): To assess the efficacy of using an endomyocardial biopsy technique in the diagnosis and management of congestive cardiomyopathy by identifying specific etiologies and/or those patients with an inflammatory cellular reaction.

Technical Approach: Patients undergo complete noninvasive assessment with laboratory echocardiogram, MUGA, and Gallium. Then, if eligible, endomyocardial biopsy is performed. NIH interprets the histology and Hahnemann University does immunological assessment. Patients must have cath proven normal coronary arteries. Patients should be randomized to Prednisone and noninvasive studies repeated in 6 months, 12 months, and 18 months.

Protocol has been amended to include left heart biopsy.

Progress: Data analysis ongoing. No more patient enrollment is necessary.

Detail Summary Sheet

Date: 15 Oct 87 Proj No: C-19-84 Status: Ongoing

Title: Dypyridamole MUGA Studies Compared with Quantitative Tomographic Stress and Dypyridamole Infusion TL201 Scintigrams for Assessing Coronary Artery Disease.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Michael Cawthon, M.D., MAJ, MC Michael F. Hartshorne, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Coronary artery disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 12 Apr 87 Results Completed

Objective(s): To assess the sensitivity of dypyridamole MUGA study as compared to dypyridamole infusion TL 201 studies to detect significant coronary artery disease.

Technical Approach: IV Persantine, 60 mg/kg, is given over 4 minutes. TL^{201} is given 2 minutes after infusion. For MUGA, TCM^{99} is given and rest study performed before infusion. Studies are then done at 3 minute intervals x 4. All patients are submitted to cardiac catheterization and results of anatomy are determined.

Phase II approach changed and approved by IRB to use ventriculography instead of DSA.

Progress: At the time of annual review of this protocol, the principal investigator reported the study as having been completed. However, when progress was requested for this report, the principal investigator stated that he is ready to start phase II of the study; and therefore, the study remains open.

Detail Summary Sheet

Date: 19 Jun 87	Proj No: C-27-84	Status: Terminated

Title: Treatment of Graves' Ophthalmopathy with Cyclosporin. (Collaborative Study with WRAMC)

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator (vice Taylor) Albert M. Thomason, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators: Leonard Wartofsky, M.D., COL, MC, WRAMC
Key Words: Graves' Ophthalmopathy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' Disease.

Technical Approach: The study will be composed of a random cross-over design comparing Cyclosporin treatment to the most commonly employed current therapy, high dose oral prednisone.

Progress: Since this study was opened three years ago, no patients have been enrolled. It was the consensus of the IRB that the study should be terminated. However, if a patient becomes eligible for enrollment, emergency approval may be obtained.

Detail Summary Sheet

Date: 22 Jun 87	Proj No: C-32-84	Status: Ongoing

Title: Effect of Discontinuance of Smoking on Gastroesophageal Reflux.

Start Date 10 May 84	Est Comp Date:
Principal Investigator Fred Goldner, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words: Gastroesophageal reflux	
Accumulative MEDCASE Cost: $9,920.00	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To determine if discontinuance of cigarette smoking will decrease gastroesophageal reflux in a population of smokers with pyrosis.

Technical Approach: Ambulatory 24 hour pH monitoring technology will be applied to a group of smoking patients with pyrosis before and after discontinuance of smoking. A standard set of criteria will be applied to determine if the discontinuance of smoking has a significant effect on gastroesophageal reflux.

Progress: This study has been revised and patient enrollment will begin in the near future.

Detail Summary Sheet

Date: 19 Jun 86	Proj No: C-37-84	Status: Terminated

Title: Clinical Trial of Ipratropium Bromide (Atrovent [R]) in Patients with Refractory Asthma and/or Chronic Obstructive Pulmonary Disease.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Herman M. Blanton, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators:
Key Words: Asthma, refractory Chronic obstructive pulmonary disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To provide emergency medication for patients who do not respond to currently marketed medications.

Technical Approach: Eligible patients must have a diagnosis of bronchial asthma, chronic bronchitis, or emphysema. Inhalations should not exceed 12 per day.

Progress: Four patients currently enrolled on this study had significant improvement in the management of their disease. However, since Atrovent has been approved for general use by the FDA, this study is terminated.

Detail Summary Sheet

Date: 10 Sep 87	Proj No: C-43-84	Status: Ongoing

Title: Assessment of Radiocontrast Induced Acute Renal Failure Following Coronary Angiography: An Evaluation of Intravenous Mannitol Infusion as a Preventive Measure.

Start Date 17 Jul 84	Est Comp Date:
Principal Investigator (vice Condos) Alan Kono, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven Bailey, MAJ, MC J. Brian Copley, COL, MC
Key Words: Angiography, Coronary Renal failure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 28

Total Number of Subjects Enrolled to Date: 48

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine the incidence of radiocontrast-induced acute renal failure in a high risk subgroup following selective cardiac angiography, to determine the effects of hemodynamic status on this incidence, and to compare the effect of intravenous mannitol infusion following angiography as compared to placebo on the incidence of development of acute renal failure.

Technical Approach: Patients with renal failure (creatinine > 2.0) or diabetes mellitus requiring treatment were randomized to receive either mannitol or saline at catheterization. Renal function was followed closely before and after catheterization to assess differences in development of renal failure.

Progress: Forty-eight patients have been entered into the study. Data analysis is being performed with expected completion of data acquisition in February 1988.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-44-84	Status: Terminated

Title: Hematuria as a Complication of Anticoagulation.

Start Date 17 Jul 84	Est Comp Date:
Principal Investigator David C. Tapp, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John C. Copley, M.D., LTC, MC Steven R. Bailey, M.D., MAJ, MC C. Ritchie Spence, M.D., COL, MC William S. Grabowski, M.D., COL, MC
Key Words: Hematuria Anticoagulation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the incidence of hematuria in patients on various anticoagulants; specifically coumadin, heparin, and streptokinase; and then to identify the specific etiology of the hematuria by employing selected diagnostic tests (IVP, cystoscopy, etc.).

Technical Approach: Patients with hematuria on coumadin, heparin, streptokinase are identified and then receive a work-up to determine etiology (IVP, cystogram, culture, PPD, serologies).

Progress: The principal investigator does not wish to continue this study; therefore, it was terminated.

Detail Summary Sheet

Date: 10 Sep 87	Proj No: C-49-84	Status: Completed

Title: A Test of the Colonic Hyperalgesia Hypothesis in Patients with Irritable Bowel Syndrome (IBS).

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Fred Goldner, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: John B. Powell, Ph.D., CPT, MSC
Key Words: Irritable bowel syndrome (IBS)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 23

Total Number of Subjects Enrolled to Date: 26

Date of Periodic Review 10 Sep 87 Results Completed

Objective(s): To determine if abdominal pain in patients with IBS is due to a hypersensitivity of the colon to distention versus a hypersensitivity of the patient to pain in general.

Technical Approach: Noxious stimuli will be applied in a controlled manner to a group of irritable bowel patients with abdominal pain. Gut distention pain will be evaluated by balloon distentionof the rectum and somatic discomfort tested by cold water hand immersion. Control and IBS populations will be compared as to pain sensitivity in each parameter.

Progress: Twenty-six patients and controls have been studied without incident. No difference in pain threshold between groups was noted.

Detail Summary Sheet

Date: 10 Sep 87	Proj No: C-50-84	Status: Ongoing

Title: The Effect of Weight Loss on Gastroesophageal Reflux.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Fred Goldner, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words: Gastroesophageal reflux	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine if weight loss achieved through caloric restriction will improve gastroesophageal reflux of acid.

Technical Approach: 24-hour ambulatory pH testing will be performed on a group of obese subjects with pyrosis, before and after weight loss. A standard set of reflux criteria will be applied to determine if weight loss affects the degree of gastroesophageal reflux.

Progress: No progress has been made due to time constraints of the principal investigator. It is anticipated that this study will be started in the near future.

Detail Summary Sheet

Date: 26 Oct 86	Proj No: C-64-84	Status: Terminated

Title: Utilization of Mixed Venous Oxygen Saturation (Sv_2 Sat) in the Management of the Critically Ill.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator(vice Glendening) Harvey M. Richey, III, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Joseph I. Matthews, M.D., COL, MC Bruce A. Bush, M.D., MAJ, MC Herman M. Blanton M.D., CPT, MC
Key Words: Opticath	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review n/a Results_____

Objective(s): 1) To determine if continuous SvO_2 monitoring reduces numbers of other evaluative tests/procedures in the managemennt of the critically ill.

2) To determine if continuous SvO_2 monitoring affects the duration of vasoactive drug therapy or mechanical ventilatory assistance.

3) To determine if insertion failures or procedure complications vary between catheters or indications.

Technical Approach: Information will be gathered regarding the effectiveness of a new catheter, called an Opticath, in the care of the seriously ill patient.

Progress: This study was terminated due to lack of progress.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-73-84	Status: Ongoing

Title: Comparison of Micromanometer Tip Left Atrial Catheter Monitoring with Fluid Pulmonary Artery Pressure Monitoring in Postoperative Open Heart Surgery Patients, a Trend Analysis in the SICU.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator (vice Bailey) John W. McClure, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC Bernard J. Rubal, Ph.D. Steven R. Bailey, MAJ, MC
Key Words: Catheter, left atrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To compare the pressures obtained from a high fidelity, micromanometer transducer mounted on a left atrial catheter to those obtained from a flow-directed, balloon-tipped catheter in the pulmonary artery in patients recovering from open heart surgery.

Technical Approach: At the time of surgery, a micromanometer tip left atrial catheter will be inserted through the pulmonary vein into the atrium. A flow-directed, balloon-tipped catheter will be inserted into the pulmonary artery in the routine manner. Pressure and blood gas measurements will be recorded at two hour intervals or more often if indicated. Analysis will continue until the catheters are removed.

Progress: Due to technical limitations, only three patients have been enrolled in this study. The necessary equipment has been repaired and an early completion is expected.

Detail Summary Sheet

Date: 31 Aug 87	Proj No: C-74-84	Status: Completed

Title: Hemodynamic Effects of IV Dipyridamole in Normal Man Compared with Patients with Significant Arteriosclerotic Heart Disease.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator (vice Wrenn) Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words: Dipyridamole, IV	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To establish the acute effect of IV dipyridamole (IVD) in normal subjects on cardiovascular hemodynamics routinely measured in the cardiac catheterization laboratory.

Technical Approach: Patients scheduled for elective cardiac catheterization were asked to participate, and cardiac catheterization was performed in the standard fashion. IVD (0.6 mg/kg) was administered after completion of the exercise study when the patients returned to their resting state. The parameters measured included: heart rate; cardiac output; arterial, left ventricular, and pulmonary artery pressures; dp/dt; oxygen consumption; and pulmonary artery oxygen saturation. Systemic vascular resistance and double product were calculated.

Progress: In normal subjects during exercise and IVD, heart rate, cardiac output and dp/dt increased ($p < 0.05$) and SVR decreased ($p < 0.05$). Similar changes occurred in patients with coronary artery disease during exercise; however, only significant changes in SVR were demonstrated with IVD. There was a trend for stroke volume to increase in both groups, but changes were not significant. Systolic and mean aortic blood pressures increased during exercise, but decreased with IVD. Double product was increased more by exercise ($p < .01$) than by IVD; thus, IVD does not cause an increase in MVO_2 as seen with exercise. Although IVD has been shown to produce myocardial perfusion defects in patients with coronary artery disease by thallium scintigraphy, our data suggest it is not "exercise in a syringe."

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-4-85	Status: Terminated

Title: Evaluation of Continuously Determined Mixed Venous Oxygenation (MVO_2) via Fiberoptic Catheter in the Critically-Ill Patient.

Start Date 14 Nov 84	Est Comp Date:
Principal Investigator Gregg T. Anders, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Catheter, fiberoptic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 15 Jan 87 Results Terminated

Objective(s): To correlate a continuous spectrophotometric mixed venous oxygenation saturation to changes in cardiac output, peripheral/systemic vascular resistance, and other physiologic parameters in critically-ill cardiac patients.

Technical Approach: Various patients with cardiac dysfunction (AMI, acute decompensation of CHF) are monitored in BAMC CCU with fiberoptic Swan-Ganz catheter, and mixed venous oxygentation state is compared with more standardized critical-care monitoring parameters, including cardiac output and systemic vascular resistance.

Progress: This study was terminated due to lack of sufficient personnel to conduct the study.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-16-85	Status: Terminated

Title: Significance of Post Radiotherapy Constrictive Pericarditis in Patients.

Start Date 21 Jan 85	Est Comp Date:
Principal Investigator (vice Ross) Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Jerry Miller, M.D., MAJ, MC, (WBAMC) Gregory G. Friess, M.D., MAJ, MC
Key Words: Pericarditis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 11 Mar 87 Results Terminated

Objective(s): To study Hodgkins patients post thoracic radiation therapy in order to determine: 1) the incidence of overt constrictive pericarditis; 2) the incidence of occult constrictive pericarditis; 3) a correlation of Doppler flow profile across the tricuspid or mitral valve and right heart pressure events in overt constrictive and occult constrictive pericarditis; 4) a correlation between myocardial interstitial fibrosis with abnormal hemodynamics and abnormal pericardium in overt constrictive and occult constrictive pericarditis.

Technical Approach: Outpatient Echo/Doppler evaluation right heart catheterization with endomyocardial biopsy.

Progress: Study terminated due to poor patient accrual.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-20-85	Status: Terminated

Title: Pressure Waveforms and Reflections in the Human Aorta: Comparison of a Cadaver Model with In Vivo Results.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D. Joseph P. Murgo, M.D., COL, MC Nico Westerhof, Ph.D. Renu Virmani, M.D. M. Rabinowitz, M.D., AFIP
Key Words: Pressure waveforms	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 12 Mar 87 Results Continue

Objective(s): 1) Identify site(s) of wave reflection affecting wave shapes in the aorta of man.

2) Correlate changes in wave reflection and pulse transmission characteristics with changes in compliance in the cadaver aorta.

3) Investigate simultaneous regional impedances with changes in arterial reflection induced by controlled variance of terminal resistances or compliance.

4) Correlate changes in compliance with impedance changes and compare the cadaver results to in vivo results.

5) Compare descending aorta impedance changes in normals, hypertensive, and atherosclerotic peripheral vascular disease patients.

Technical Approach: The aorta will be measured in a fresh human cadaver for longitudinal dimensions to be maintained in the model set up. The aorta and its branches will be dissected free. In order to characterize the effects of handling procedures on elasticity, a pilot trial in swine aorta will be performed.

Progress: Due to equipment difficulties, the project has been on hold. Therefore, the study is terminated and a new one may be submitted when hardware difficulties are solved.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-21-85	Status: Terminated

Title: Doppler Ultrasound Applied to Studies of Pulmonary Blood Flow in Pulmonary Hypertension.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Stephen D. Hoadley, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Jacelyn F. Miller, R.D.M.S.
Key Words: Hypertension, pulmonary Doppler ultrasound	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review 11 Mar 87 Results Terminated

Objective(s): To validate Doppler ultrasound as a non-invasive tool for evaluating pulmonary blood flow velocity in patients with pulmonary hypertension.

Technical Approach: In order to evaluate the accuracy of Doppler ultrasound in assessing pulmonary hypertension, it was performed in the cath lab with simultaneous right heart catheterization using Millar high fidelity multisensor catheters. Twenty patients were studied with mean pulmonary artery pressures in the range of 10 to 85 mmHg. A correlation was made between the pulmonary artery pressure and the pulsed Doppler signal obtained from the left parasternal window, with the sample volume in the right ventricular outflow tract. The following intervals were measured from the Doppler signal: (1) pre-ejection period, (2) acceleration time, (3) the right ventricular ejection time, (4) the ratio PEP/RVET, and (5) the ratio AT/RVET.

Progress: Due to time constraints on the part of the principal investigator, no progress was made, and the study was terminated.

Detail Summary Sheet

Date: 15 Dec 86	Proj No: C-27-85	Status: Completed

Title: Hemodynamic Effects of the Muller Maneuver.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator William R. Condos, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, M.D., CPT, MC Stephen D. Hoadley, M.D., MAJ, MC Ares Pasipoularides, M.D., Ph.D.
Key Words: Muller maneuver	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review 19 Mar 86 Results Continue

Objective(s): To study hemodynamic effects and changes in aortic compliance during the Muller maneuver.

Technical Approach: Ten subjects with normal hemodynamics were studied during elective cardiac catheterization with right and left heart multisensor micromanometry to assess hemodynamic responses to the Muller maneuver. Simultaneous right atrial, right ventricular, pulmonary capillary wedge, left ventricular, pulmonary arterial and aortic pressures were recorded, in addition to pulmonary arterial and aortic flow velocities. Steady state cardiac outputs were determined by thermal dilution; all hemodynamic variables were measured at rest and during the Muller maneuver.

Progress: Aortic systolic and mean pressures were not significantly changed during the Muller maneuver, in contrast to a lower diastolic ($p = .019$) and higher pulse pressure ($p = .016$). Right atrial mean pressure decreased from 7 ± 1 to -13 ± 4 mmHg ($\pm$SE. $p = .0002$) and the right atrial "x" descent was markedly accentuated. Left ventricular end-diastolic pressure decreased from 12 ± 4 to -3 ± 14 mmHg ($p = .0025$). Systemic vascular resistance and left ventricular peak positive dp/dt were increased during the Muller maneuver ($p < .02$) while cardiac output and stroke volume were reduced ($p < .05$) with no

C-27-85 (continued)

significant change in heart rate. Right left peak flow velocities showed a trend toward a decrease bilaterally (right, $p = .054$; left, $p > 0.1$) and times to peak flow velocity were increased in the pulmonary artery ($p = .007$) and reduced in the aortic root ($p = .03$).

These data suggest reduced flow through right and left heart chambers during a sustained Muller maneuver in humans, in contrast to prior theory and animal data suggesting that right heart flow is increased during sustained forced inspiratory effort.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-29-85	Status: Terminated

Title: Apical Methods of Cardiac Output Determination with Doppler Ultrasound.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator Stephe D. Hoadley, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Doppler ultrasound	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 13

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To determine which of the apical views is more accurate in estimating cardiac output via doppler ultrasound.

Technical Approach: Five patients studied; four were technically adequate. Due to time constraints, have often had to delete pulmonary artery (RVOT) part of protocol.

Progress: No new patients have been enrolled on this study. Protocol terminated at request of principal investigator.

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-38-85	Status: Ongoing

Title: Carbohydrate Binding by Activated Charcoal In Vivo and In Vitro and Its Effect on the Production of Breath Hydrogen.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Bernard Feldman, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators: Fred Goldner, M.D., COL, MC Regina Marshall, R.N
Key Words: Carbohydrate binding Breath hydrogen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To assess the efficacy of activated charcoal in binding carbohydrates in the GI tract.

Technical Approach: A fasting breath hydrogen sample will be obtained. After ingesting the carbohydrate, subjects will blow a sample of their breath into special Mylar-coated foil bags and stored until analyzed. They will be asked to obtain samples hourly for eight hours and will be given a diary to record symptoms. Samples will be analyzed and a rise of greater than 20 parts per million of hydrogen gas over fasting concentration will be interpreted as carbohydrate malabsorption. Comparison will be made between the treated and placebo groups to determine if activated charcoal can bind carbohydrate and prevent fermentation and production of breath hydrogen.

Progress: A similar project was published just after this protocol was approved. A revised protocol addressing different aspects of the problem will be submitted.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-42-85	Status: Terminated

Title: Comparison of the Two Topical Antifungal Agents, Ciclopirox Olamine and Econazole, in the Treatment of Onychomycosis of the Toenails.

Start Date 3 May 85	Est Comp Date:
Principal Investigator (vice Kraus) William H. Raddentz, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators:
Key Words: Onychomyocosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: 35

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To compare, in a double-blind clinical study, the efficacy of two commercially available topical antifungal creams in the treatment of fungal infections of the toenails.

Technical Approach: KOM prep of fungal nail and subungual debris will be done. If KOM is positive then fungal culture will be done. If culture is positive then enrollment with either econazole or ciclopirox cream b.i.d. Baseline photographs and notching of toenail at the proximal end of involvement. Follow-up progress initially at one month and then every two months.

Progress: This study was terminated because: (1) Mycology section of the laboratory was not able to identify the large number of cultures this study generated; (2) Poor results obtained - 3 slight improvement, 0 significant improvement, 26 no improvement, and 6 lost to followup.

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-49-85	Status: Ongoing

Title: Skin Test Responses to Wholebody Fireant Extracts: Allergic vs. Irritant Reactivity.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Ana A. Ortiz, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy	Associate Investigators: Dane C. McBride, M.D., MAJ, MC
Key Words: Fireant extrcts	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To define a range of dilutions of imported fireant (IFA) wholebody extracts which will differentiate patients with immediate (Type I) hypersensitivity to imported fireants from those with negative or irritant responses to skin testing.

Technical Approach: Once participants have been classified into one of the three study groups, they will complete a questionnaite. They will then be skin tested by the prick method with commercially produced IFA wholebody extracts. Participants will also be skin tested by the intradermal method to IFA wholebody extracts.

Progress: It is too early to report any meaningful results.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-50-85	Status: Terminated

Title: Randomized Evaluation of Cis-platinum and 5-Fluorouracil with and without Etoposide (VP-16-213) in Extensive Non-Small Cell Lung Cancer. A Pilot Study.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Irwin L. Levey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Gregory G. Friess, D.O., MAJ, MC Kenneth L. Beougher, MAJ, MS
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): 1) To assess the response rate and toxicity of cis-platinum and 5-fluorouracil (5-FU) in the initial treatment of extensive non-small cell lung cancer.

2) To evaluate the contribution of a vinca alkaloid to the combination of cis-platinum and 5-FU in thre treatment of extensive non-small cell lung cancer.

3) To offer structured investigational therapy to patients at BAMC with lung cancer not covered by current Southwest Oncology Group (SWOG) protocols.

Technical Approach: Technical approach as described in the initial proposal has been functional. The only problem encountered to date has been acquisition of eligible patients.

Progress: Study terminated due to poor patient accrual.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-52-85	Status: Completed

Title: A Randomized Controlled, Prospective Study of a Percutaneous J-Wire Exchange Technique for Safety and Efficacy.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator David S. Goya, M.C., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: David L. Grisell, M.D., CPT, MC Gregg T. Anders, M.D., CPT, MC C. Kenneth McAllister, M.D., LTC, MC Harvey M. Richey, M.D., MAJ, MC John L. Carpenter, M.D., COL, MC
Key Words: J-wire exchange	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 17

Total Number of Subjects Enrolled to Date: 42

Date of Periodic Review 18 Jun 87 Results Completed

Objective(s): To evaluate percutaneous J-Wire exchange technique for (1) safety and (2) risk of infection during prolonged central venous catheterization in the critical care setting.

Technical Approach: Forty-two patients in the ICU were prospectively randomized to one of two groups. Patients in Group I had their central lines changed through a new percutaneous site. Patients in Group II had their central lines changed over a guidewire. In both groups, the catheter was semiquantitatively cultured and two sets of blood cultures were obtained.

Progress: Patients in Group I had 2.56 $\pm$ 0.88 central lines; whereas, patients in Group II had 2.84 $\pm$ 1.17 central lines (p = NS). Three patients in Group I (4.2%) and one patient in Group II (1.9%) had catheter-related sepsis. In eight cases, the guidewire was introduced through a site where the previous catheter showed bacterial growth on culture plates. Follow-up cultures revealed growth in one catheter but sepsis did not occur. None of the catheters were inserted through a grossly infected site. Three pneumothoraces occurred in Group I, but none in Group II. Our study suggests the guidewire exchange of central lines decreases the incidence of procedural complications. It would appear that if the catheter site does not appear grossly infected, guidewire exchange does not increase the incidence of infectious complications.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-54-85	Status: Terminated

Title: Rifampin for the Treatment of Serious Infections Caused by Gram-Negative Bacilli, Especially P. aeruginosa.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator (vice Michael) C. Kenneth McAllister, M.D., LTC,MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Infectious Disease	Associate Investigators: Clifton A. Hawkes, M.D., MAJ, MC William Kelly, M.D., CPT, MC
Key Words: P. aeruginosa	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Continue to 1 Oct 87

Objective(s): To investigate the clinical efficacy of the use of rifampin as an adjunct to standard therapy (aminoglycoside plus extended-spectrum penicillin) for serious infections caused by gram-negative bacilli, especially those caused by P. aeruginosa.

Technical Approach: Hospitalized patients with suspected or documented infection with a gram-negative bacillus, especially P. aeruginosa, will be sought for admission to the study. Patients with the following infections will be considered for inclusion: 1) Bacteremia and a syndrome compatible with an infectious process, with or without a known primary focus of infection: 2) Endocarditis accompanied by a compatible clinical syndrome and documented with blood cultures; 3) Meningitis documented by appropriate CSF abnormalities and positive CSF cultures; 4) Urinary tract infection accompanied by fever, evidence of systemic toxicity and positive urine culture; and 5) Pneumonia, accompanied by appropriate clinical syndrome and documented by sputum gram stain, sputum culture, and new pulmonary infiltrate.

Progress: Since no patients have been enrolled, the study was terminated as recommended at the time of annual review.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-57-85	Status: Completed

Title: Double-Blind Crossover Study of the Antiemetic Efficacy of High-Dose Haloperidol versus High-Dose Metoclopramide.

Start Date 16 Aug 85	Est Comp Date:
Principal Investigator Irwin L. Levey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Kenneth L. Beougher, MAJ, MS Gregory G. Friess, M.D., MAJ, MC Sharon S. DeRuvo, CPT, AN Annette Etnyre, CPT, AN
Key Words: Antiemetic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 25

Total Number of Subjects Enrolled to Date: 25

Date of Periodic Review 18 Jun 87 Results Completed

Objective(s): 1) To assess the efficacy of haloperidol, dexamethasone plus diphenhydramine in prevention of chemotherapy-induced nausea and emesis.

2) To compare these results in a randomized double-blind crossover study to the "standard" antiemetic regimen currently used at BAMC (i.e., metoclopramide, dexamethasone and diphenhydramine).

Technical Approach: Patients with malignant disease were eligible for study if they were scheduled to receive at least two cycles of chemotherapy containing cisplatin. Patients were randomly assigned to receive either metoclopramide or haloperidol during the first cycle of cisplatin-containing chemotherapy, then crossed over to receive the alternative antiemetic during the next treatment cycle. Patients were interviewed by a blinded observer on the morning following treatment to assess aspects of nausea, emesis, side-effects, and overall discomfort. Following the completion of two cycles of antiemetic therapy, patients were asked to compare the two antiemetic regimens according to relative efficacy and side-effects, and to state which, if either, they would prefer to receive with future chemotherapy.

Progress: Twenty-one patients completed two successive courses of chemotherapy and were fully evaluable. Of the 21 evaluable patients, 14 were male and 7 were female. Patients ranged in age from 21-68 years, with a median of 57 years. Both drugs provided effective control against cisplatin-induced nausea with 16 and 11 patients describing no nausea or only mild nausea after metoclopramide and haloperidol, respectively. Overall, 17/21 (81%) of patients receiving haloperidol and 20/21 (95%) of patients receiving metoclopramide described tolerable nausea with drug treatment.

C-57-85 (continued)

Conclusions: Haloperidol given in high intravenous doses is a safe and effective antiemetic agent for patients receiving cisplatin chemotherapy and may prove valuable as an alternative antiemetic for patients who cannot tolerate or benefit from metoclopramide therapy. Further studies investigating higher doses and different treatment schedules, including those adaptable to outpatinet use, should be done.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-60-85	Status: Completed

Title: Phase I Study of the Oral Administration of Menogaril in Patients with Advanced Cancer (Collaborative Study with University of Texas Health Science Center)

Start Date 9 Sep 85	Est Comp Date:
Principal Investigator Thomas D. Brown, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Kenneth L. Beougher, MAJ, MS Geoffrey R. Weiss, M.D., UTHSCSA
Key Words: Cancer, advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 14 (5 at BAMC)
Total Number of Subjects Enrolled to Date: 44 (20 at BAMC)
Date of Periodic Review 10 Sep 87 Results Completed

Objective(s): 1) To determine the maximally tolerated dose (which is both predictable and reversible) of menogaril given orally every 4 weeks.

2) To determine the qualitative and quantittative toxicities of menogaril given orally.

3) To determine the recommended oral dose for menogaril to be used for initial clinical trials.

4) To determine the basic pharmacokinetics of menogaril by study of plasma and urinary levels of the agent in man.

5) To collect information about anti-tumor effects of menogaril if an anti-tumor effect is observed.

Technical Approach: Eligible patients must have a microscopically confirmed diagnosis of metastatic cancer and a life expectancy of at least 12 weeks. Only patients with solid tumors will be eligible for the study. Patients tumors must be refractory to all known forms of effective therapy as well as other investigational agents of higher potential efficacy.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was closed to accrual in November 1986 and all patients were removed from study at BAMC as of 7 Jan 87. In this study M was given monthly by mouth (PO), dissolved in grape juice and drunk over <15 minutes. Thirty five patients (pts) (25 male-10 female, median age - 61) received 67 courses of M ranging from 85 to 625 mg/M^2. Nine additional pts received monthly doses of IV M at 250 mg/M^2 alternated with doses of PO M at 250 or 500 mg/M^2, for bioavailability determination. Dose limiting toxicity (DLT) occurred at

C-60-85 (continued)

625 mg/M^2 with 5 of 7 pts vomiting drug within 1.5 hours (hrs) of dosing. With antiemetic premedication, 3 of 6 pts at 625 mg/M^2 vomited within 1.5 hrs of dosing. At 500 mg/M^2 4 of 5 pts without medication had vomiting at >2 hrs from dosing that was readily controlled with antiemetics. Other dose related toxicities at 625 mg/M^2 included leukopenia, thrombocytopenia, and abdominal pain/diarrhea. Toxicities not dose related of WHO grade $\leq$ included malaise, alopecia, dermatitis, and anemia. Two episodes of possible drug related cardiotoxicity were observed. One patient with non-small cell lung cancer achieved a minor response at 500 mg/M^2. Preliminary pharmacokinetic data reveal 40% bioavailability of PO M with a harmonic mean terminal T 1/2 of 32.5 hrs. The maximally tolerated dose of M on the PO monthly schedle is 625 mg/M^2, and the recommended phase II dose on this schedule is 500 mg/M^2.

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-68-85	Status: Completed

Title: Correlation and Comparison of Blood Cultures from Indwelling Central Venous Catheters and Peripheral Venipuncture Sites in the Febrile Patient in a Special Care Setting

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Gregg T. Anders, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gen. Medicine	Associate Investigators: John L. Carpenter, M.D., COL, MC C. Kenneth McAllister, M.D., LTC, MC David S. Goya, M.D., CPT, MC David L. Grissell, M.D., CPT, MC Harvey M. Richey, M.D., MAJ, MC
Key Words: Cultures, Blood	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To quantify and statistically correlate the relationship between peripheral and central cultures in the critically ill, febrile patient.

Technical Approach: This study will analyze the data obtained from patients enrolled on the study C-52-85.

Progress: As reported in protocol C-52-85.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-2-86	Status: Ongoing

Title: Expectations and Experience Evaluation of Oncology Patients Participating in Phase II Clinical Trials

Start Date 28 Oct 86	Est Comp Date:
Principal Investigator (vice Etnyre) Deborah G. Tracy, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing/Oncology	Associate Investigators: Pam Clement, Ph.D. Thomas D. Brown, M.D., MAJ, MC
Key Words: Patients, oncology	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 34

Date of Periodic Review 15 Jan 87 Results Continue

Objective(s): To describe the expectations of patients entering a phase I clinical trial and to describe their evaluations of their experience after their particpation.

Technical Approach: Participants will be interviewed before the drug study begins and again approximately two months later. They will be asked to complete the Millon Behavioral Health Inventory questionnaire after the first interview.

Progress: Study in progress. Will probably be closed before January 1988.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-4-86	Status: Terminated

Title: A Clinical Trial to Evaluate Natural History and Treatment of Patients with Non-Invasive Intraductal Adenocarcinoma (NSABP 17)

Start Date 6 Jan 86	Est Comp Date:
Principal Investigator (vice Reed) Walter H. Harvey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, intraductal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To evaluate postoperative breast irradiation following segmental mastectomy plus axillary dissection in patients with non-invasive intraductal adenocarcinoma.

Technical Approach: All females who had had a segemental mastectomy, as defined in this protocol, for non-invasive intraductal adenocarcinoma will be considered for inclusion in this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Study terminated at request of principal investigator.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-6-86	Status: Terminated

Title: A Randomized Trial Comparing the Efficacy, Toxicity and Compliance of Empiric Antibiotic Therapy in Neutropenic/Febrile Patiens Using Mezlocillin/ Amikacin vs. Cefoperazone/Amikacin.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator (vice Stapleton) Walter H. Harvey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: C. Kenneth McAllister, LTC, MC William K. Kelly, CPT, MC
Key Words: Therapy, antibiotic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): 1) To determine if the combination of Cefaperazone and Amikacin is as effective as Mezlocillin/Amikacin in the empiric therapy of the febrile neutropenic patient utilizing a q12h frequency of administration of Amikacin and Cefaperazone.

2) To determine the incidence and types of toxicities encountered in the prolonged (greater than 5 days) use of empiric antibiotic therapy (to include toxicities of nephrotoxicity, hypokalemia, hematological abnormalities, and development of resistant organisms).

3) To determine if there is a financial savings, a decrease in nursing responsibilities or an increase in dosing compliance when comparing the two empiric regimens.

Technical Approach: Cancer patients with absolute granulocyte count of <1000/mcl and temperature >101°F on two readings thirty minutes apart and having not received blood products or transfusions recently are eligibile.

Therapy will follow the schema outlined in the study protocol.

Progress: In view of new SWOG antibiotic regimens, the principal investigator requested terminationof this study.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-7-86	Status: Terminated

Title: Renal Failure in the Cirrhotic Patient, An Expanded Definition.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator David M. Slife, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: William G. Wortham, CPT, MC John B. Copley, LTC, MC Howard M. Cushner, MAJ, MC
Key Words: Failure, renal Cirrhosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 218.00

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To determine the utility of the serum creatinine and creatinine clearance in assessing renal function in the patient with hepatic cirrhosis.

Technical Approach: Patients will be admitted to the Clinical Research Center. A Foley will be placed for purposes of accurate urine collection for the clearances. One hour before the clearance studies, the free water clearance will be assessed by a modified free water load of 15cc/kg of 185mM glucose and water. Renal function will be assessed using Inulin clerance for GFR and PAH for renal blood flow. A 24 hour urine collection will be obtained for purposes of determining creatinine clerance.

Progress: Because of problems encountered using inulin as a marker for GFR, sodium iothalamate-I^{125} will be substituted and a new protocol submitted.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-8-86	Status: Completed

Title: Utility of Latex Agglutination Test for Detection of Candida Antigen in the Diagnosis of Systemic Candidiasis.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator (Battafarano) William J. Kelly, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: C. Kenneth McAllister, LTC, MC
Key Words: Candidiasis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 400.00

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review n/a Results

Objective(s): To determine the sensitivity and specificity of the Ramco Latex Agglutination Test for the diagnosis of systemic candidiasis.

Technical Approach: Blood obtained for routine laboratory tests which is ordinarily discarded will be subjected to the Ramco Latex Agglutination Test.

Progress: Forty serum specimens were taken from normal controls and suspected candidemia patients. The test was not a better predictor of systemic candidiasis than usual clinical criteria.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-9-86	Status: Ongoing

Title: Validation of Formula for QRS Prediction Utilizing QRS Duration and R-R Interval

Start Date 19 Jun 87 Reopened	Est Comp Date:
Principal Investigator James K. Gillman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: John P. Mulrow, M.D.
Key Words: Electrocardiography	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: 180

Date of Periodic Review 18 Jun 87 Results _____

Objective(s): To validate a new formula for Q-T prediction developed from the European Communities Project on Common Standards in Quantitative Electrocardiography (CSE) utilizing QRS Duration and R-R interval.

Technical Approach: ECG's will be performed using standard multichannel Marquette HC equipment. Computer determined values for QRS duration, R-R interval, and Q-T interval will be utilized in both the CSE formula and Bazett's formula for Q-T prediction. All ECG's will be measured blindly to verify T wave offset by one of the investigators.

Bazett's and the CSE formulae will be compared for the prediction of QT interval. Additionally, the CSE formula developed in Europe will be compared to the equation derived from the Sam Antonio study.

Progress: New formula for Q-T predictor does perform better than Bazett's but numbers preclude statistical significance. Approximately 80 new patients will be studied.

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-11-86	Status: Completed

Title: A Prospecitve Study of Fatigue.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator Kurt Kroenke, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: David Wood, MAJ, MC J. Brad Powell, MAJ, MS
Key Words: Fatigue	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,365.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): To prospectively study a cohort of patients with fatigue to determine its incidence, etiology, natural course, and predictors or chronicity.

Technical Approach: A Simple Fatigue Survey Form will be administered to consecutive patients attending the four adult primary care clinics at BAMC: Internal Medicine; Acute Care; Troop Medical; Gynecology. Those for whom fatigue is a major problem will be shcedules for an appointment to the Fatigue Clinic.

Progress: Of 1159 consecutive patients surveyed in two adult primary care clinics, 276 (24%) indicated that fatigue was a major problem. Fatigue was more prevalent in women than in men (28% vs 19%). Extensive clinical, laboratory, psychometric, and fnctional data were gathered on 102 fatigued patients and 26 controls. Laboratory testing was not useful in detecting unsuspected medical conditions or in determining the cause of fatigue. Depression, somatic anxiety, or both were suggested by screening psychometric instruments in 80% of fatigued patients, vs 12% of controls. After one year of follow-up, fatigued patients

C-11-86 (continued)

and controls had similar rates of clinic visits, hospitalization, and new diagnoses; however, only 28% of fatigued patients improved. The high prevalence, persistence, and functional consequences of fatigue mandate a search for effective therapy. Interventions worth exploring include reassurance, counselling, psychoactive drugs, and exercise.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-12-86	Status: Completed

Title: Dipyridamole Echocardiography for the Detection of Coronary Artery Disease.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator (vice Hoadley) Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Michael Crawford, M.D. John M. Bauman, MAJ, MC
Key Words: Echocardiography	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 166.00

Number of Subjects Enrolled During Reporting Period: 25

Total Number of Subjects Enrolled to Date: 49

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To assess the sensitivity, specificity, and predictive value of echocardiography during dipyridamole infusion for the presence of coronary artery disease.

Technical Approach: Two-dimensional echocardiography (2DE) and TI-201 scintigraphy (TS) have been used successfully with intravenous dipyridamole (D) for detecting coronary artery disease (CAD), but no comparative data exists. Thus, we studied 47 patients (pts) with chest pain syndromes and no prior infarctions; 22 with and 25 without CAD by cardiac catheterization. Biapical 2DE and planar TS were obtained immediately after 0.9 mg/kg D and compared to appropriate control images in a blinded fashion.

Progress: Segmental wall motio abnormalities before or after D were considered 2DE evidence of CAD and were present in 9 of the 22 CAD pts (sensitivity 41%). Normal wall motion was found in 23 of the 25 normals (specificity 92%). Also, of the 11 positive 2DE studies, 10 were abnormal at baseline before D. 2DE ejection fraction (EF) was calculatedin 41 pts and increased with D from 61$\pm$11% to 68$\pm$12% ($p<.001$). EF increased in 71% of CAD pts and 88% of normals. In the CAD pts, this increase in EF may have masked the effects on wall motion of the ischemia demonstrated by TS. Therefore, despite high specificity, 2DE with intravenous dipyridamole is inferior to Ti-201 scintigraphy for the detection of CAD.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-20-86	Status: Terminated

Title: Role of Bronchoalveolar Lavage (BAL) in the Diagnosis of Malignant Pulmonary Nodules and Infiltrates.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator (vice Morales) Joseph I. Matthews, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators:
Key Words: Lavage, bronchoalveolar	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To define the role of bronchoalveolar lavage as an adjunct in the diagnosis of malignant pulmonary nodules in comparison with other conventional techniques employed during fiberoptic bronchoscopy.

Technical Approach: Criteria for entry into study will include patient with radiographic evidence of solitary or multiple lung nodules on which a diagnosis of malignancy had been confirmed by either positive cytology by bronchoscopy, needle aspirate, or open lung biopsy. For each patient entering the study, the instillation and recovery of the initial 30 cc's of saline to which the lesion is felt to correspond will constitute the "washing" sample. This will be followed by the instillation of an additional 100-120 cc's of saline given in aliquots of 20 cc's at a time followed by suction. Recovered fluid on this second specimen will constitute the "lavage" sample.

Progress: The principal investigator reported that since this protocol was approved, several papers have appeared in the literature which show this technique not to be useful. In addition, studies in patients with peripheral nodules strongly indicate that BAL is not helpful in diagnosing malignancy in patients with a peripheral nodule.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-23-86	Status: Ongoing

Title: The Role of Intravenous Immune Globulin in 10% Maltose-pH 4.25 in Reducing the Mortality and Morbidity of Infection in Cancer Patients at Risk for Severe Neutropenia.

Start Date 26 Feb 86	Est Comp Date:
Principal Investigator Robert N. Longfield, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words: Globulin, immune	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 11

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To determine if prophylactic administration of high-dose IG IV to patients undergoing intensive cancer chemotherapy reduces the morbidity and mortality from infectious complications.

Technical Approach: The clinical efficacy of high dose intravenous immunoglobulin in preventing or ameliorating infections in neutropenic patients is being evaluated in a double blind - placebo controlled - multicenter trial. Consenting patiens are given weekly infusions of study agent coinciding with the onset of chemotherapy and continuing until the absolute neutrophil count rises above $500/mm^3$. Antibiotic therapy, febrile episodes and proved infections are recorded for further analysis.

Progress: Including the National Institutes of Health and Bethesda Naval Hospital, the study has accrued a total of 83 (approximate) patients to date. No complications, misadventures or adverse drug reactions have been encountered to date. No new toxicity information has become available which might affect the patient's willingness to participate.

Detail Summary Sheet

Date: 19 Mar 87	Proj No: C-29-86	Status: Terminated

Title: Assessment of Long-Term Bone Marrow Injury from Cytotoxic Chemotherapy by Culture of Pluripotential Hematopoietic Stem Cells.

Start Date 12 Mar 86	Est Comp Date:
Principal Investigator Irwin L. Levey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Chemotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): 1) To establish in vitro clonal assay for human marrow hematopoietic progenitor cells (CFU-GEMM).

2) To assess the acute and possible chronic effects of cytotoxic chemotherapy on human hematopoiesis.

Technical Approach: Patients scheduled to receive adjuvant chemotherapy will be eligible for the study if they have received no prior cytotoxic treatment; i.e., drugs or irradiation of the axial skeleton. Bone marrow aspirates will be collected on day 0 (before drug treatment) and day 14 of the first course of therapy, on day 14 of the last course of therapy, and at 8 week intervals after completion of therapy. CFU-GEMM culture will be performed as described by Ash et al. The proliferative state of CFU-GEMM will be estimated by sensitivity to radioactive thymidine.

Progress: This study was terminated at the request of the principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-30-86	Status: Ongoing

Title: Incidence and Significance of a Presystolic "A-Wave" as Determined by Doppler Echocardiography.

Start Date 12 Mar 86	Est Comp Date:
Principal Investigator Joseph P. Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Stephen D. Hoadley, MAJ, MC
Key Words: Echocardiography, Doppler	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,190.16

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: 77

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To assess the frequency and hemodynamic significance of a presystolic Doppler "A-wave", as observed in the left ventricular outflow tract.

Technical Approach: The presence of a presystolic wave has been shown in previous doppler studies of the pulmonary artery. To examine and the prsence and significance of this wave in the LVOT, two approaches are being taken. (1) Noninvasive echo/doppler studies of normal patients are being compared to patients with HTN, LVH, or aortic stenosis. (2) Simultaneous doppler and left ventricular pressure measurements are being obtained in an attempt to define significance of this finding.

Progress: Protocol is nearly complete regarding data acquisition. No complications to patients have occurred as a result of this study.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-34-86	Status: Ongoing

Title: A Trial Combination of Alpha-2 IFN and Gamma IFN in Advanced Malignant States.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC Kenneth Beougher, MAJ, MS
Key Words: Interferon, Alpha-2 Interferon, Gamma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 21

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): 1) To determine the safety/toxicity of IFN gamma when given in combination with IFN Alpha-2 in patients with advanced malignant disease.

2) Although efficacy is not a primary objective, periodic evaluations for response will be made.

Technical Approach: This will be an open label study of approximately 18 patients with advanced malignancy for whom no known standard treatment exists. Patients will be entered sequentially to the first dose level. The next dose level should not be opened to potent entry until a safety and tolerance has been assessed at the previous level.

Progress: Twenty one patients have been studied at five dosage levels. Three of six patients at the 1.0×10^6 IU/M^2 level of gamma IFN had treatment interrupted due to toxicity. At the 2.0×10^6 IU/M^2 level of gamm interferon four patients have been traeted with one patient having treatment discontinued due to cardiotoxicity. The three remaining patients at this level have had toxicities of WHO grade ≤ 2.

At present the plan is to enter at least one patient at the 4×10^6 IU/M^2 level of gamma IFN. This dose represents the maximally tolerated dosage level. By definition, six patients will be studied at the maximally tolerated dosage level.

C-34-86 (continued)

Other observed toxicities have included WHO grade ≤ 2 nausea/vomiting, transient abnormal liver functions, leukopenia and hypotension. No tumor responses have been seen.

In summary, dose limiting toxicity hsa not yet been defined and therefore a maximally tolerated dose has not been reached. Cardiotoxicity appears to be idiosyncratic in occurrence. Patient accrual continues.

Detail Summary Sheet

Date: 20 Oct 87 Proj No: C-37-86 Status: Terminated

Title: Role of Corticosteroids in the Treatment of Lung Disease in Sarcoidosis.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator (vice Matthews) James E. Johnson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators:
Key Words: Sarcoidosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): 1) To determine if findings on bronchoalveolar lavage (BAL) correlate with the activity of the disease in sarcoidosis, using clinical, radiographic, and physiologic criteria.

2) To establish the usefulness of BAL in predicting the natural history of pulmonary disease in sarcoidosis.

3) To explore the effect of corticosteroids on the natural course of lung disease in sarcoidosis.

4) To determine the utility of BAL to guide therapy with corticosteroids.

Technical Approach: Patients with biopsy proven sarcoidosis will be asked to undergo bronchoalveolar lavage. Total cell count, total protein, albumin will be obtained and lavage differential count performed. Next, we will attempt to look prospectively at the response of the lung disease on a randomized trial of corticosteroids (prednisone) versus placebo in a double blind fashion.

Progress: Only one patient was enrolled, and he was taken off the protocol and treated with steroids because of failure to improve. There are no plans to enroll more patients in this study.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-38-86	Status: Completed

Title: Evaluation of Diagnostic Significance of Hemosiderin Laden Macrophages in Bronchoalveolar Lavage Fluid.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator James H. Johnson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Harvey M. Richey, III, MAJ, MC Joseph I. Matthews, COL, MC Bruce A. Bush, MAJ, MC Herman M. Blanton, MAJ, MC David A. Goya, CPT, MC
Key Words: Lavage, bronchoalveolar	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 105

Total Number of Subjects Enrolled to Date: 105

Date of Periodic Review 18 Jun 87 Results Completed

Objective(s): To investigate the quantity of hemosiderin in alveolar macrophages in patients undergoing bronchoscopy in order to access the value of the iron stain of bronchoalveolar lavage fluid in diagnosing pulmonary hemorrhage.

Technical Approach: All patients undergoing fiberoptic bronchoscopy during the study period had bronchoalveolar lavage (BAL) performed and Prussian blue stains made of the fluid. Four of the 105 patients studied had acute alveolar hemorrhage (AAH) syndrome.

Progress: Based on a scoring system rating of a total of 100 cells, Drew et al. proposed that a score of greater than 75 out of a possible 200 was consistent with acute alveolar hemorrhage. Based on this system, three of the four had increased hemosiderin while 15 of the 101 patients without AAH also had this finding. Therefore, this finding had a sensitivity of 75%, a specificity of 85%, a positive predictive value of 16.7%, and a negative predictive value of 98.9%. In 33 patients undergoing biopsy, alveolar macrophage ehmosiderin scores from BAL fluid correlated poorly with scores from lung tissue. We conclude that while AAH is unlikely in the absence of stainable hemosiderin in BAL fluid, the presence of this finding is often due to causes other than AAH.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-44-86	Status: Terminated

Title: Review of Sternal Wound Infections: The BAMC Experience.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator J. William Kelly, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, LTC, MC
Key Words: Infection, sternal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: n/a

Total Number of Subjects Enrolled to Date: n/a

Date of Periodic Review n/a Results n/a

Objective(s): To review cases of sternal wound infections following midline sternotomy for open-heart surgery with attention to particular management strategies which may have positively or negatively affected the patients' outcome.

Technical Approach: Hospital records for patients undergoing median sternotomy at BAMC between 1975 and 1985 will be reviewed to determine those patients in whom sternal wound infection developed.

Progress: Twenty charts were reviewed. Only five true cases of mediastinitis were found; thus, there were too few cases to allow for an accurate description of the disease. Therefore, the study was terminated.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-50-86	Status: Terminated

Title: Enalapril Study.

Start Date 13 May 86	Est Comp Date:
Principal Investigator David C. Tapp, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John B. Copley, LTC, MC
Key Words: Enalapril	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To test the efficacy of enalapril as a remittive agent in the treatment of steroid-unresponsive nephrotic syndrome secondary to various disease entities and to test whether or not enalapril can slow the progression of chronic renal failure in patients with idiopathic focal segmental glomerulosclerosis and diabetic nephropathy.

Technical Approach: Patients with nephrotic syndrome will be eligible for entry into the study only if they have a biopsy confirmed diagnosis of minimal change disease, mesangial proliferative glomerulonephritis, IgM nephropathy or idiopathic focal and segmental glomerulosclerosis. Also amyloidosis complicated by nephrotic syndrome will be included.

Patients will be started on enalapril and seen in the Nephrology Clinic once a week to monitor blood pressure, serum creatinine, BUN, electrolytes, CBC and urinalysis.

Progress: This study was terminated by the principal investigator.

Detail Summary Sheet

Date: 18 Nov 87	Proj No: C-53-86	Status: Terminated

Title: Cardiovascular Monitoring of Oncology Patients Receiving Alpha and Gamma Interferon During Phase I Therapy.

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator Gregory G. Friess, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Thomas D. Brown, MAJ, MC Romel C. Wrenn, MAJ, MC
Key Words: Monitoring, cardiovascular Interferon, alpha and gamma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): 1) To assess the incidence of noteworthy cardiac ventricular and supraventricular events in patients receiving gamma and alpha interferon relative to individual patient baseline control.

2) To asssess potential cardiac myopathic events before and after administraiton of alpha and gamma interferons.

Technical Approach: A physical examination will be performed with attention being paid to the vasculature and heart. An EKG, electrolytes, and CBC will be obtained in the antecedent 24 hours to tretment. An ejection fraction will be obtained in the week prior to administration of alpha and gamma interferon. For five consecutive days prior to receiving alpha and gamma interferon the patient will determine their individual baseline cardiac rhythm by wearing a Holter monitor. Monitoring will continue during the first five days of therapy. Upon completion of therapy, repeat history and physical exam as well as repeat echocardiogram and Muga scans.

Progress: Study terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-54-86	Status: Terminated

Title: Atrial Fibrillatory Wave Size and Left Atrial Enlargement: An Echocardiographic Analysis.

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator (vice Wrenn) Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Stephen D. Hoadley, MAJ, MC
Key Words: Fibrillation, atrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): To determine if atrial fibrillatory wave size correlates with left atrial size by m-mode and 2-D echo assessment.

Technical Approach: The Data Base Search Program will be utilizd to recall electrocardiograms with an interpretation of atrial fibrillation from the CAPOC ECG Retrieval Program. The ECG tracings will be those recorded at BAMC from January 1985 through February 1986.

Progress: Study terminated due to ETS of principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-55-86	Status: Ongoing

Title: Right Heart Flow Dynamics ("Flow Dynamics in the Right Ventricular Outflow Tract" previous title)

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator (vice Hoadley) Joseph Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ares Pasipoularides, M.D., Ph.D.
Key Words: Ultrasound, Doppler	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To use Doppler ultrasound combined with high fidelity pressure measurements in the right ventricular outflow tract and proximal pulmonary artery to determine the pressure-flow relationships in that region.

Technical Approach: A complete two-dimensional and M-mode echocardiographic examination will be performed with particular attention to discovering right heart valvular disease or intracardiac shunts. Right heart catheterization with a Millar high-fidelity triple tip catheter will be performed in the standard manner. The electromagnetic flow probe will be calibrated using simultaneous Fick and thermal dilution cardiac outpus. This will be used to correlate with the doppler flow probe. Doppler ultrasound will be calibrated in the usual manner, ensuring that each strip chart has a "menu" with a stop-frame 2-D echo.

Progress: One patient has been studied; further studies are planned on a weekly basis. No complications have occurred.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-56-86	Status: Ongoing

Title: Splitting of the Second Heart Sound in Constrictive Pericarditis.

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator Lawrence E. Pupa, Jr., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Stephen R. Bailey, MAJ, MC
Key Words: Pericarditis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To evaluate the respiratory variation of the aortic and pulmonary components of the second heart sound in patients with constrictive pericarditis.

Technical Approach: Retrosepctive analysis of cases of constrictive pericarditis will be performed from among the data already obtained over the past 10 years at BAMC. All data will be analyzed by comparing at least six resting respiratory cycles in each patient at peak inspiration and end-expiration, analyzing for changes in the time intervals as well as the total $Q-A_2$ and $Q-P_2$ intervals.

Progress: Eight patients have been retrospectively entered. Awaiting final statistical analysis.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-60-86	Status: Ongoing

Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start Date 25 Jun 86	Est Comp Date:
Principal Investigator C. Kenneth McAllister, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words: HTLV-III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.)

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for future testing.

Progress: Patient accrual and information gathering continues. No data are available at this time.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-63-86	Status: Ongoing

Title: A Descriptive Study of the Relationships Between Perceived Level of Social Support and Self-Reported Symptoms of Stress in Hemodialysis Patients and Their Spouses.

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator Cynthia Collins, RN	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John B. Copley, LTC, MC
Key Words: Hemodialysis Stress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To examine the relationships between perceived level of social support and self-reported symptoms of stress, as identified by both hemodialysis patients and their spouses.

Technical Approach: This study is directed towards the observation and analysis of three interrelated research problems:

1. How does an individual's perceived level of social support influence his/her self-reported symptoms of stress?

2. What relationship exists between a hemodialysis patient's self-reported stress symptoms and his/her spouse's perception of social support availability?

3. What is the relationship between the patient-spouse combined measures of perceived social support and the spouse's self-reported stress symptoms?

Progress: Data collection completed and being analyzed.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-70-86	Status: Ongoing

Title: The Use of Nebulized Cromolyn in Status Asthmaticus

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator Gabriel E. Gonzalez, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy	Associate Investigators: Ana A. Ortiz, LTC, MC
Key Words: Asthma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine whether nebulized cromolyn can alter the immediate and the post-hospitalization period of status asthmaticus.

Technical Approach: Patients admitted from the ER or specialty clinics with the diagnosis of status asthmaticus will be entered into the study. All asthmatics will be treated according to established criteria. Patients will be randomly assigned to two study groups. Group I will receive 20 mg of nebulized cromolyn and Group II will be given nebulized saline.

Progress: The principal investigator is in private practice. If a resident or fellow is interested, we will proceed with the project.

Detail Summary Sheet

Date: 21 Oct 86	Proj No: C-74-86	Status: Ongoing

Title: Intensive Chemotherapy, Delayed Local Irradiation, Total Body Irradiation and Autologous Bone Marrow Rescue in Treating High Risk Ewing's Sarcoma

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator (vice Harvey) Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC Paul J. Thomas, COL, MC Barbara Reeb, GS-9 John J. Posch, Jr., GS-11
Key Words: Sarcoma, Ewing's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To improve disease-free survival of patients with Ewing's sarcoma having a high risk of treatment failure.

2) To test the effectiveness of intensive induciton chemotherapy, delayed RT to the primary tumor and TBI with ABMR.

3) To test the toxicity of such a regimen.

4) To test the accuracy of currently available staging techniques and monitoring techniques in recognizing residual primary and metastatic tumor.

5) To test whether tumor size independently of other variables predicts long-term disease-free survival.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been treated to date and remains in complete remission 12+ months from treatment.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-77-86	Status: Ongoing

Title: A Phase I Evaluation of DUP 785 in Cancer Patients on a Single Daily Intravenous Dosing Schedule Over a 5-Day Period

Start Date 14 Aug 86	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 27 (14 BAMC)
Total Number of Subjects Enrolled to Date: 27 (14 BAMC)
Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To determine the maximally tolerated dose of DUP 785 in cancer patients following intravenous dose administration over a 5-day period, with repeats every four weeks.

2) To determine the qualitative and quantitative and reversibility of adverse reactions of DUP 785 administered in this fashion.

3) To determine the dose limiting toxicity of DUP 785.

4) To determine the pharmacokinetics of DUP 785.

5) To document any antitumor activity of DUP 785 in cancer patients.

Technical Approach: All patients with histologic proof of malignancy who are not candidates for known regimens or protocol treatments of higher efficacy or priority are eligible. Patients must have a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: To date 27 patients have received 60 courses of DUP 785 ranging from 36 to 170 mg/M^2. Dose limiting toxicity has not been reached. Non-dose limiting toxicities have included malaise, nausea/vomiting, leukopenia, anemia, and thrombocytopenia. Three cardiac events have occurred on study, with two these events at BAMC. One patient suffered a subendocardial infarction on day 7 course 2 of DUP 785 as a complication of cancer related recurrent seizures. These events were not felt drug related. A second patient developed a sinus tachycardia during his second course of DUP 785 with associated malaise, fatigue and a monocytosis in the peripheral blood. Follow-up Muga scan revealed a drop

in left ventricular ejection fraction from a baseline of 54% to 41%. This picture was felt most consistent with a viral syndrome and associated cardiomyopathy, yet drug toxicity could not be ruled out. The patient at UTHSCSA appeared to have suffered a silent anteroseptal myocardial infarction on day 28 course 5 of DUP 785. Again, drug related toxicity could not be excluded.

Adverse drug reaction forms have been submitted on the above patients, and amendments to the protocol have been submitted which will prohibit entry of patients with active/significant cardiovascular disease and also increase the intensity of cardiovascular monitoring on all on-study patients. Immediate plans are to dose escalate to the 210 mg/M^2 level and to stratify patients into good and poor risk categories (re: prior treatment), to see if different maximally tolerated doses exist for each of these categories.

Detail Summary Sheet

Date: 11 Aug 87	Proj No: C-85-86	Status: Ongoing

Title: Evaluation of Right and Left Ventricular Performance During V.V.I. and D.V.I. Pacing

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator John P. Mulrow, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: A. Pasipoularides, M.D., Ph.C.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To describe ejection and hemodynamic parameters for right and left ventricular function before and during cardiac pacing.

Technical Approach: Eligible patients will be divided into three groups as follows: Group A - Ten patients with normal ventricular function demonstrated by a normal EKG, chest x-ray, cardiopulmonary physical examination, and echocardiogram; Group B - ten patients with a history of single myocardial infarction documented by prior hospitalization or EKG; Group C - ten patients with global left ventricular dysfunction demonstrated by physical examination, chest x-ray, and EKG, who demonstrate no symptoms of ischemic heart disease and have normal coronary anatomy. Each group will undergo resting and left Millar triple-tip hemodynamics with flow and determination of cardiac output followed by atrioventricular pacing with decreased atrioventricular conduction time. Atrioventricular pacing will then be terminated and V.V.I. pacing will commence. Right and left Millar triple-tip hemodynamics with flow and thermal dilution during V.V.I. will be performed.

Progress: No patients have been enrolled in the pacing induced ventricular function study. Priority for patients had been given to other protocols.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-86-86	Status: Terminated

Title: Arrhythmia Variability in the Elderly

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator John P. Mulrow, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Romel C. Wrenn, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Terminate

Objective(s): To evaluate the variability of asymptomatic ventricular arrhythmias for a period of one year in stable cardiac outpatients over the age of 65.

Technical Approach: Patients meeting the criteria for inclusion in this study will undergo the following: (1) baseline 72-hour Holter monitoring, MUGA, 12-lead ECG; (2) repeat 72 hour ECG monitoring and 12-lead ECG at 4, 8, and 12 months; (3) final MUGA will be obtained at 12 months.

Progress: Due to the fact that MASJ Wrenn is no longer at BAMC and Dr. Mulrow does not have sufficient to continue with this project, the study is terminated.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-91-86	Status: Completed

Title: Evaluation of Photoprotective Properties (Sun Protection Factors) of Certain Formulations Containing Antioxidants

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator (vice Kraus) James H. Keeling, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Madhu Pathak, M.B., Ph.D., Harvard Medical School
Key Words: Sunscreens	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 17

Total Number of Subjects Enrolled to Date: 17

Date of Periodic Review 10 Sep 87 Results Completed

Objective(s): To establish and evaluate: (1) whether the commonly used antioxidants are beneficial to human skin when incorporated into sunscreen formulations; and (2) whether these inredients influence melanogenesis.

Technial Approach: Ten to twelve volunteers of skin types III and IV will be studied. Five formulations labeled as 1,2,3,4, and 5 will be applied to rows A,B,C,D, and E. Leave center row labeled as MED as control row. The product treated sites and control sites will be exposed to 1, 2, and 3 times the MED of UVB radiation. Observations on skin erythema and tanning response will be done on days 2, 3, and 8 after exposure.

Progress: Seventeen (17) patients were studied for assessment of sunscreening properties with antioxidants. Preliminary data suggests that at one minimal erythema dose, there is protection from erythema and inhibition of delayed tanning. There seems to be no effect of the antioxidants on either erythema or tanning once one MED is excluded.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-94-86	Status: Ongoing

Title: Human Pyloric Response to Intraduodenal Blood: A Manometric Study

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator Julian E. Armstrong, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine the association between the presence of blood in the duodenum and pyloric manometric response.

Technical Approach: Forty patients will be studied; 20 would be controls (normal endoscopic exam of duodenum) and 20 patients would have duodenal ulcers. All patients would undergo endoscopi exam in the standard manner. At the completion of the diagnostic exam, pyloric sphincter measurements will be made.

Progress: Five patients have been enrolled without incident. The principal investigator has been reassigned to Europe but may be able to continue the study if the necessary equipment is available. If not, a new principal investigator will be assigned at BAMC.

Detail Summary Sheet

Date: 21 Aug 87	Proj No: C-96-86	Status: Completed

Title: Blood Pressure and the Rolled up Armsleeve. Does It Matter?

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator David R. Wood, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Internal Med.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 51

Total Number of Subjects Enrolled to Date: 51

Date of Periodic Review 10 Sep 87 Results Completed

Objective(s): To investigate the accuracy of a blood pressure taken in the usual manner with the arm sleeve rolled up about the proximal arm.

Technical Appraoch: The right or left arm will be selected based upon a random number sequence. A 1 inch by 24 inch mercury gravity sphygomomanometer will be applied proximately to mimic the rolled up armsleeve. A zero-muddler mercury manometer will then be applied more distal and approximately one inch proximal to the anticubital fossa. The zero muddler manometer will be inflated to 250 mmHG for each determination of the blood pressure. Blood pressure will be recorded with 0, 20, 40, 60, 80, and 100 mmHg applied.

Progress: There appears to be no clinically significant alterations of blood pressure with the method used.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-2-87	Status: Ongoing

Title: Percutaneous Transluminal Valvuloplasty in Adult Mitral/Aortic Stenosis

Start Date 19 Nov 87	Est Comp Date:
Principal Investigator Steven R. Bailey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Robert A. Helsel, COL, MC Brent A. Grishkin, COL, MC
Key Words: Stenosis, aortic Stenosis, mitral	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To apply the technique of percutaneous balloon dilatation of valvular aortic/mitral stenosis to a patient population at high risk of morbidity and mortality from aortic/mitral valve replacement and/or chronic anticoagulation.

Technical Approach: All patients age 21 or older with hemodynamically proven symptomatic aortic stenosis of either calcific/degenerative or congenital etiologies or patients age 21 or older with hemodynamically proven, significant mitral valve stenosis will be eligible if they are clinically considered to be a high risk for surgical valve replacement or chronic anticoagulation. Cardiac catheterization and valvuloplasty will be performed as outlined in the study protocol.

Progress: This is a clinical trial based on patients at high risk for surgery. To date no patients unacceptable to surgery have been identified.

Detail Summary Sheet

Date: 30 Apr 87	Proj No: C-4-87	Status: Completed

Title: The Tilt Test: Determination of Normal Ranges in Patients on Medication for Chronic Medical Conditions

Start Date 19 Nov 86	Est Comp Date:
Principal Investigator Carlos Angueira, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Internal Med.	Associate Investigators: Fred Goldner, COL, MC Regina Marshall, RN
Key Words: Tilt test	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine orthostatic variations in blood pressure and pulse in asymptomatic patients on medications for chronic medical problems, to include hypertensive patients on diuretics, beta blockers, or a combination of these, as well as insulin and non-insulin dependent diabetics.

Technical Approach: One hundred and thirty-three asymptomatic outpatients (34 diabetics, 28 patients on diuretics plus beta blockers, 31 patients on diuretics alone, 20 patients on beta blockers alone, and 20 patients on clonidine) underwent Tilt Testing. Pulse and blood pressure determinations were made in the supine position and repeated immediately upon standing and again two minutes later. The readings obtained from each subgroup were compared to 33 age and sex matched controls who had no medical problems and were on no medications.

Progress: The Tilt Test is a commonly used clinical tool in the assessment of volume depletion. Most data pertaining to the normal limits of the Tilt Test were determined by studying normal, healthy volunteers. However, many patients presenting with possible volume depletion may have medical complications (e.g., diabetes) or are taking medications (e.g., antihypertensives) which may affect the cardiovascular response to orthostasis.

C-4-87 (continued)

The data indicate that in patient groups as defined in this study there were no significant differences in othostatic vital signs when compared to a control population. The clinical implication is that when such patients present with clinical orthostasis (dizziness, syncope), these findings cannot be attributed to underlying disease or medications, and true volume depletion should be suspected.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-8-87	Status: Ongoing

Title: Effect of Fish Oil Supplementation on Essential Hypertension

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Edwin J. Whitney, MAJ, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joe M. Moody, Jr., LTC, MC Stacey Adams Mary Dunn, MAJ, MC
Key Words: Hypertension Fish oil	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 79

Total Number of Subjects Enrolled to Date: 79

Date of Periodic Review _____ Results _____

Objective(s): To determine whether or not fish oil supplementation (eicosapentanoic acid [EPA] and docosahexanoid acid [DHA]) can lower blood pressures in patients with essential hypertension.

Technical Approach: Patients referred to the Cardiovascular Risk Clinic will be eligible for this study. The patients will attend the cardiovascular risk management program with at least three follow-up visits at six week intervals. Two hundred eligible patients will be block randomized in a double blind manner to the fish oil supplement (20 ml in gelatin capsules) or an identical appearing placebo (10 ml oilive oil in gelatin capsules). The patient will consume the fish oil supplement or the placebot for eight weeks.

Progress: Seventy percent of the patients have a significant reduction in systolic, diastolic or mean arterial blood pressure. The placebo had no significant effect on blood pressure.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-9-87	Status: Ongoing

Title: Effect of a Commercially Available Fish Oil Preparation on Serum Lipids in a Group of Patients with Documented Coronary Artery Disease

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Edwin J. Whitney, MAJ, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Mary Dunn, MAJ, MC Stacey Adams
Key Words: Fish oil Coronary artery disease Hyperlipidemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 79

Total Number of Subjects Enrolled to Date: 79

Date of Periodic Review _____ Results _____

Objective(s): To determine the effect of commerdially available fish oil preparations containing eicosapentanoic acid (EPA) and docosahexanoic acid (DHA) on serum lipids in a large group of patients with hyperlipidemia and documented coronary a-tery disease.

Technical Approach: Patients who have attended the cardiovascular factor modification risk clinic and who have demonstrated stable total cholesterol, triglycerides, HDL cholesterol and weight levels over a four month period will be eligible for this study. The patients will receive four hours of detailed instruction in risk factor modification in the Cardiovascular Risk Clinic. Serum lipids will be determined at six week intervals. After lipid and weight stabilization, the patients will be blod randomized in a double blind manner to fish oil or placebo. The fish oil supplementation will be to 3.6 gm per day of EPA and 2.4 gm of DHA. This amount of EPA and DHA is contained in roughly 20 ml of fish oil (which will be supplied in 325 mg capsules). The placebo will be identical appearing capsules containing olive oil. The supplements will be administered for 8 weeks. Serum lipids will be determined at 2 week intervals.

Progress: Serum triglycerides were significantly reduced in virtually all patients consuming fish oil. The placebo had no effect. There was no consistent effect on cholesterol or HDL cholesterol by the fish oil or the placebo.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-10-87	Status: Ongoing

Title: Effect of Reducing the Total Cholesterol/HDL Cholesteral Ratio to Less than 3.0

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Edwin J. Whitney, MAJ, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Mary Dunn, MAJ, AN Stacey Adams
Key Words: Cholesterol, total Cholesterol, HDL	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): To determine the effect of reducing the TC/HDL cholesterol ratio to less than, or equal to 3.0 in patients with angiographically documented coronary artery disease.

Technical Approach: Patients who have received cardiac catheterizations within 3 months of entry and have measurable stenoses will be eligible. One hundred patients will be randomized to a control group or the active treatment group. The control group will receive the routine cardiac rehabilitation program. They will not receive lipid lowering medications. Patients in the active treatment group will receive detailed instructions in risk factor modification and followed serially every 6 weeks to ensure optimization of serum lipids. Primary intervention will consist of diet and lifestyle changes (exercise, stop smoking, diet, weight loss); however, medications will be used in those whose ratio of TC/HDL remains above 3.0. Standard lipid lowering agents will be used to optimize the TC/HDL cholesterol ratio and total cholesterol.

Progress: It was determined that the control population was too difficult to recruit for enrollment. We will probably select catheterized patients who have undergone aggressive therapy and have lowered their TC/HDL rates to less than 3.0. There are only five patients who have achieved this goal therapeutically.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-11-87	Status: Ongoing

Title: Atrial Natriuretic Peptide and Hemodynamics in Orthotopic Cardiac Transplantation.

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator (vice Mulrow) Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: John B. Copley, COL, MC
Key Words: Transplantation, cardiac	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review_____ Results_____

Objective(s): To examine the relationship of cardiac pressures, atrial natriuretic peptide levels and catecholamine levels during rest and exercise in patients with orthotopic cardiac transplantation.

Technical Approach: To assess the responsiveness of atrial natriuretic factor (ANF) in orthotopic cardiac transplantation (TX), we obtained peripheral (P) and central (PA) ANF levels at rest (R) and exercise (E) in 4 patients (pts) on a high salt diet (200 mEq sodium [NA], 80 mEq potassium). There were 3 females, a 1 male, mean age 42±16 years who were 10±3.0 months post-TX, clinically stable and free from rejection on biopsy. Medications except for immunosuppressives were stopped before study. Daily 24 hour urine collections documented NA balance and serum creatinine was less than 1.5 mg/dl in all pts. ANF determinations (pg/ml) were performed on extracted plasma. Simultaneous right and left hi-fidelity hemodynamics were obtained with P and PA ANF levels at R and E.

Progress: While ANF levels increased from P to PA at R and E, only increases from PA R to PA E (178±69 to 452±260) were significant ($p<0.05$). A significant increase in RA from R to E occurred (6±1 to 26±2) but did not correlate with R and E changes in PA ANF levels.

We conclude ANF can respond in the TX heart to a high salt diet and exercise. Mechanisms of release of ANF are not clear.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-12-87	Status: Ongoing

Title: Clinical and Outpatient Follow-up of Cardiac Transplantation

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator (vice Mulrow) Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC
Key Words: Transplantation, cardiac	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To describe the evolution and present state of the art for cardiac transplantation and to describe the clinical follow-up of patients at BAMC.

Technical Approach: Patients referred by BAMC for cardiac transplantation to institution(s) in San Antonio will return to Brooke following the immediate postoperative care at the surgical center. At each follow-up visit, the following will be obtained: ECG, urine analysis, creatinine clearance, chest x-ray, CBC, PA20, cyclosporin level and titers for cytomegalic herpes and varicella virus. Five-day ambulatory ECG monitoring, radionuclide assessment of diastolic, systolic function, and echo cardiography Doppler will be performed at appropriate intervals. Endomyocardial biopsies to detect rejection will be performed weekly for the first six weeks, monthly for the next six to seven months, and then every two to three months for life.

Progress: Patient enrollment and data collection are ongoing.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-13-87	Status: Ongoing

Title: Evaluation of Biventricular Performance in the Deinnervated Heart

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator (vice Mulrow) Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Ares Pasipoularides, M.D., Ph.D.
Key Words: Heart, deinnervated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review n/a Results

Objective(s): To examine the following biventricular parameters in the deinnervated heart at rest, volume expansion (leg raising) and submaximal dynamic exercise: (1) systolic ejection indices; (2) pressure volume loops; (3) diastolic indices of stress-strain; and (4) hemodynamic response to Valsalva and Mueller maneuvers.

Technical Approach: To evaluate the exercise (E) response in cardiac transplant (Tx) patients (pts) on cyclosporine, we performed right and left heart catheterization at rest (R) and supine bicycle (E) using multisensor high fidelity catheters. Four pts (3 females, 1 male) mean age 47±15 years, mean 10±months post transplant, who were clinically stable and free of rejection by biopsy were studied off cardiac medications.

Progress: Simultaneous right and left heart hemodynamics were similar to central (C) except for increased peripheral resistance (rp), mean aortic pressure (Ao) and decreased stroke work index (SWI). With E, Tx pressures (mmHg ± SD) were increased vs C for LVED (22±4) vs (10±4) right atrial (16±2 vs 4±2) and RVED (16±3 vs 7±3). SWI in Tx was unchanged with E vs R (.44±.05 vs .41±07 joules/m^2). in contrast to C (0.54±12 vs 0.76±18). Resting Rp was elevated (2267±670 $d*x*cm^{-5}$), decreased with E but remained greater than C with E (1195±322 vs 773±223) $d*s*cm^{-5}$). We find persistent significant biventricular diastolic and mild systolic dysfunction determined invasively with supine exercise stress almost one year post-operation.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-14-87	Status: Ongoing

Title: Prospective Randomized Clinical Trial of the Capillary Cloning System for Patients with Extensive Small Cell Lung Cancer

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator (vice Friess) Arlene J. Zaloznik, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, small cell lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review_____ Results_____

Objective(s): To perform a prospective randomized single agent clinical trial of the newly developed capillary cloning system.

Technical Approach: A portion of tumor will be removed and sent to the laboratory for capillary cloning to determine which drugs will or will not be effective in the treatment of small cell lung cancer.

Progress: Five patients were registered on this study. All are off study - 4 disease progression; one early death due to exacerbation of COPD - not drug related.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-18-87	Status: Ongoing

Title: Use of Lysine Vasopressin in the Treatment of Hemodialysis Induced Hypotension

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator Jill S. Lindberg, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John B. Copley, COL, MC Kenneth Melton, MAJ, MC
Key Words: Hypotension Hemodialysis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review_____ Results_____

Objective(s): To assess the serum levels of ADH, catecholamines and renins in patients with unknown dialysis induced hypotension.

Technical Approach: We are evaluating use of intranasal lysine vasopressin vs. intranasal placebo in controlling dialysis induced hypotension.

Progress: We have found significantly less hypotensive episodes with lysine vasopressin intranasal spray.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-20-87	Status: Ongoing

Title: Analysis of Frequency of HTLV-III Seropositivity in a Hemodialysis, Peritoneal Dialysis and Transplant Population and Its Implication Concerning Current Methods of Staging of HIV Associated Disease

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator William G. Wortham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John B. Copley, COL, MC David G. Burleson, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To demonstrate the overall T-cell count including T-cell subsets in our chronic hemo and peritoneal diaglysis population and renal transplant population.

2) To determine and compare delayed cutaneous hypersensitivity in both end stage renal disease patients and normal controls.

3) To compare the T-cell subsets and absolute lymphocyte counts in HIV+ and HIV- end stage renal disease patients.

4) To determine the frequency of HLA-D, Dr4 antibodies in the serum of end stage renal disease patients, false positive patients, and controls.

Technical Approach: The Walter Reed Staging System for HIV infection utilizes the response of patients to a standard anergy panel (delayed hypersensitivity) as well as the absolute number of T_4 (helper) cells per cubic millimeter of blood to assess HIV-related disease propagation. To determine whether this method of staging for HIV infeciton can be applied to the dialysis patient, we performed a prospective evaluation of this population based on the Walter Reed System. Thus, total T-cell subsets in HIV Elisa negative dialysis patients were compared to HIV Elisa negative controls. In addition, we assessed delayed hypersensitivity by application of a standard anergy panel to dialysis patients and healthy controls.

Progress: We found that total lymphocytes, total and percentages of OKT_3, OKT4, OKT11 and Leu-3-positive cells were significantly less in dialysis patients compared to controls. This negative trend did not appear to be a function of time on dialysis in months. Delayed hypersensitivity was severely depressed in dialysis patients and normal in controls.

C-20-87 (continued)

We conclude that the current method of staging HIV infections by the Walter Reed system cannot be applied to the dialysis patient because of inherent immunologic abnormalities associated with end-stage renal disease.

Detail Summary Sheet

Date: 17 Nov 87	Proj No: C-23-87	Status: Ongoing

Title: Open-Label Phase I Study to Evaluate the Safety of Recombinant Beta Interferon (Betaseron--IFN-B_{ser}) Given Intravenously in Combination with 5-Fluorouracil (5FU) in Patients with Advanced Cancer

Start Date 17 Feb 87	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Departmentof Medicine/Oncology	Associate Investigators:
Key Words: Beta Interferon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine maximal tolerated dose for Betaseron when given by intravenous injection in a dose of 45, 90, 180, 270, or 360 x 10^6 IU, once a day, 3 days a week in combination with 5FU therapy.

2) To determine safety and tolerance of the stated combination regimen in these patients.

Technical Approach: Patients with histologically confirmed carcinoma of the lung, liver, biliary system, pancreas, stomach, esophagus, small intestine, colon, or rectum are eligible for this study. The malignancy must be surgically incurable and not treatable with any standard antineoplastic therapy known to be effective.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into the study.

Detail Summary Sheet

Date: 18 Nov 87	Proj No: C-24-87	Status: Ongoing

Title: A Multicenter Open Label Phase II Study to Evaluate the Safety and Efficacy of Escalating Doses of IFN-B_{ser} Given Intravenously in Patients with Advanced Renal Cell Carcinoma, Melanoma, or Non-Small Cell Lung Cancer

Start Date 17 Feb 87	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Beta Interferon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): 1) To determine maximum tolerated dose when IFN-B_{ser} is given by intravenous injeciton in doses escalating from 90 to 540 x 10^6 IU, on a once-a-day Monday, Wednesday, and Friday schedule for 12 weeks or longer in patients with measurable renal cell carcinoma, melanoma, or non-small cell lung cancer

2) To determine the safety, tolerance, and therapeutic effect of IFN-$_{ser}$ when given in the stated regimen.

Technical Approach: Patients with histologically confirmed renal cell carcinoma, melanoma, or non-small cell lung cancer, incurable by radiation or surgery are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on the study.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-25-87	Status: Completed

Title: Uncontrolled Clinical Trial of the Long-Term Safety of AZT™

Start Date 18 Feb 87	Est Comp Date:
Principal Investigator Clifton A. Hawkes, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words: AZT AIDS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review_____ Results_____

Objective(s): To provide for the administration of AZT to eligible patients with careful supervision, and to monitor survival, disease progression and toxicity.

Technical Approach: AIDS patients who have recovered from one or more episodes of histologically confirmed *Pneumocystis carinii* pneumonia without AIDS-defining condition(s) presently requiring system chemotherapy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The one patient entered on this study died of progressive disease. Since the drug has been released by the FDA and is no longer considered investigational, the study is completed.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-26-87	Status: Completed

Title: A Seven Year Retrospective Review of Transbronchial Biopsy without Fluoroscopy

Start Date 1 Mar 87	Est Comp Date:
Principal Investigator Gregg T. Anders, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: James E. Johnson, MAJ, MC Howard M. Richey, MAJ, MC Joseph I. Matthews, COL, MC
Key Words: Fluoroscopy Biopsy, transbronchial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 247

Total Number of Subjects Enrolled to Date: 247

Date of Periodic Review_____ Results_____

Objective(s): To compare the efficacy and complication rate of transbronchial biopsies (TBB) performed with and without fluoroscopic guidance done during the same seven year period.

Technical Approach: All cases involving fiberoptic bronchoscopy done by the Pulmonary Disease Service at BAMC were reviewed from 1980 thru 1986. In the total 1,232 fiberoptic bronchoscopies performed, 247 transbronchial biopsies were obtained. Of these cases, 135 transbronchial biopsies were done without fluoroscopy, and 112 were performed with fluoroscopy. Of the 135 done without fluoroscopy, 127 (94%) were performed via the transnasal approach.

Progress: The incidence of pneumothorax was low in both groups (one pneumothorax in the group without fluoroscopy and one in the group with fluoroscopy). In the patient group having transbronchial biopsy in the lower lobes, there was no pneumothorax. In the group of patients who had transbronchial biopsy without fluoroscopy, 3 (2.2%) experienced post-biopsy fever, and none had hemoptysis requiring transfusion. In the group of patients biopsied without fluoroscopy, 77 cases of diffuse disease were reviewed, and in 54 of these cases (77%) a definitive histopathologic or strong presumptive

diagnosis was made. The highest yield was observed in Stage II and III sarcoidosis patients (30 of 34 patients, or 88.2%). The yield of Stage I sarcoidosis and in other diffuse processes was lower but comparable to data presented in other studies.

We conclude that transbronchial biopsy via the fiberoptic bronchoscope without fluoroscopic control in the lower lobes is a safe procedure with a reasonable diagnostic yield.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-28-87	Status: Ongoing

Title: Free 1.25-dihydroxyvitamin D_3 Levels in Patients with Renal Failure and in Patients Who Have Received Successful Renal Transplants

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Cushner) Jill Lindberg, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators:
Key Words: Transplant, renal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review_____ Results_____

Objective(s): To determine the level of serum free 1.25-dihydroxy Vitamin D_3 ($1.15\text{-}(OH)_2D_3$) levels in patients with moderate chronic renal failure, end-stage renal disease, and those patients with renal failure who have received a successful renal transplant.

Technical Approach: 1.25-dihydroxy Vitamin D_3 levels will be drawn on patients prior to and 6-8 weeks post transplant.

Progress: Vitamin D levels are being assayed.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-29-87	Status: Ongoing

Title: Influence of Campylobacter pyloridis Associated Non-Ulcerative Gastritis on Gastric Emptying

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator Christophe N. Barrilleaux, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words: Campylobacter pyloridis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 22

Total Number of Subjects Enrolled to Date: 22

Date of Periodic Review_____ Results_____

Objective(s): To evaluate the effect of histologically proven, Campylobacter pyloridis infection associated, non-ulcerative gastritis on solid-phase gastric emptying.

Technical Approach: Study to evaluate the effect, if any, on solid phase gastric emptying of Campylobacter pyloridis related non-ulcerative gastritis as measured by nuclear solid phase gastric emptying studies. Also involved in the study is an evaluation of the utility of cytologic brushings to detect the presence of Campylobacter pyloridis in the gastric antrum. Plan is to obtain 40 patients randomized to a cross-over group (evaluated after 2 weeks of "routine" therapy as prescribed by the primary physician, and also after 2 weeks of combination therapy with Pepto-Bismol and Amoxicillin), and a treatment group (evaluated before and after 2 week course of combination therapy with Pepto-Bismol and Amoxicillin).

Progress: Results are still inconclusive. This is mainly due to the fact that finalization of study results from the gastric brushings and the solid phase emptying studies are not as yet complete. No adverse reactions, misadventures or complications have been noted.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-36-87	Status: Terminated

Title: Balloon Expandable Intracoronary Stents (BEIS) in Human Cadaver Hearts

Start Date 17 Mar 87	Est Comp Date:
Principal Investigator Richard A. Schatz, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Julio Palmaz, M.D., University of Texas Health Science Center
Key Words: Balloon expandable intracoronary stents	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To further define the biological response to balloon expandable intracoronary stents in human atherosclerosis.

Technical Approach: Study subjects will consist of 10 consecutive fresh human cadaver hearts identified to have ASHD identified at the time of autopsy. The cadaver heart will be positioned on a radiolucent prep tray to approximately a standard 30° RAO angiogram. Through IV tubing sutured into the right and/or left main coronary artery, 10-15 cc's of contrast material will be hand injected under portable fluoroscopy. After identifying the target lesion, an appropriately sized standard balloon catheter (with a BEIS mounted) will be passed coaxially over a standard guidewire across the lesion. One dilatation to 6-10 ATM of pressure will be performed and the balloon deflated, then removed (leaving the BEIS behind). Arteriography will be repeated. The stented arterial segment will be surgically excised and placed in formalin to be prepped and section by Pathology (UTHSC).

Progress: This study was terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-37-87	Status: Ongoing

Title: Phase II Study of Carbetimer in Lung Carcinoma

Start Date 18 Mar 87	Est Comp Date:
Principal Investigator (vice Friess) Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Carbetimer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine the response rate and response duration in subjects with advanced non-small cell carcinoma of the lung treated with carbetimer.

2) To define the qualitative and quantitative toxicities of carbetimer administered in a Phase II study.

Technical Approach: For inclusion in the study, all subjects must have a histologic diagnosis of recurrent or metastatic non-small cell cacner of the lung. Subjects with recurrent or metastatic non-small cell cancer of the lung must be previously untreated except for surgery and/or radiotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to report any meaningful results.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-39-87	Status: Completed

Title: Does Phenylpropanoloamine Affect Blood Pressure in Mildly Hypertensive Patients?

Start Date 6 Apr 87	Est Comp Date:
Principal Investigator Deborah Omori, MAJ, Mc	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Internal Med.	Associate Investigators: Kurt Kroenke, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2,298.00

Number of Subjects Enrolled During Reporting Period: 26

Total Number of Subjects Enrolled to Date: 26

Date of Periodic Review_____ Results_____

Objective(s): To evaluate the effects of phenylpropanolamine (PPA) on blood pressure in mildly hypertensive patients taking the usual dose found in over-the-counter (OTC) preparations.

Technical Approach: We conducted a prospective, double-blind, placebo-controlled crossover study using 24-hur ambulatory blood pressure recordings. Compliance was measured using pill counts and PPA drug levels. Participants were obtained through the use of a survey form in the Internal Medicine Clinic. Volunteers were asked to participate if they had stable, mild hypertension, treated or untreated, with systolic pressures less than 160 and diastolic pressures less than 100 on three recent readings. Participants were either on no antihypertensive drug, a diuretic alone, an ACE inhibitor, a beta-blocker, or a combination of these drugs. No one was on an alpha-blocker. Volunteers were excluded if they had moderate or severe hypertension, coronary artery disease, peripheral vascular disease, renal insufficiency, and ischemic or conduction changes on ECG. Subjects with glaucoma or urinary retention were also excluded. The dose of PPA used was that approved by the FDA (25 mg q 4h). The half-life of PPA is 5.6 hours and a steady state concentration should be achieved after 28 hours. Subjects were randomly assigned to take PPA capsules one week and placebo capsules the other week for 2½ days each week. On the 2nd day of each phase (30 hours after starting the capsules), a 24-hour blood pressure recorder was applied. Readings were programmed for every hour. The subject returned 24 hours later for monitor removal and blood collection for PPA levels.

Progress: Twenty-six volunteers were entered with a mean age of 57. There were 14 men and 12 women with 73% Caucasian, 15% Blacks and 12% Others. Fifteen

C-39-87 (continued)

percent were on no drugs, 42% on diuretic alone, 12% on ACE inhibitor ± diuretic, and 31% on beta-blocker ± diuretic or ACE inhibitor. No clinically significant differences (using paired t-test) in systolic blood pressures were found. Likewise, no clinically significant differences were found with respect to diastolic pressures, mean pressures or heart rate. Compliance based on pill counts was excellent (98% of total prescribed capsules were taken).

Immediate release phenylpropanolamine was not found to cause a clinically significant increase in systolic or diastolic pressure nor did it significantly affect heart rate in our mildly hypertensive participants. We conclude that PPA, when used at the recommended FDA dosage, does not increase blood pressure and can be used in the stable mild hypertensive patient.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-41-87	Status: Ongoing

Title: Shortening of Left Ventricular Isovolumic Contraction Time During Exercise in Normal Man

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Joe M. Moody, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Johns, MAJ, MC Ares Pasipoularides, M.D., Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 9

Total Number of Subjects Enrolled to Date: 9

Date of Periodic Review n/a Results

Objective(s): To assess, using noninvasive tools, the relative timing of mitral valve closure and aortic valve opening at rest and during exercise in normal volunteers.

Technical Approach: Simultaneous M-mode echocardiography of aortic and mitral valves isperformed during upright bicycle exercise in normal volunteers. Recordings are obtained at increasing heart rates to assess changes in MC-AO interval.

Progress: Nine subjects have been enrolled thus far with good technical quality in six. Data analysis will be started shortly.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-42-87	Status: Ongoing

Title: Total Systemic and Regional Aortic Compliance at Rest and with Exercise

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Edward A. Matthews, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To compare compliance as determined by a three-element wind-kessel arterial model (using aortic input pressure and flow) at rest and with exercise, to compliance determined by the standard RC model in normal man.

2) To compare aortic compliance by each method in normal and hypertensive patients.

3) To evaluate the regional proximal aortic contribution to the total systemic capacitance.

Technical Approach: To evaluate the exercise response of systemic compliance (C) and arterial elastance (E_a), supine bicycle exercise was performed during cardiac catheterization in 10 hypertensive (H) patients and compared to 10 normotensive (H) controls. Steady state high fidelity LV and aortic root pressures and thermodilution cardiac outputs were measured at baseline and with exercise. Digitized Ao signals and systemic resistance (R) were used to calculate C from a monoexponential RC model. Estimates of E_a were calculated from end-systolic pressure/stroke volume.

Progress: Respective resting N & H mean Ao, pulse pressure, R, tau, E_a and C were similar. With exercise, C decreased in H vs an increase in N. The change in $1/E_a$ was lower for H vs N and with less an increase in cardiac output in H vs N. Changes in heart rate, R, mean Ao, and pulse pressure were not different. Resting invasive hemodynamics and C did not differentiate middle-aged H vs N but significant differences in C and $1/E_a$ occurred with supine exercise.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-43-87	Status: Ongoing

Title: Silent Myocardial Ischemia in Diabetic Patients with Cardiac Autonomic Dysfunction

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator David M. Slife, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): To evaluate diabetic patients to determine if there is a correlation between autonomic dysfunction and silent cardiac ischemia.

Technical Approach: Each participant will undergo five separate tests in evaluation of autonomic neuropathy. In evaluation of silent myocardial ischemia, a holter monitor for 48 hours, exercise stress test with thallium, and exercise MUGA scan will be performed.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-44-87	Status: Ongoing

Title: Follow-up of Hot Biopsy Forceps Treatment of Diminutive Colon Polyps

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Francis E. Peluso, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words: Polyp Hot biopsy forceps	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 23

Total Number of Subjects Enrolled to Date: 23

Date of Periodic Review_____ Results_____

Objective(s): 1) To determine whether hot biopsy forceps technique destroys diminutive (< 5mm) polyps.

2) To determine the extent of surrounding tissue damage induced by this technique.

Technical Approach: Twenty-five subjects undergoing routine colonoscopy requiring hot biopsy will be entered into the study. Patients will have the hot biopsy forceps procedure used in accordance with standards of practice. To be included, at least one of the biopsies will have been obtained in the recto-sigmoid colon, so as to be easily accessible with a follow-up flexible sigmoidoscopy. At the time of colonoscopy, the physician will make specific note of the biopsy location, coagulation current setting, duration of current, and any complication. Each subject will then undergo flexible sigmoidoscopy on days 5-7 and 12-14 post-biopsy. Photographs of the biopsy site(s) will be obtained and ulcer diameter measured using a measuring wire.

Progress: Study will be completed with two additional patients. No complications to date. A surprisingly high percentage of patients have residual polyp(s).

AD-A190 939 ANNUAL RESEARCH PROGRESS REPORT FISCAL YEAR 1987 VOLUME 1(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX F H GOLDNER 01 OCT 87 3/4

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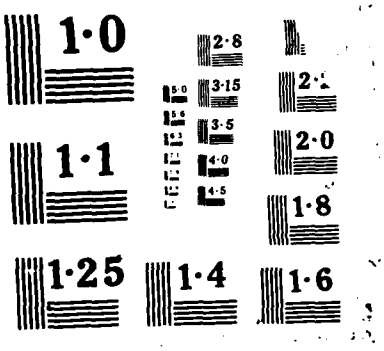
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Detail Summary Sheet

Date: 14 Sep 87	Proj No: C-45-87	Status: Ongoing

Title: Utility of Solubilized Calcium Citrate in the Management of Moderate and End-Stage Renal Failure

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Jill Lindberg, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: J. Brian Copley, COL, MC Howard M. Cushner, MAJ, MC John M. Bauman, MAJ, MC
Key Words: Renal failure, end-stage	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 60

Total Number of Subjects Enrolled to Date: 60

Date of Periodic Review_____ Results_____

Objective(s): To assess the value of solubilized calcium citrate (Super-Citracal^{tm}) in the management of moderate and end-stage renal failure.

Technical Approach: Seventy-five to 150 adult patients of either sex with endogenous creatinine clearance ranging from 25-60 ml/min will participate in the study. Eligible participants will be randomly assigned into three groups. Patients in Group I will receive Super-Citracal 500 mg calcium three/day (with meals). Those in Group II will take calcium carbonate 500 mg calcium three/day (with meals). Patients in Group III will receive placebo medication three/day (with meals). The remainder of the study will be conducted as outlined in the study protocol.

Progress: We have evaluated supercitracal vs. alternagel/basagel in patients with end-stage renal disease and evaluated supercitracal versus placebo in patients with early and moderate renal failure.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-47-87	Status: Completed

Title: Correlation of Hemodynamic Gradients in Aortic Stenosis with and without Significant Valvular Insufficiency

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Thomas L. Stoughton, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To assess the relationships between various transvalvular gradients in aortic stenosis, with and without significant aortic insufficiency.

Technical Approach: Recent studies have correlated Doppler (DOP) derived pressure gradients (G) with the severity of aortic stenosis (AS). The validity of thse "pressure" indices was evaluated using simultaneous left ventricular (LV) and aortic micromanometer pressures in 26 AS patients (pts). Range of aortic area (AVA) was 0.5 to 2.4 cm^2, and ejection fraction 46 to 87%. An instantaneous G was electronically derived and peak G (Gmax), peak-to-peak G (Gp-p), mean G(Gm), G at 80 msec before the end of LV ejection (Gt-80) and the ratio of time to peak gradient to LV ejection time (TPG)/LVET) compared to AVA.

Progress: In predicting AVA >1.0cm^2 using Gmax <53mmHg, sensitivity = 100%, specificity = 81%, positive predictive value (PV) = 77%, and negative PV = 100%. The remaining gradient parameters had similar accuracy, using Gp-p <33mmHg, Gt-80 <30mmHg, G, <34,,Jg. amd TPG LVET <.30. Of interest, there was a very close linear correlation (r=0.97) between Gt-80 and Gp-p. These results provide hemodynamic validation of proposed DOP indices of AS severity in pts with preserved LV function. They show that Gmax (corresponding to the simple peak velocity with DOP) is as accurate as the other gradients to assess AS.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-48-87	Status: Terminated

Title: Compassionate Use of Mevinolin (MK-803) in Very-High-Risk Patients with Hypercholesterolemia

Start Date 7 May 87	Est Comp Date:
Principal Investigator Edwin J. Whitney, MAJ, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To provide mevinolin for very-high-risk patients with hypercholesterolemia.

2) To ensure that the safety, tolerability and efficacy of mevinolin used on a compassionate-use basis are carefully monitored and documented.

Technical Approach: Patients must be a high risk of succumbing to atherosclerotic heart disease within five years and be refractory to or intolerant of standard lipid-lowering agents in order to be considered for this study. Therapy will follow the schema outlined in the study protocol.

Progress: This study was terminated due to approval of the drug by the FDA.

Detail Summary Sheet

Date: 22 Sep 87	Proj No: C-49-87	Status: Ongoing

Title: Phase II Study of Carbetimer in Advanced Breast Carcinoma

Start Date 11 May 87	Est Comp Date:
Principal Investigator Arlene J. Zaloznik, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): 1) To determine the response rate and response duration in subjects with advanced breast carcinoma treated with carbetimer.

2) To define the qualitative and quantitative toxicities of carbetimer administered in a Phase II study.

Technical Approach: To be eligible for this study, all subjects must have a histologic diagnosis of breast carcinoma. Subjects must have an estimated survival of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into the study at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-51-87	Status: Completed

Title: Lung Cancer in Former Tobacco Users

Start Date 13 May 87	Est Comp Date:
Principal Investigator Joseph I. Matthews, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____
Total Number of Subjects Enrolled to Date:_____
Date of Periodic Review_____Results_____

Objective(s): To look at the incidence of lung cancer in former users of tobacco, and to compare cell type of lung cancer between former and current users of tobacco.

Technical Approach: The Tumor Registry at BAMC meets weekly and publishes a brief clinical history of all patients with cancer. Additionally, the majority of patients with bronchogenic carcinoma are seen in consultation by the Pulmonary Service and a brief synopsis of their history is kept on record. Since January 1981, an accurate record of all patients evaluated for bronchogenic carcinoma has been kept as part of a study evaluating the use of CT scan in the preoperative evaluation of patients with bronchogenic carcinoma. A chart review of these records will be conducted with particular attention given to the tobacco history of these patients. In addition, an accurate history of tobacco use and discontinuation of the same will be kept prospectively on all patients being evaluated for primary bronchogenic carcinoma.

Progress: Six hundred and forty-eight patients were diagnosed with lung cancer from January 1981 thru July 1986 at Brooke Army Medical Center (BAMC). Ninety-seven patients were identified who were non-smokers or ex-smokers. The distribution of cell type was not different between current and former smokers. Eleven patients had never used tobacco. Ten of these patients were female. All had either adenocarcinoma (7 patients) or bronchoalveolar (BAC) carcinoma (4 patients). Three patients had never used cigarettes and lightly used either a pipe or cigars. Two had adenocarcinoma and 1 squamous cell carcinoma. BAMC has a population base of approximately 210,000 patients. However, this is a

C-51-87 (continued)

transient population making incidence statistics unreliable. Nevertheless, 1.7% of our patients with lung cancer are nonsmokers, 13% of our patients are former smokers, and 4.47% of our patients had not used tobacco in more than 15 years. This suggests that a) quitting tobacco us may reduce the risk of developing lung cancer, but the risk is still considerably greater than the risk in a nonsmoker, and b) unidentified factors may be contributing to the risk of developing lung cancer.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-52-87	Status: Ongoing

Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC)

Start Date 13 May 87	Est Comp Date:
Principal Investigator (vice Harvey) Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Paul J. Thomas, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC John J. Posch, Jr., DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review_____ Results_____

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex-vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or agressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients with AML were treated in second complete remission. One patient is alive and in complete remission 120+ days; one patient died day 10 of necrotizing fasciitis.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-53-87	Status: Ongoing

Title: An Evaluation of Flow Cytometry in the Cytologic Analysis of Bronchial Washings

Start Date 13 May 87	Est Comp Date:
Principal Investigator William A. Crosland, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators: Michael Jackson, MAJ, MC Harvey M. Richey, III, MAJ, MC Janice Grassel
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To investigate whether the frequency of DNA distribution as determined by flow cytometry can increase the sensitivity and specificity of bronchial washings in the diagnosis of patients with lung cancer.

Technical Approach: Patients entered into the study were those with lung cancer as a probable diagnosis and indication for bronchoscopy. If a lesion was visible at bronchoscopy (central), an initial bronchial washing (BW) was performed with 100 cc of a physiologic solution in the appropriate bronchus. If a lesion was not visible at bronchoscopy (peripheral), an initial bronchoalveolar lavage (BAL) with 100 cc of a physiologic solution was performed in the subsegment corresponding to the radiographic abnormality. In the Cytology Laboratory, the specimen was briefly homogenized to break up mucus strands and the speciment divided with one being submitted for routine microscopic cytopathology and the other for flow cytometric DNA quantification. The cells for flow cytometry were preserved in 70% alcohol and stained with Propidium Iodine. Histologic Diagnosis was obtained from biopsies and surgical specimens.

Progress: Due to loss of samples in the Department of Pathology, only 10 patients with lung malignancy are enrolled presently, and 10 controls are patients with probable cancer as a reason for bronchoscopy without malignancy.

Results of the initial series of patients are pending quantitative DNA analysis of samples.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-54-87	Status: Ongoing

Title: Left Ventricular Systolic Dynamics in Coronary Arterial Disease at Rest and in Exercise

Start Date 13 May 87	Est Comp Date:
Principal Investigator Steven R. Bailey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ares Pasipoularides, M.D., Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review _____ Results _____

Objective(s): To develop indices for LV pumping efficiency and regional wall contractility in CAD. We will quantify intraventricular pressure distributions promoting the displacement of blood in the LV chamber towards the aortic valve in the course of systolic isovolumic contraction and ejection.

Technical Approach: Twenty patients with suspected CAD will be prospectively evaluated during routine diagnostic cardiac catheterization prior to retrograde left ventriculography. All patients will undergo standard retrograde arterial catheterization from the arm using an #8 high fidelity catheter with two laterally mounted micromanometrs and an electromagnetic flow sensor at the level of the proximal pressure sensor. The study will be carried out as outlined in the protocol.

Progress: One patient has been studied. No reportable data are available at this time.

Detail Summary Sheet

Date: 18 Nov 87	Proj No: C-57-87	Status: Ongoing

Title: Phase I Trial of Intrapleurally Administered Intron-A®

Start Date 29 May 87	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine the tolerance to and toxicity of intrapleural administration of Intron-A® in patients with malignant pleural effusions.

Technical Approach: To be eligible for this study the patient must have histologically proven diagnosis of cancer involving the pleura, as demonstrated by pleural fluid cytology or pleural biopsy positive for carcinoma or lymphoma, or histologically proven intrathoracic malignancy with a cytologically negative effusion, without other apparent etiology. The patient's malignant pleural effusion must be refractory to standard systemic therapy, or the patient's tumor must have no known effective standard therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 18 Nov 87	Proj No: C-58-87	Status: Ongoing

Title: Phase I Study of LY186641 (Sulfonylurea)

Start Date 29 May 87	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review _____ Results _____

Objective(s): To determine the maximum tolerated dose (which is both predictable and reversible) of LY186641 as a single dose given every 3 weeks.

Technical Approach: In order to be eligible for inclusion in this study, all patients must have microscopically confirmed diagnosis of advanced or metastatic cancer. All patients' tumors must be refractory to all known forms of effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks and a performance status less than or equal to 2.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to report any meaningful results.

Detail Summary Sheet

Date: 18 Nov 87	Proj No: C-59-87	Status: Ongoing

Title: Phase I Study of LY188011 (Difluorodeoxycytidine)

Start Date 29 May 87	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review_____ Results_____

Objective(s): To determine the maximum tolerated dose of LY188011 as a single dose given for 5 consecutive days with each cycle repeated every 21 days.

Technical Approach: Patients msut have a microscopically confirmed diagnosis of metastatic or advanced cancer. Patients' cancers must be refractory to effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to report any meaningful results.

Detail Summary Sheet

Date: 23 Sep 87	Proj No: C-62-87	Status: Ongoing

Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol)

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator (vice Harvey) Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Paul J. Thomas, COL, MC Allen Potter, LTC, MC John J. Posch, Jr., DAC Barbara Reeb, DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion.

This is the master protocol for the autologous bone marrow transplant program.

Progress: This study is a continuation of the protocol C-38-82. BAMC has been approved by the Southwest Oncology Group and Pediatric Oncology Group as a bone marrow transplant institution, and all patient data will be reviewed by these two groups.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-64-87	Status: Ongoing

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance

Start Date 2 Jul 87	Est Comp Date:
Principal Investigator James E. Johnson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Gregg T. Anders, CPT, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 33

Total Number of Subjects Enrolled to Date: 33

Date of Periodic Review _____ Results _____

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evauation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a D_LCO, cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GMS stains; 2) culture fo AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4) quantitation of lymphocytes, PMN's, monocytes as well as lymphocyte subsets particiularly OKT4 and OKT8.

Progress: Thirty patients have been enrolled so far as well as three normal controls. So far, the results show that the patients with dyspnea have no specific exercise limitations. None of the patients have unexpected infecting organisms. BAL lymphocyte analysis shows normal numbers of T4 cells, increased T8 cells with a reduced Tr/T8 ratio.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-66-87	Status: Ongoing

Title: Immunosuppressive Therapy for Biopsy Proven Myocarditis (Collaborative Study with University of Utah Medical Center and Centers for Multicenter Trial)

Start Date 2 Jul 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: William R. Condos, LTC, MC
Key Words: Myocarditis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review_____ Results_____

Objective(s): To test the hypothesis that immunosuppressive therapy is beneficial in myocarditis.

Technical Approach: This is a national muticenter trial including 23 patient enrollment centers. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early to report any significant data.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-67-87	Status: Ongoing

Title: Laser Vaporization versus Dermabrasion for the Treatment of Hypertrophic Actinic Keratoses

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator (vice Yevich) Alfred J. Hockley, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Stuart J. Salasche, COL, MC
Key Words: Keratoses, actinic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To compare two different treatment modalities of active keratoses, namely CO_2 laser vaporization versus dermabrasion.

Technical Approach: The study will be a paired comparison of the two modalities including a minimum of twenty outpatients. These persons will have have three to five hypertrophic actinic keratoses on the dorsum of their hand or foreamr. Each patient will service as his own control as actinic keratoses of one hand will be treated with CO_2 laser and the other will be treated with dermabrasion.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Sep 87	Proj No: C-70-87	Status: Ongoing

Title: High Dose Busulfan with Autologous Bone Marrow Rescue

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator (vice Harvey) Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: R. Foulke, MAJ, MC Paul Thomas, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC John J. Posch, DAC E. Nash, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review n/a Results

Objective(s): 1) To study the toxicities associated with the treatment of refractory malignancies, utilizing cyclophosphamide, busulfan and etoposide.

2) To evaluate the response rates and the response duration of patients treated with the above regimen.

Technical Approach: An IND for busulfan was obtained in March 1987. The protocol was amended in June to include the use of cycophosphamide and etoposide (VP-16). Inclusion/Exclusion criteria and therapy is as outlined in the study protocol.

Progress: This study replaces protocol C-77-83. Five patients have been enrolled. Two patients have been engrafted and returned home.

Detail Summary Sheet

Date: 17 Jul 87	Proj No: C-71-87	Status: Ongoing

Title: Use of Clofazimine in Immunocompromised Patients for the Treatment of Infections Caused by Mycobacterium Avium-Intracellulare and Other Atypical Mycobacteria Resistant to Conventional Antituberculous Therapy.

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator Clifton A. Hawkes, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To use and determine the effectiveness of the investigaitonal drug clofazimine (Lamprene®) for the treatment of infections due to Mycobacterium avium-intracellulare and other atypical mycobacteria in immunocompromised patients.

Technical Approach: Selection of patients will be on the basis of medical history, physical examination and laboratory studies including an evaluation of immunological status. Attempts will be made to culture body fluids and or tissue specimens from patients to substantiate the presence of atypical mycobacterial infection. All mycobacterial isolates will be tested in vitro for sensitivity to clofazimine.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-72-87	Status: Ongoing

Title: Rifabutin (Ansamycin LM 427) CDC Protocol

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator Clifton A. Hawkes, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review_____ Results_____

Objective(s): To determine the effectiveness of Rifabutin in the treatment of patients with disseminated M. avium complex disease, localized M. avium complex disease unresponsive to standard therapy, selected patients with rifampin-resistant M.tuberculosis, and other selected patients with mycobacterial infections.

Technical Approach: Under the compassional release IND, Rifabutin is intended for immunocompromised patients with disseminated M. avium complex disease, patients with pulmonary MAC disease unresponsive to standard therapy, and patients with rifampin-resistant tuberculosis. Other patients with mycobacterial diseases which have not responded to standard therapy may also be eligible to receive Rifabutin. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-76-87	Status: Ongoing

Title: A STudy of Patterns of Ambulatory Oxygen Saturation in Patients with Chronic Obstructive Lung Disease

Start Date 13 Aug 87	Est Comp Date:
Principal Investigator William A. Crosland, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators:
Key Words: Oxygen saturation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine by 24 hours ambulatory oxygen saturation monitoring if constant low flow oxygen therapy is an effective method of preventing oxygen desaturation and if oxygen desaturation occurs in patients without room air hypoxemia.

Technical Approach: Data to be collected on each patient meetig the inclusion criteria are the patient's age, sex, duration on oxygen therapy, pulmonary function, room air arterial blood gas, arterial blood gas on oxygen, hematocrit, EKG, and rate of oxygen flow. The patient will then wear an ambulatory pulse oximent and maintain a log of daily activities. Patients that show evidence of desaturation will have a second period of ambulatory oxygen saturation monitoring. During this second period, a 24 hour Holtor monitor will be performed. The 24 hour pulse oxymeter and Holtor monitor recordings will be examined to determine if periods of desaturation are associated with dysrhythmias.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-77-87	Status: Ongoing

Title: The Efficacy of Lactaid vs Lactrase in 'ne Treatment of Lactose Intolerance

Start Date 13 Aug 87	Est Comp Date:
Principal Investigator Bernard M. Feldman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicinte/Gastroenterol.	Associate Investigators: Fred Goldner, COL, MC
Key Words: Lactaid Lactrase Lactose	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To assess the efficacy of two forms of lactase therapy (Lactaid and Lactrase) in patients with lactase deficiency.

Technical Approach: Following a 12 hour fast, each patient will dring 25 grams of lactose dissolved in water. In a random fashio, all patients will initially receive Lactaid or Lactrase tablets at the manufacturers recommended dose with the lactose meal. Breath hydrogen samples will be collected immediately prior and every hour for eight yours following lactose ingestion.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-85-87	Status: Ongoing

Title: Assessment of Calcium Acetate as a Phosphate Binder and Calcium Supplement in Patients with Chronic Renal Failure

Start Date 9 Spe 87	Est Comp Date:
Principal Investigator J. Brian Copley, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators:
Key Words: Renal failure, chronic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To assess the usefulness of calcium acetate as a phosphate binder and calcium supplement in patients with end-stage renal disease.

Technical Approach: All patients who consent to enter the study will have their phosphate binding agents discontinued for one week. Only those patietns who have a serum phosphorus greater than 5.5 mg/dl will be continued on this study. Patients will be treated with either an aluminum containing phosphate binding agent or calcium acetate in a double blinded fashion. At the completion of two months on the study drug, the patients will be switched to the other phosphate binding agent. Every two weeks during the study a PA20 will be drawn mid-week predialysis. At four and eight weeks after beginning the study drug, a serum albumin and C terminal PTH will be drawn.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-88-87	Status: Ongoing

Title: A Survey of Intracolonic Combustible Gas Compositions with Various Endoscopic Preparations

Start Date 10 Sep 87	Est Comp Date:
Principal Investigator Francis E. Peluso, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words: Gas, intracolonic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): 1) To determine whether phosphate enema is an adequate preparation for rectosigmoid electrocautery during sigmoidoscopy, with respect to concentrations of conbustible gases.

2) To determine how an oral polyethylene glycol preparation (Colyte, Edlaw Preparations) and phosphate enema (C.B. Fleet Co.) compare with respect to combustable gas concentrations in the rectum.

3) To determine how regional concentrations of combustible gases in the colon correlate with regional visual assessments of bowel preparation with polyethylene glycol.

Technical Approach: Thirty patients undergoing routine flexible sigmoidoscopy and thirty patients undergoing routine colonoscopy will be entered into the study. The standard bowel cleansing regimens for each procedure will be utilized. At colonoscopy, six gas samples will be obtained via a polyvinyl tube passed through the scope. The method of collecting gas samples during flexible sigmoidoscopy will be identical.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-91-87	Status: Ongoing

Title: Phase I Study of LY188011 (Difluorodeoxycytidine - Seven Day Continuous Intravenous Infusion)

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Thomas D. Brown, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the maximum tolerated dose (which is both predictable and reversible) of LY188011 as a single dose given as a 7 day continuous infusion with each cycle repeated every 28 days.

Technical Approach: Patients must have a microscopically confirmed diagnosis of metastatic or advanced cancer. The cancers must be refractory to effective therapy (surgeyr, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 6 Nov 87	Proj No: C-48-86	Status: Ongoing

Title: Animal Facilitated Therapy (AFT) in the Brooke Army Medical Center Pediatric Department.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator (vice Mantooth) Lynn J. Anderson, MAJ, VC	Facility Brooke Army Medical Center
Dept/Svc Department of Ministry & Pastoral Care	Associate Investigators: Carolyn Randle, MAJ, MC Robert VanIngen, MAJ, CH Jesse DelaCruz, LTC, AN
Key Words: Therapy, animal facilitated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review n/a Results_____

Objective(s): 1) Determine patient and staff opinions of animal facilitated therapy before and after such therapy has been utilized.

2) Educate staff, subjects, and subjects' families of the potential values of AFT to them.

3) Evaluate specifically: (a) the distractive value of an animal to a child during a stressful exam or test, and (b) the value of an animal as a cotherapist in mental health counseling sessions.

4) Identify other potential studies for future evaluation.

Technical Approach: Subjects will be selected from childen currently being treated by the BAMC Pediatric Department. They will be chosen on the basis of their desire to be involved in the program. We will evaluate the distractive value of an animal to a child during a stressful exam or procedure such as repeated withdrawal of blood samples from patients being evaluated for diabetes. It is hypothesized that the presence of an animal during those times would distract the patient from the procedure, thus making the procedure easier for the patient and also for the staff involved.

Progress: No controlled studies have yet been accomplished although great strides have been made in objectives 2 and 4. Since the programs' beginning, visits have been made by either MAJ Anderson or Chaplains Mantooth or VanIngen with a visiting dog to the pediatric ward approximately once a week. MAJ Randle and LTC DelaCruz have observed daily interaction between the therapy animals and patients for more than a year. Literally hundreds of patients and family members have thus had contact with the Animal visitation program. Statements such

as I didn't know the Army cared this much" or "Dr. Polly Dog is the best thing that has happened around here in years" exemplifies the thoughts and comments that the visitations have stimulated.

Objective 4 was to "Identify other potential studies for future evaluation." Currently in process of formulation are studies in the Psychiatry department where "Dr. Polly Dog" has been first a full time resident, when the inpatient service was at Chambers Pavilion, and than an every day visitor once the inpatient service was eliminated leaving only outpatient services. MAJ Randle will soon begin utilizing the dog in her therapy sessions with patients and will be recording observations made during these sessions. She will also be utilizing an instrument to measure results to either confirm or reject subjective findings. Other studies in psychiatry and pediatrics are being developed.

Case Reports:

A 4-year-old boy who was diagnosed with advanced Wilm's Tumors with Metz, upon entering the hospital, was withdrawn and wouldn't talk or respond to anyone. For approximately 2 weeks I visited daily and tried to communicate without result. At that time I brought Polly in to see him. As we approached the bedside a smile came across his face. AFter a few minutes, he reached out for Polly and I put her on the bed beside him. From then on I was able to talk with him and his outlook on life became much more positive. Three weeks later he was well enough to leave the hospital.

The patients was a 5-year-old boy whose father had been drunk and accidentally shot him in the stomach. In the hospital he was extremely withdrawn and distrustful of everyone on the staff. He also seemed to be angry with hit mother and would not respond to her either - at least when I was present. When I would walk up to him he would be lying on his back with his hands behind is head like an adult. When I would try to talk with him he would stare off into space as if he didn't hear me. His mother would try to coax him to talk without success. The day I took Polly up his behavior was the same until I put her on his bed. She immediately went over and started licking him. A smile came across his face, and he began to respond to me. From then on we communicated regularly and he seemed much happier and friendly with everyone.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-72-86	Status: Ongoing

Title: Development and Testing of an Expected Sensation Preoperative Teaching Tool Utilizing Sensation Descriptions of Postoperative Patients

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator Pamela J. Hildreth, CPT, AN	Facility Brooke Army Medical Center/UTHSC
Dept/Svc Department of Nursing	Associate Investigators: Reginald D. Williams, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To develop and test a preoperative teaching tool which incorporates sensations surgical patients can expect to experience.

Technical Approach: In phase I, a postoperative interview schedule will be developed to assess the surgical sensation experiences of postoperative patients. The questions will relate to sensations encountered by the patient during the pre-operative, recovery room, and first 24-48 hours postoperative periods.

For Phase II, a second postoperative interview schedule will be developed to determine the effectiveness of the expected sensation preoperative teaching tool.

Progress: Phase I has been completed. Surgical patients were able to accurately recall and describe surgical sensations occurring during the preoperative, recovery and postoperative periods. A surgical teaching tool was developed for orthopedic patients based on these descriptions.

Detail Summary Sheet

Date: 21 Aug 87	Proj No: C-75-86	Status: Ongoing

Title: Position Change for Electrocardiograms in Patients with Chronic Obstructive Pulmonary Disease

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator Sheila Westbrook, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 42

Total Number of Subjects Enrolled to Date: 42

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine if there is a difference in electrocardiograms recorded in a supine position compared to a position of rest in chronic obstructive airway patients.

Technical Approach: A two part study will be conducted to determine the effects of two positions (flat and 45° angle) on electrocardiograms measured by the 12 lead EKG on a group of 30 normal healthy volunteers and a group of 50 patients with chronic obstructive pulmonary disease. Two EKGs will be recorded - one in the supine position and one in the 45° position. The first reading will be in the 45° position and the second in the supine. A lead placement will be marked on the chest wall of all subjects to assure that no change in lead placement will take place with the change in body position.

Progress: Data has been collected on 42 subjects. There have been 22 normal subjects, and data analysis is in progress. No complications or misadventures have been encountered.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-7-87	Status: Completed

Title: The Effect of Changes in Backrest Position on Mixed Venous Oxygen Saturation in Intubated Post-Cardiac Surgery Patients

Start Date 11 Dec 86	Est Comp Date:
Principal Investigator Mary Lou Noll, Rn, MS, CCRN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Fran Anderson, MAJ, AN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 30

Total Number of Subjects Enrolled to Date: 30

Date of Periodic Review_____ Results_____

Objective(s): 1) To examine the effects of changing the backrest position on mixed venous oxygen saturation in post-cardiac surgery patients who are intubated and mechanically ventilated.

2) To determine if there is a relationship between cardiac output/index and mixed venous oxygen saturation.

3) To determine if there is a relationship between intraoperative factors (time on cardiopulmonary bypass and type of surgical technique) and postoperative mixed venous oxygen saturation.

Technical Approach: Thirty subjects were studied 6.0-9.5 hours after coronary artery bypass surgery; all were mechanically ventilated. Subjects were randomly assigned to one of three groups and baseline data were recorded on all subjects in a flat position. The backrest was adjusted according to group assignment: Group 1 - 20°, Group 2 - 40°, and Group 3 - flat (control). Measurements were taken at 0, 5, 15, and 30 minutes after change in position. After 30 minutes, patients were returned to the flat position and measurements were repeated.

Progress: There were no significant differences in SvO_2 from baseline among the three groups while the backrest was elevated ($p = .081$) or when flat ($p = .405$). There were no significant differences in SvO_2 from baseline among the times that SvO_2 was measured in either the elevated ($p = .344$) or flat positions ($p = .118$). There were no significant interaction effects of position and time on difference in SvO_2 from baseline in either the elevated ($p = .134$) or flat positions ($p = .218$).

C-7-87 (continued)

There were no significant correlations between baseline SvO_2 and cardiac output ($r = .266$; $p = .156$) or cardiac index ($r = .261$; $p = .163$). There were no significant correlations between time on cardiopulmonary bypass and baseline (SvO_2 ($r = .134$; $p = .481$). There were no significant differences between the two surgical techniques (saphenous vein graft and internal mammary) and baseline SvO_2 ($p = .457$).

The findings support elevating the head of the bed 20° to 40° after cardiac surgery once hemodynamic stability has been established. However, nurses should continue to observe for effects of position change on SvO_2. Additional findings of the study support case studies which noted a decrease in SvO_2 with activity and suctioning. When SvO_2 does change, the patient should be assessed for changes in cardiac output, hemoglobin, arterial oxygen saturation, and/or oxygen consumption.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-61-87	Status: Ongoing

Title: The Cost Effectiveness and Treatment Efficacy of an Outpatient Self-Management Program for Patients with Respiratory Problems: Asthma, Chronic Bronchitis, or Emphysema

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator Laura Terriquez, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing/Emergency Room	Associate Investigators: Terry Newton, CPT, AN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 22

Total Number of Subjects Enrolled to Date: 22

Date of Periodic Review_____ Results_____

Objective(s): 1) To assist patients in coping and understanding their disease process by teaching them how to assume responsibility for their care and the techniques that will help them achieve self-management of their disease.

2) To organize the initial and follow-up care of the asthmatic patients to reduce the number of return visits to the emergency room and the number of admissions.

Technical Approach: Self-care management teaching program with emphasis on COPD, asthma, chronic bronchitis, and emphysema patients. Each lesson is approximately one hour long with group participation. Patients are utilizing a self needs assessment along with a set lesson plan. Spirometry readings are taken the first, third and last class sessions. Each patient is keeping a log book of their participation and self management program. The principal investigator will look at the number of hospital ER visits, pulmonary clinic visits, and hospital days 6 months prior to the course, and the participants ER and clinic visits and hospital stays will be monitored six months after completion of the program.

Progress: First group of patients all seem to have improved mental attitudes toward their health care and disease process. The patients have stated that the program has decreased their anxiety level. Eight out of ten participants have brought spouses with them to the meeting.s The other two participants were widowers. Spouses have participated jointly with the patients. All spirometry readings have not been completed and the data collected so far is inconclusive.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-75-87	Status: Ongoing

Title: Oxygenation During Suction in Neonates

Start Date 13 Aug 87	Est Comp Date:
Principal Investigator Allison L. Mirakian, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words: Neonates	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To provide three different levels of oxygen supplementation during suction and to describe the patient's response in terms of oxygen saturation and its relationship to oxygen content to determine if any of the three levels will consistently maintain the infant's oxygen saturation within the normoxemic range throughout the suction procedure.

Technical Approach: Criteria for admission to the study includes the requirement that the infant be less than 10 days of age, born after 26 weeks gestation and prior to 37 weeks gestation, have a diagnosis of respiratory distress syndrome, and have an oxygen requirement between 25 and 60%. Three different amounts of additioanl oxygen will be given during the suctioning procedure. Suctioning will be done once using 100% oxygen. The next time the infant is suctioned 10% more oxygen will be used and then 20% more the next time.

Progress: This is a new study which has not been started.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-86-87	Status: Ongoing

Title: A Descriptive Study of the Effectiveness of Patient Controlled Analgesia (PCA): Morphine vs Meperidine (Demerol) in Postoperative Gynecological Patients

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Lorraine Sneed, 1LT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words: Analgesia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To compare the effects of a patient controlled analgesia (morphine sulfate vs meperidine) on bowel and urinary function in postoperative gynecological patients.

2) To compare the effects of morphine vs meperidine via PCA in the incidence of nausea and vomiting in immediate postoperative gynecological patients.

3) To compare the effectiveness of morphine vs meperidine via PCA for postoperative pain management.

Technical Approach: Participants will be assigned to either the morphine or demerol group and instructed in the proper use of the PCA machine. Bedside assessments will be made of each patient every 2 hours for 12 hours and then every 4 hours for 12 hours, and then every 4 hours until completion of the study. Bedside assessments will include recording urinary output, bowel activity, incidence of nausea and vomiting and pain control.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-95-87	Status: Ongoing

Title: A Comparison Study of Elderly Patient Utilization of Army Emergency and Outpatient Departments

Start Date 29 Sep 87	Est Comp Date:
Principal Investigator Vicky M. Sheldon, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To identify specific factors associated with emergency and outpatient department use by patients over 65 years of age.

Technical Approach: Patients reporting to the emergency and outpatient departments will be given a questionnaire to complete. They will be asked what factors differentiate the use of a specific department (emergency or outpatient) when seeking health care.

Progress: This is a new study. Data collection will begin in the near future.

Detail Summary Sheet

Date: 15 Mar 87	Proj No: C-18-83	Status: Terminated

Title: A Double Blind Comparative Study of Ritodrine vs Terbutaline on Arresting Premature Labor.

Start Date 3 Mar 83	Est Comp Date:
Principal Investigator (vice Jirak) Arthur H. Schipul, Jr., M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Premature labor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 48

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To compare the effectiveness of two beta-2 specific receptor agonists on arresting premature labor.

Technical Approach: Ritodrine or Terbutaline are administered in a blinded fashion to randomized patients in premature labor. Measures of outcome include delay of delivery by 48 hours. Observation of side effects include: incidence of maternal/fetal tachycardia, hypotension, tremor, headache, etc., need for discontinuation of therapy secondary to side effects.

Progress: No data are available from prior investigators, and the present investigator is not interested in continuing the study.

Detail Summary Sheet

Date: 23 Sep 87	Proj No: C-13-86	Status: Terminated

Title: Gonadotropin (GTN) and Steroid Receptor Content in Ovarian Cancer and Correlation with Bioactivity in Tissue Culture.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator Rafat Abbasi, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Debra J. Krikorian, CPT, MS Gerald Merrill, M.S. Michael Peek, Biochemist Eleanor Ayala, Medical Technologist
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 301.20

Number of Subjects Enrolled During Reporting Period:_____
Total Number of Subjects Enrolled to Date:_____
Date of Periodic Review_____Results_____

Objective(s): 1) To determine follicle stimulating hormone (FSH), luteinizing hormone (LH) (hCG) (gonadotropins) and estrogen (E_2) and progesterone (P) (steroids) binding in ovarian cancer cells.

2) To assess therapeutic implications of the receptor data by manipulating ovarian cancer cells in tissue culture.

Technical Approach: Approximately 10 ml of blood will be obtained from each patient prior to surgery for the purpose of determining serum concentrations of estrogen, progesterone, sex hormone binding globulin (SHBG), testosterone, androstenedione (4A), and dehydroepi androsterone (DHEA) by RIA. Serum samples will be stored at -20°C for subsequent RIA.

Primary cell lines of tumor derived and normal controls will be subjected to manipulation to include addition of FSH, hCG (LH), E_2, P and E_2+P in varying concentrations. The effects of these treatments on the biological activity of these cells will be assessed by analysis of growth rate + cell size and karyotypic changes.

Progress: This study was terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-14-86	Status: Terminated

Title: The Evaluation of Carboxyhemoglobin in Pregnancies with Chronic Maternal Smoking History.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator Arthur H. Schipul, Jr., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Samuel A. Chaney, COL, MC Thomas E. Wiswell, MAJ, MC J. Devn Cornish, MAJ, USAF MC
Key Words: Carboxyhemoglobin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 16

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review _____ Results _____

Objective(s): Evaluation of maternal serum carboxyhemoglobin levels with potential fetal arterial endothelial cell damage.

Technical Approahc: All patients with a positive history of smoking during pregnancy will be screened for carboxyhemoglobin levels. At the time of routine OB lab studies, an extra venous sample would be obtained. In those patients with carboxyhemoglobin levels above the level of nonsmokers, an arterial carboxyhemoglobin would be obtained from the mother and from a segment of umbilical cord and placenta postpartum. All patients noted to have elevated carboxyhemoglobin levels would be treated with standard therapy to lower the fetal risk. The major point to be tested is the level of carboxyhemoglobin at which arterial damage to the infant could be expected to occur.

Progress: This study was terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-31-86	Status: Terminated

Title: Androgen Metabolism by Peritoneal Macrophages from Patients with Endometriosis.

Start Date 12 Mar 86	Est Comp Date:
Principal Investigator Rafat Abassi, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics and Gynecology	Associate Investigators: Gerald Merrill, GS11 Michael Peek, GS9
Key Words: Endometriosis Metabolism, androgen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 5,003.90

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine whether incrased androgens contribute to infertility in patients with endometriosis.

Technical Approach: Patients admitted for diagnostic laparoscopy in the proliferative phase for evaluation of infertility will be enrolled. Cul-de-sac fluid will be subjected to separation techniques to isolate peritoneal macrophages. Metabolites will be quantified by high performance liquid chromatography (HPLC) and their presence confirmed by recrystallization to constance specific activity.

Progress: This study was terminated due to release from active duty of the principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-32-86	Status: Terminated

Title: Determination of Estradiol and Progesterone Receptor Concentrations in Human Endometrium and Myometrium; Correlation with 17 β-ol Dehydrogenase Activity.

Start Date 12 Mar 86	Est Comp Date:
Principal Investigator Rafat Abassi, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics and Gynecology	Associate Investigators: Gerald Merrill, GS11 Michael Peek, GS9
Key Words: Estradiol Progesterone	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To determine serum steroids (estradiol and progesterone) and tissue steroid receptor level in the pregnant uterus; assess 17 β-ol dehydrogenase activity.

2) To assess the impact of these changes in the initiation of parturition by measuring changes in receptor concentrations and tissue levels.

Technical Approach: Patients undergoing Cesarean Section (repeat and primary) for fetopelvic disproportion will be studied. The following studies will be performed: Serum RIA for estradiol and progesterone and sex hormone binding globulin levels, receptor assay for estradiol and progesterone in endometrial and myometrial tissue, assessment of 17 β-ol dehydrogenase activity in endometrial and myometrial tissue, and cord blood for estradiol and prosterone.

Progress: This study was terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-35-86	Status: Terminated

Title: Controlled Comparison Study of ORF 17070 to Danazol for the Treatment of Endometriosis - A Phase II Collaborative Study.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Rafat Abassi, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Endometriosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To compare the safety and efficacy of ORF 17070 (100 mcg/day or 10 mcg/day; subcutaneously) to danazol (800 mg/day; orally) in the treatment of endometriosis.

Technical Approach: Patients scheduled to undergo laparoscopy for endometriosis and infertility will be asked to participate. If they agree, they will be referred to UTHSCSA where they will receive either ORF 17070 or Danazol therapy. Upon completion of therapy, they will be asked to return to BAMC for repeat laparoscopy.

Progress: This study was terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-36-86	Status: Completed

Title: A Study for the Detection of Iron Deficiency Anemia in Pregnancy.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Fred A. Simon, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics and Gynecology	Associate Investigators: Frank Roberts, CPT, MC
Key Words: Anemia, iron deficiency	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 180

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To determine a hemoglobin level at which a pregnant patient in our population can be statistically certain to have iron deficiency.

Technical Approach: Approximately 150 patients with hematologically uncomplicated pregnancies will be studied. In addition to routine prenatal blood work, blood for serum iron, iron binding capacity, ferritin, and folate will be drawn. These additional tests will also be obtained with routine lab work at 28 and 36 weeks gestation.

Progress: The original project could not achieve statistical significance, so in order to increase the numbers, the project was altered to include only "anemic" OB patients.

Detail Summary Sheet

Date: 13 Nov 87	Proj No: C-60-87	Status: Ongoing

Title: Double-Blind Study to Compare Bleeding Patterns in Estrogen Replacement Therapy (Cooperative Study with UTSA Health Science Center)

Start Date 24 Jun 87	Est Comp Date:
Principal Investigator Harry T. Hutchinson, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Estrogen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review_____ Results_____

Objective(s): To evaluate the efficacy and safety of continuous vs interrupted regimens of estropipate combined with norethindrone (NET), compared to estropipate alone, when administered for the treatment of estrogen deficiency.

Technical Approach: To be eligible for admission into the study, patients must be in good health, have an intact uterus, and be candidates for estrogen replacement therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a relatively new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-65-86	Status: Ongoing

Title: Identifying Pathogenic Coryneform Bacteria

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator S. Vern Juchau, COL, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology/Microbiology	Associate Investigators: Bruce A. Gunn, LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To investigate a means of identifying and separating coryneform bacteria that can be isolated from the human body.

2) To attempt to correlate identified groups with normal flora or pathogenic potential.

3) To provide clinical microbiologists and physicians with a tool to better interpret the significance of the isolation of a gram-positive, non-spore forming bacillus which does not fall into one of the groups of known primary pathogens.

Technical Approach: The major focu of this study will be to classify coryneform bacteria of human origin on the basis of cellular fatty acids with the aid of a gas-liquid chromatography. Profiles of ATCC strains of human coryneforms will be constructed to serve as a data base to which clinical isolates will be compared.

Progress: Twenty-three ATCC strains of Coryneform bacteria have been characterized using traditional biochemical methods. This provides somewhat of a data base for identification of clinical isolates. However, the major focus of the study, which was to attempt to classify human coryneforms on the basis of cellular fatty acids, was stymied by the failure to obtain the Hewlett Packard Microbial Identification System. Characterization by other methods will be continued until the equipment is received.

Detail Summary Sheet

Date: 3 Dec 87	Proj No: C-78-86	Status: Ongoing

Title: The Effect of Ionizing Radiation upon Components of Normal Human Blood, Bacteria Contaminating Platelet Concentrates and Cytomegalovirus Naturally Occurring in Leukocytes Incidentally Present in Blood Components for Transfusion Therapy

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator David F. Jadwin, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators: Robert C. Allen, MAJ, MC Janet Martinez, SSG
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $4642.00

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To quantify the dose effect of extracorporeal ionizing radiation upon in vitro platelet function, as measured by platelet aggregation in response to collagen, to adenosine diphosphate, and to epinephrine stimuli. (Protocol 1)

Note: This project is composed of eight protocols. Objectives 2 thru 8 are as listed in the protocol.

Technical Approach: Protocol 1 - Platelet concentrates from approximately 100 different donors will be utilized. Platelet concentrates will be partitioned into experimental aliquots from which baseline platelet count and aggregometry will be performed. Leukocyte counting and limited differential counts will also be obtained. Following collection and processing, platelet concentrates will receive exponential doses of ionizing gamma radiation (between 10,000 and 200,000 rads from a Cesium 137 source); control aliquots of platelet concentrates will not be subjected to irradiation.

Progress: Data are being analyzed.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-34-85	Status: Ongoing

Title: Effect of Dietary Modifications on Weight Change in Obese Children with Different Insulin Responses to Glucose and Leucine Challenge.

Start Date	Est Comp Date:
Principal Investigator Chandra M. Tiwary, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Regina Marshall, R.N. Isidoro Chapa Elizabeth A. Milner, 1LT, MS
Key Words: Children, obese	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

2) To develop a profile for these children by identifying common characteristics according to their insulin responses to tolerance testing.

Technical Approach: Eligible patients will have a complete history, physical, CBC, SMAC-20, oral glucose tolerance test (1.75 gm/kg, max. 100 gms); and oral leucine tolerance test (150 mg/kg). Subjects will be classified into elevated and normal insulin goups in accordance with their insulin response to glucose and leucine challenges. All paritcipants will receive dietary instructions and will be provided with behavior modification instructions.

Progress: Fifty-six children with obesity have been studied. The endocrine and anthropometric data are available in these children. Review of the data shows that the insulin responsse to oral glucose tolerance test is exaggerated in the majority of children but the insulin response to oral leucine is exaggerated in a minority of children. Glucagon response to leucine was not pronounced. The fat distribution in obese children is variable but is predominantly in the abdominal and thigh region or shoulder, trunk, and thigh region.

C-34-85 (continued)

Dietary support has not been available. Therefore, the effect of particular dietary advice could not be studied in a controlled manner. The children were given dietary advice by me according to their insulin response to glucose/ leucine. All children received similar behavior modification plans. The children who followed the advice either did not gain weight or lost weight.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-69-85	Status: Completed

Title: Fever Response to Antipyretics Correlated with Etiology of Fever

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Martin E. Weisse, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Fever Antipyretics	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 13

Total Number of Subjects Enrolled to Date: 100

Date of Periodic Review 26 Sep 86 Results Continue

Objective(s): To compare the fever response to acetominophen seen in bacterial and viral infections.

Technical Approach: One hundred children who presented to the pediatric clinic with a rectal or oral temperature of 102°F (38.9C) or greater were studied. All study patients were given acetaminophen, 15 mg/kg, and their temperatures were rechecked at one hour. In the meantime, the patient was seen by pediatric staff or housestaff. Laboratory tests were ordered at the discretion of the examining physician and usually included viral and bacterial cultures and complete blood counts.

Progress: Ages of participants ranged from 9 days to 17 years with a median age of 2 years. Sixteen patients had viral illnesses and 17 had bacterial infections. The change in temperature and the white blood cell count were compared in the viral and bacterial groups. There was a significant difference ($p < 0.02$) in the WBC count between the two groups with higher values in bacterial infections. There was no significant difference in the fever response to acetaminophen between the two groups ($p = 0.37$). We conclude that there is no correlation between a child's fever response to acetaminophen and the etiology of the fever.

Detail Summary Sheet

Date: 30 Nov 87	Proj No: C-73-85	Status: Ongoing

Title: Prospective Study of Chlamydia Infection in Neonates and Infants of Carrier Mothers Using Culture and EIA Techniques.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Carol Robertson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Thomas E. Wiswell, M.D., MAJ, MC Summers W. Taylor, M.D., CPT, MC
Key Words: Chlamydia infection	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1610.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To determine Chlamydia trachomatis infection rate in BAMC Obstetric population.

2) To determine transmission rate of Chlamydia to neonates.

3) To evaluate morbidity of infants at risk for Chlamydia infections.

4) To compare Elisa technique to culture technique in nasopharynx, conjunctiva, and rectum for detection of Chlamydia trachomatis.

Technical Approach: At time of speculum examination upon admission to the labor suite, chlamydia culture and EIA will be obtained on the mother. Infants will have nasopharynx, rectum, and conjunctiva swabs for culture and EIA within 24 hours of birth while in nursery. Only infants of positive mothers or infants who are positive in the nursery will have follow-up cultures at 2 and 16 weeks or prn with the development of symtpoms.

Progress: Previous studies have documented a 15-30% incidence of cervical chlamydia infection in women of child bearing age and a 50% incidence of neonatal transmission. We have to date cultured 200 infants with chlamydia culture and chlamydiazyme EIA. We have not had cooperation from the Obstetrics Department to day in that only 10-12 women have been cultured at time of delivery. Only one infant was cultured at birth (chlamydiazyme negative) and no mothers have been positive. A study by Dr. Summers (OB) revealed a 12% positive chlamydia culture in our OB population. If the previously reported incidence of neonatal transmission is correct, we are seeing a reduced incidence of chlamydia infections in our OB population.

Detail Summary Sheet

Date: 11 Aug 87	Proj No: C-74-85	Status: Terminated

Title: Routine Screening for Neonatal Hyperviscosity

Start Date 27 Sept 85	Est Comp Date:
Principal Investigator (vice Wiswell) Jan Carter, CPT. MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hyperviscosity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the range of blood viscosities in newborn infants.

Technical Approach: 500 consecutive neonates born at Brooke Army Medical Center will be enrolled into the study. Viscosity measurements will be taken: a) from cord blood; b) from each infant at 2 hours of age; and c) from each infant at 24 hours of age.

Progress: Study terminated at the request of principal investigator.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-16-86	Status: Ongoing

Title: A Comparison of Periurethral Bacterial Flora in Circumcised and Uncircumcised Males Infants During the First Six Months of Life.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator (vice Wiswell) Gea Miller, M.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Hugh M. Gelston, Jr., MAJ, MS Sheila Jones, SSG
Key Words: Infections, urinary tract	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 8,775.00

Number of Subjects Enrolled During Reporting Period: 300

Total Number of Subjects Enrolled to Date: 300

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To assess the possible differences in periurethral bacterial flora and the role this may have in urinary tract infections in male infants.

Technical Approach: Specimens for bacterial culture will be obtained from six patient groups: newborn, 2 weeks, 2 months, 4 months, 6 months, and 1 year of age. Calgiswabs will be used to obtain specimens from the urethra and the glans/foreskin area of 25 circumcised and 25 uncircumcised male infants from each group. The specimens will be assayed to enumerate the aerobic species present and to determine the colony count for each species. The specimens will be placed directly into a tube containing 2.0 ml of sterile saline. The tubes containing the swabs will be vortexed at maximum speed for 20 seconds. Three tenfold dilutions of the specimens will be made and plated on enriched and selective media. The speciation will be accomplished using conventional methods. Colony counts will be determined for each specie.

Progress: Over 95% of the required specimens have been obtained for this protocol. Bacterial identification and colony counts have been determined for each of the specimens. All of the circumcised patients have been sampled. Only 10 more uncircumcised patients are required to complete the study. Currently the data are being analyzed.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-21-86	Status: Ongoing

Title: A Comparison of High Frequency Oscillatory Ventilation and Conventional Ventillation in the Management of Respiratory Distress Syndrome in Infants Less Than 1750 Grams. (Collaborative Study with Wilford Hall USAF Hospital)

Start Date 19 Mar 86	Est Comp Date:
Principal Investigator (vice Wiswell) Jan Carter, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Syndrome, respiratory distress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 470.00

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To evaluate the efficacy of using high frequency oscillatory ventilation (HFOV) in the management of respiratory distress syndrome (RDS) in premature infants, as compared to using the conventional neonatal ventilation (CV) therapy of intermittent mandatory ventilation and continuous distending pressure.

Technical Approach: The study population will consist of premature infants less than 33 weeks gestational age, less than 1750 grams birth weight, and less than 24 hours of age who require mechanical ventilation for treatment of RDS. Patients will be separated into four categories by birth weight and then randomly assigned to one of three treatment groups: CV only, HFOV initially followed by CV, or HFOV only.

Progress: Since March, only three infants have been entered into the protocol. All three were in the HFOV only treatment group, and all three were treatment failures. Of the three treatment failures, two failed because they were not sick enough for HFOV. The other patient was a respiratory failure and died. This patient was very sick before going on HFOV and had airlead (PIE) prior to HFOV.

Since June, we are reassessing patient entry (to ensure randomization and HFOV use. Before entering any new patients, we plan to re-educate concerning HFOV

C-21-86 (continued)

including respirator, nurses, and residents. Also new assigned personnel ware to be certified on HFOV before entering any new patients. We plan to continue the HFOV/CV protocol once the HFOV education update is complete.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-22-86	Status: Ongoing

Title: Prophylactic Intravenous Immunoglobulin in High Risk Neonates. (Collaborative Study with Walter Reed Army Medical Center)

Start Date 26 Feb 86	Est Comp Date:
Principal Investigator (vice Wiswell) Jan Carter, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Leonard E. Weisman, LTC, MC John Woodall, COL, MC Howrd Heiman, MAJ, MC
Key Words: Neonate, high risk	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To evaluate, in a double blind manner, the effectiveness, compared to an albumin placebo, of IVIG in preventing infectious disease and/or reducing morbidity and mortality in the high risk neonate.

Technical Approach: Participants will be given one of two medications. One will contain antibody to Group B streptococci and the other will contain human albumin and sugar. One dose of the medication will be given by vein over a one hour period. 2 cc. of blood will be drawn before the medicine is given, immediately after it is given, and at one, two, and eight weeks later. Babies will be followed over an 8 weeks period for evidence of infection.

Progress: No complications have been encountered in the ten patients studied. It is too early for data analysis.

Detail Summary Sheet

Date: 18 Jun 87	Proj No: C-58-86	Status: Terminated

Title: Evaluation of Three Family Members with Physical Markings for Diastematomyelia.

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator Carol Robertson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Isidoro Chapa, GS7
Key Words: Diastematomyelia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 18 Jun 87 Results Terminated

Objective(s): 1) To investigate the spectrum of sequelae resulting from diastematomyelia to determine if surgical intervention is always mandatory.

2) To investigate the potential for a chromosomal marker or a structural abnormality consistently associated with diastematomyelia.

Technical Approach: Participants will undergo a complete physical, neurologic, and CAT scan evaluation. Blood will be obtained for culture and karytotyping.

Progress: This study was terminated due to inability to test two of the three family members.

Detail Summary Sheet

Date: 17 Sep 87	Proj No: C-59-86	Status: Ongoing

Title: Chlamydia Urethral Colonization in Sexually Active Teenage Males.

Start Date 25 Jun 86	Est Comp Date:
Principal Investigator John A. Baker, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Richard Takao, COL, MC Thomas Perez, GS12
Key Words: Chlamydia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To determine the presence of Chlamydia trachomatis colonization in the urethra of teenage males who are or have been sexually active.

Technical Approach: Teenage males who enter the BAMC Adolescent Clinic will be given a questionnaire pertaining to the chlamydia study. They will be interviewed by one of the physicians in the adoescent clinic for the purpose of explaining the study. If they agree to participate in the study, urethral smears will be obtained and sent to the laboratory for chlamydia culture and Chlamydiazyme assays.

Progress: A significant problem has arisen in that there is a lack of personnel to initiate entry into the study when patients enter Adolescent Clinic.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-61-86	Status: Terminated

Title: Pediatric Infection and Surveillance Study of a Totally Implanted Venous Access System in Oncology Patients.

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator James H. Brien, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Isidoro A. Chapa, GS7
Key Words: Port-A-Cath Infection, pediatric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): To determine if the infection rate is lower in children who have an indwelling Port-A-Cath than in children with external catheters, such as the Hickman and Broviac.

Technical Approach: All Hematology-Oncology patients with a Port-A-Cath system in place will be eligible for the study. At the time of routine blood studies, additional blood will be obtained and sent to the laboratory for culture. The skin over the catheter puncture site will also be cultured.

Progress: Study terminated by principal investigator because of lack of patient accrual.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-71-86	Status: Ongoing

Title: Prospective Analysis of HTLV-III Infection in Children and Its Effect on Childhood Immunization

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator James H. Brien, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Infection, HTLV-III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): The clinical and immunologic assessment and follow-up of HTLV-III infected (and *high risk) children will be performed. The objectives of this protocol will be to collect, organize, and analyze this data prospectively so that changes in each patient's status can be detected quickly and so that changes in the gorup as a whole can be identified and responded to with minimum delay.

Technical Approach: Information is obtained and entered into a computerized data base. Blood studies concerning AIDS will be analyzed at Walter Reed Army Medical Center.

Progress: This multicenter study continues to enter information into the data base. No data are available at this time.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-40-87	Status: Ongoing

Title: Surfactant Production by Bacteria

Start Date 8 Apr 87	Est Comp Date:
Principal Investigator Chandra M. Tiwary, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Hugh M. Gelston, Jr., MAJ, MS Sheila Jones, SSG
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $200.00

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review n/a Results_____

Objective(s): To measure the surface tension lowering activity of pathogenic, non-motile bacteria and compare the same with that of motile pathogenic bacteria.

Technical Approach: Several different species will be assayed for surfactant production. The bacteria will be obtained from the collection of control organisms that are maintained by the DCI bacteriology laboratory. An overnight trypticase soy broth (TSB) culture will be used for the determination of the colony count and for surfactant production by each species of bacteria. A chloroform-methanol extraction will be made from each culture using the following: 1) cell free TSB, 2) the overnight culture, and 3) sonicated bacteria from the overnight culture. The surfactant production will be measured by the reduction of the surface tension of water produced by the addition of aliquots from the three different chloroform-methanol extractions from each culture. The reduction in surface tension/10^7 bacteria will be determined for each species of bacteria. The data will be analyzed to determine if there is a difference in surfactant production between pathogenic and nonpathogenic bacteria.

Progress: The initial difficulties with the surface tension monitoring equipment have been ironed out. In addition, several of the parameters of the culturing and the extraction procedure have been established. The project is now in the initial stages of data collection. Each experiment will be replicated five times so that sufficient data will be obtained so that a statistical analysis can be acocmplished.

Detail Summary Sheet

Date: 13 Nov 87	Proj No: C-56-87	Status: Ongoing

Title: Carbamazepine Therapy for Aggressive Behavior in Children

Start Date 13 May 87	Est Comp Date:
Principal Investigator Cindy Juster, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review_____ Results_____

Objective(s): To establish through a double blind evaluation the effectiveness of Carbamazepine in controlling aggressive behavior in childhood.

Technical Approach: A double blind crossover protocol will be used with each patient serving as his her own control. Using a table of random numbers, the patient will be randomized to initially receive either carbamazepine or a placebo daily for one month. Following a two week washout period, the patient will receive the other form of therapy. Carbamazepine will be initiated in a dose of 6-10 mg/kg/day in all age groups.

Progress: Too few patients have been entered into this study to report any meaningful information.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-79-87	Status: Ongoing

Title: Appetite and Pectin

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Chandra M. Tiwary, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Appetite Obesity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To assess the role of pectin in suppression of hunger in obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-80-87	Status: Ongoing

Title: Efficacy of Sedation with Chloral Hydrate in Children

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Peter D. Rumm, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Richard Takao, COL, MC
Key Words: Chloral hydrate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review_____ Results_____

Objective(s): 1) Determination of the expected duration of sedation with dosages of chloral hydrate.

2) Determination of the rate of failure on the first attempt of sedation with chloral hydrate and analysis of the factors that may have contributed to the initial failure.

Technical Approach: Children ages 2 months to 18 years admitted to the BAMC Pediatrics Inpatient Service will be screened for procedures requiring sedation. Chloral hydrate will be given one-half hour prior to starting the diagnostic test and vital signs and initial comment on the patient's activity will be recorded. The time of this dosage will be recorded, as well as any problems in giving the patient the prescribed dosage. Additional data recorded during the sedation process will include the time of beginning and ending the actual procedure, dosage and time of second or third dosages of chloral hydrate administered if needed, any other drug used for sedation due to failure of the chloral hydrate, complications, and any technical difficulties with completing the study.

Progress: Six children have been enrolled in the study with 100% effective sedation and without any side effects recorded. However, it is too early to report any significant results.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-87-87	Status: Ongoing

Title: Evaluation of Blood Pressure Measurement in Children

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Richard Takao, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Myung Park, M.D., UTHSCSA
Key Words: Blood Pressure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To obtain normative data on blood pressure measurements in children.

Technical Approach: After informed consent is obtained, children being seen in the Pediatric Clinic will have blood pressures taken three times on the arm, thigh or leg over a 3-5 minute period.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 10 Sep 87	Proj No: C-79-84	Status: Completed

Title: Biofeedback Treatment of Patients with Irritable Bowel Syndrome (IBS).

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator John B. Powell, Ph.D., CPT, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Psychiatry/Psychology	Associate Investigators: Fred Goldner, M.D., COL, MC
Key Words: Irritable bowel syndrome	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 10 Sep 87 Results Completed

Objective(s): To determine if abdominal pain in patients with IBS can be significantly reduced by treatment in a structured program of biofeedback and stress management procedures.

Technical Approach: Patients with IBS will be asked to attend one group session and two individually-scheduled EMG biofeedback sessions weekly, for four weeks. The group sessions will be designed to teach stress management and relaxation skills, with the individual sessions designed for practice and reinforcement of those skills. Participants will be asked to practice at home with a tape of relaxation exercises.

Progress: Initial results on the effectiveness of the Biofeedback/Stress Management Program look very favorable. Self-report measures reflected clinically significant improvements in symptom frequency, severity and control, and in ability to relax.

Detail Summary Sheet

Date: 28 May 87	Proj No: C-35-87	Status: Completed

Title: Evaluation of a Comprehensive Biofeedback/Stress Management Program.

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator John B. Powell, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Psychiatry	Associate Investigators:
Key Words: Biofeedback/Stress Management Program	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To evaluate, through medical records review, the effectiveness of an on-going biofeedback/stress management treatment program in terms of a) self-rated symptom improvement, b) physiological change in the patient's ability to relax, and c) reduction in subsequent use of medical resources.

Technical Approach: Records of the first 96 patients enrolled in the program were evaluated. These patients constituted everyone acceptd into the first ben iterations of the group program between January 1985 and April 1986. The Biofeedback/Stress Management Program was designed with the aim of providing cost effective behavioral medicin support to patients with a wide range of medical and psychiatric problems.

Progress: Initial results on the effectiveness of the Biofeedback/Stress Management Program appear to be favorable. Self-report measures reflected clinically significant improvements in symptom frequency, severity and control, and in ability to relax. Little change in these folow-up ratings is noted six months after treatment, suggesting that the subjective sense of improvement is maintained over time. There was no evidence that this long-term positive rating was due to a respondent selection bias toward more motivated or cooperative patients. The physioogical changes recorded during biofeedback are also in the directions suggested by the self-ratings, and tend to reinforce the hypothesis that improved coping techniques will lead to less physiological stress

C-35-87 (continued)

reactivity. Finally, there is a highly significant decrease in the use of out-patient medical facilities by program participants during the six months following involvement in the program.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-12-77	Status: Ongoing

Title: Intravenous Administration of I^{131} (NP 59) for Adrenal Evaluation of Imaging.

Start Date 15 Nov 76	Est Comp Date:
Principal Investigator (vice Bunker) Michael F. Hartshorne, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department Radiology/Nuclear Medicine	Associate Investigators:
Key Words: Adrenal scan	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review _____ Results Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1mCi in adults and 15mCi/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on th 4th, 7th, and 11th day following injection using scintillation camera.

Progress: Three patients have been enrolled in the protocol since the last yearly report. Two were normal (showed no activity in the adrenal areas during dexamethasone suppression) and one was abnormal. The abnormal study detected an adenoma of the left adrenal.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-90-86	Status: Ongoing

Title: Investigation of I-123 Iofetamine HCl in Brain Scanning

Start Date 11 Dec 86	Est Comp Date:
Principal Investigator Michael F. Hartshorne, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators:
Key Words: Iofetamine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 23

Total Number of Subjects Enrolled to Date: 23

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To evaluate the clinical utility of I-123 Iofetamine.

2) To allow clinicians at this facility to have access to a more physiologic brain imaging agent thereby improving the quality of patient care.

Technical Approach: Patients will be selected and referred to the Nuclear Medicine Service primarily by Neurology and/or Neurosurgery Service. Both in-patients and outpatients will be accepted.

Progress: A total of 23 patients have had I-123 Iofetamine/SPECT Brain Scans under this protocol. Technical improvements made during the course of standardization include optomization of camera/collimator geometry and iterative solution of the acquisition sequence problem. Prospects for improvement include the use of Dual Head SPECT with new equipment/software and possible Dual Head/Slant Hole/SPECT to perfect image quality.

Clinical cases handled include evaluation of two brain primary tumors, several Vascular Surgery referred patients for perfusion mapping, some senility

C-90-86 (continued)

evaluations (Alzheimer's vs multi-infarct), and four partial complex seizure patients. Of note are abnormal, diagnostic SPECT/Iofetamine scans in patients with normal EEGs, normal CTs, and normal MR Scans.

Detail Summary Sheet

Date: 18 Sep 87	Proj No: C-19-87	Status: Terminated

Title: Effect of Inversion Posture on Cardiovascular Function

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator Bill F. Byrd, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: John M. Bauman, MAJ, MC Michael F. Hartshorne, MAJ, MC
Key Words: Posture	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To observe the effect of full and partial inversion on cardiovascular function determined by radionuclide ventriculogram (RVG) measuring left ventricular ejection fraction (LVEF).

Technical Approach: As outlined in the study protocol.

Progress: This study was terminated due to REFRAD of the principal investigator.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-21-78	Status: Ongoing

Title: Clinical Study of Intraocular Lenses.

Start Date February 1978	Est Comp Date:
Principal Investigator (vice Walker) Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Arthur T. Glover, MAJ, MC Donald A. Hollsten, LTC, MC Robert A. Mazzoli, MAJ, MC
Key Words: Intraocular lens Cataract extraction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 285

Total Number of Subjects Enrolled to Date: 1539

Date of Periodic Review 12 Mar 87 Results Continue

Objective(s): To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Pursuant to protocols approved by the FDA, all have selected suitable patients for insertion of both posterior chamber and anterior chamber intraocular lenses. Using standard surgical techniques, these lenses were inserted as part of a cataract operation.

Progress: We continue to study intraocular lenses at Brooke Army Medical Center. Most of the posterior chamber intraocular lenses have been approved by the FDA for general use. We continue to investigate primarily newer chamber intraocular lenses and anterior chamber lenses.

A total of 1539 lenses have been implanted in patients at Brooke Army Medical Center. Results have been excellent.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-12-83	Status: Ongoing

Title: Is Routine Intraoperative Cholangiography (IOC) a Useful Adjunct to Cholecystectomy?

Start Date 6 Jan 83	Est Comp Date:
Principal Investigator Daniel Rosenthal, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators:
Key Words: Intraoperative cholangiography	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 112

Total Number of Subjects Enrolled to Date: 412

Date of Periodic Review n/a Results

Objective(s): To determine if routine IOC significantly alters the management of patients with cholecystolithiasis by demonstrating at operation the presence of unsuspected stones in the biliary tree.

Technical Approach: All medical centers using routine IOC will be asked to participate. On a quarterly basis, they will be asked to report the number of IOCs performed, number of normals, what was done, and the number of minutes added to the procedure.

Progress: Data is being analyzed.

Detail Summary Sheet

Date: 19 Jun 87	Proj No: C-40-84	Status: Terminated

Title: Comparison and Calibration of the Gates Method for Glomerular Filtration Rate and the Tauxe Method for Effective Renal Plasma Flow Determination with Standard Inulin and Para-Aminohippurate Clearances.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Departments of Surgery/Radiology	Associate Investigators: John M. Bauman, M.D., MAJ, MC Michael F. Hartshorne, M.D., MAJ, MC Michael A. Cawthon, D.O., CPT, MC William H. Howard, III, M.D., CPT, MC
Key Words: Glomerular filtration rate (GFR) Effective renal plasma flow (ERPF)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 169.76

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 18 Jun 87 Results Terminated

Objective(s): 1) To accurately determine the values for GFR and ERPF in 15 patients with predetermined ranges of renal functional impairment.

2) To obtain values for GFR and ERPF in the same patients through current techniques employed in the Nuclear Medicine Clinic.

3) To compare the accuracy of the Nuclear Medicine techniques as employed at this institution with the accepted standards, and correct the mathematical derivations thereof, as necessary, in order to provide improved patient care.

Technical Approach: Patients undergo a standardized renogram followed by simultaneous inulin and PAH clearances.

Progress: Due to difficulty with patient accession, this study was terminated.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-72-84	Status: Ongoing

Title: Outpatient Intra-Arterial Digital Subtraction Angiography in the Evaluation of Patients with Atherosclerotic Peripheral Vascular Disease.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator David W. Olson, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Vascular Surgery	Associate Investigators: Manuel Ramirez, M.D., MAJ, MC Harrell Cox, M.D., MAJ, MC
Key Words: Angiography, digital subtraction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 54

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine the safety, feasibility, and accuracy of outpatient intra-arterial angiography using digital subtraction angiographic technology in patients with known atherosclerotic peripheral vascular disease who otherwise would undergo conventional angiography.

Technical Approach: Patients who would routinely be scheduled for elective admission for conventional angiography will be offered outpatient intra-arterial digital subtraction angiography. Routine x-ray and blood studies will be obtained prior to the date of the scheduled arteriogram. Arteriography will be performed in the Digital Subtraction Angiography Suite utilizing the standard Seldinger technique. Upon completion of the angiogram, the patient will be observed in the Recovery Room for two hours. If there are no complications, the patient will be discharged.

Progress: The total number of patients who have undergone arch and carotid angiography via this technique is now 54. Over the past 12 months, seven patients have been added, all of whom have been in the arch and carotid study category. There have been no outpatient aorta and runoff examinations for aneurysm and occlusive disease performed during this period.

The fall-off in numbers is secondary to a perceived need for more thorough and rapid indepth evaluation of patients with carotid disease specifically as relates to their cardiac coronary artery disease status. We have found it to be

C-72-84 (continued)
more expeditious in terms of evaluation and preoperative planning to accomplish this very necessary part of the patient evaluation as an inpatient which therefore has led to a decrease in the number of patients studied angiographically on an outpatient basis.

However, it is still my perception that the information gained by outpatient subtraction angiography protocol will be helpful.

Detail Summary Sheet

Date: 27 Oct 87	Proj No: C-5-85	Status: Ongoing

Title: Localization of the Distribution of Regional Anesthetics.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator Emil J. Menk, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: John M. Bauman, M.D., CPT, MC Robert E. Middaugh, M.D., CPT, MC Curtis L. Baysinger, M.D., MAJ, MC Michael A. Cawthon, D.O., MAJ, MC William J. Reynolds, M.D., LTC, MC Michael F. Hartshorne, M.D., MAJ, MC
Key Words: Anesthetic, regional	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 32

Date of Periodic Review 12 Mar 87 Results Continue

Objective(s): To define the area and extent of flow of anesthetics during regional blockades.

Technical Approach: Approximately 10 patients will be evaluated utilizing the following techniques: axillary, interscalene, stellate ganglion, intercostal nerve, and epidural blockade. Patients will be brought to the Nuclear Medicine clinic for injection and imaging whenever possible. Standard doses and volumes of the local anesthetics routinely used will be employed, as well as strict aseptic technique. Each group of 10 patients will receive the anesthetic as a single bolus injection, and the other will receive 10 cc boluses with serial imaging after each bolus.

When bone scanning is felt to be indicated to better define the anatomy of flow, injection of the MDP will take place approximately 3-4 hours prior to imaging and injection of the anesthetic agent/DTPA mixture.

Progress: The paravertebral blocks have shown us that the flow pattern ot this block is easily reproducible with reliable results as to flow pattern (i.e., dermatomes blocker per cc of local anesthetic injected) and analgesia produced. The continuous intercostal block, however, is extremely variable with at least four distinct flow patterns.

Detail Summary Sheet

Date: 11 Apr 87	Proj No: C-6-85	Status: Terminated

Title: Perioperative Myocardial Infarction in Patients Undergoing Peripheral Vascular Surgery.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator William K. Goglin, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Curtis L. Baysinger, M.D., MAJ, MC John W. Culclasure, M.D., CPT, MC Bruce M. Elliott, M.D., MAJ, MC
Key Words: Infarction, myocardial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 29

Total Number of Subjects Enrolled to Date: 59

Date of Periodic Review 11 Mar 87 Results Terminated

Objective(s): 1) To prospectively investigate the incidence of perioperative myocardial infarction as determined by cardiac enzymes and electrocardiography in patients undergoing anesthesia and non-cardiac vascular surgery for the complications of peripheral vascular disease.

2) To demonstrate if there is a significantly greater number of myocardial infarctions as measured enzymatically as compared to those detected by clinical and electrocardiographic means only.

Technical Approach: All study patients will have a routine EKG performed as part of the usual preoperative evaluation. When the patient presents to the operating room, blood for MB CPK assay will be obtained. Immediately postoperatively and each morning for five days and EKG for interpretation by the cardiology service will be obtained. Additionally, MB CPK assays immediately postoperatively and twice a day for five days will be done. Additional EKGs and laboratory tests may be done more frequently as deemed necessary.

Progress: The principal investigator requested that this study be terminated. The release from active duty and transfer from BAMC of all coinvestigators, lack of support services (EKG, laboratory, administrative), precluded the acquisition of accurate and meaningful data. While the data on all patients was incomplete and would not allow conclusions to be drawn, no clinical or laboratory evidence of myocardial infraction was found in any patient enrolled.

Detail Summary Sheet

Date: 6 Nov 87	Proj No: C-22-85	Status: Ongoing

Title: Systematic Evaluation of Recurrent Nephrolithiasis.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator (vice Thompson) Kurt L. Hansberry, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words: Nephrolithiasis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To determine if a systematic evaluation of nephrolithiasis with tailored therapeutic techniques can reduce incidence of stone disease.

Technical Approach: This is a two-part analysis of the importance of metabolic evaluation for nephrolithiasis. One part will compare the incidence of stone recurrence within a population of stone formers who did not undergo metabolic evaluation. The second part of the study will perform calcium-loading tests on stone formers in an attempt to categorize those with hypercalciuria. They will then be treated appropriately and compared with the historical controls.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 18 Mar 87	Proj No: C-24-85	Status: Terminated

Title: Determination of Normal Alphafetoprotein Range in Normal Men Over the AGe of 50.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Edward J. Shumski, M.D., LTC, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Alphafetoprotein	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): To determine if a difference exists in the range of normal values of alphafetoprotein in older men.

Technical Approach: Serum samples for AFP determination will be obtained from healthy volunteers referred to the Urology Service for non-testicular disease processes. All patients will be screened by history for potential liver disease or systemic complaints. Two groups of patients will be evaluated. One group will be men between the ages of 20 and 35 and second group between ages 50 and 70. Thirty patients will be evaluated in each group. All assays for AFP will be performed by the radioimmunoassay technique.

Progress: This study was closed as data are available in literature.

Detail Summary Sheet

Date: 16 Sep 87	Proj No: C-41-85	Status: Ongoing

Title: Evaluation of Various Techniques of Septoplasty and Total Nasal Septal Reconstructive Surgical Procedures Utilizing Rhinometric Studies.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator (vice LePore) Jesse Moss, Jr., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Robert C. Jarchow, LTC, MC
Key Words: Rhinomanometry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): 1) To utilize anterior rhinometric principles in the preoperative assessment of patients prior to nasal surgery.

2) To utilize anterior rhinometric principles in the postoperative evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery.

3) Compare the rhinometric results with the surgical techniques to gain more information which may help us elucidate the intranasal deformities most likely to be improved by intranasal surgery, and which technique may be used in similar circumstances to achieve the best results.

Technical Approach: All patients who undergo nasal surgery will have anterior rhinomanometry performed according to presently accepted methods. Patients will have intranasal photography performed to help in the evaluation. Photography will be performed prior to use of local intranasal decongestants (½% neosynephrine) and after its use as is performed in rhiinometric studies. All patients will have their visible anatomic deformities mapped out preoperatively and intraoperatively. Six weeks after surgery, anterior rhinomanometry will again be performed to ascertain objectively the results of the surgical procedure. The patient's subjective impression concerning the result will be noted. Six months after surgery and one and two years after, the patient will be asked to return for another rhinomanometric examination.

Progress: Due to many technical problems with the rhinometric equipment, no patients have been enrolled on this study.

Detail Summary Sheet

Date: 16 OCT 87	Proj No: C-59-85	Status: Ongoing

Title: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity.

Start Date 10 Jul 87 Reopened	Est Comp Date:
Principal Investigator Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Cryotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 9 (BAMC)

Date of Periodic Review_____ Results_____

Objective(s): To determine the safety and efficacy of cryotherapy of the peripheral retina in severe retinopathy of prematurity (ROP) to prevent progression of the acute disease to severe grades of cicatricial retrolental fibroplasia.

Technical Approach: Prospective data will be accumulated from infants who are at risk for developing stage 3+ ROP. Those who reach that stage will be eligible for randomization in the cryotherapy study.

Progress: The Multicenter Trial of Cryotherapy for Retinopathy of Prematurity is continuing. We do not currently have a Pediatric Ophthalmologist at BAMC. Any patients that have retinopathy of prematurity and would be eligible for the study will be referred to the principal investigator at the University of Texas Health Science Center.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-70-85	Status: Ongoing

Title: High Frequency Hearing Levels in Otherwise Healthy Children Exposed to Three or More In Utero Diagnostic Ultrasounds

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator (vice Lepore) Kenneth B. Aspinall, COL, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Leonard W. Brown, MAJ, MC
Key Words: High frequency hearing levels	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To establish a normal value for high frequency hearing thresholds in children.

2) To compare a control group of healthy children with "normal" hearing threshold to a group of healthy children exposed to three or more in utero ultrasounds.

Technical Approach: This study is a continuation of study C-41-81.

A minimum of 50 otherwise healthy children between 3-6 years of age for each of two groups will be examined for high frequency hearing thresholds. The first group will consist of children exposed to three or more in utero ultrasounds, and the second group will consist of children without a history of ultrasound exposure. The primary frequencies to be studied are between 10-20,000 Hz.

Progress: MAJ Brown reported that plans are underway to start the study in the near future.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-71-85	Status: Ongoing

Title: The Effects of a Constant Infusion of Etomidate and Sufentanil on Somatosensory Evoked Potentials in Neurosurgical Patients.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator (vice Zablocki) Jerry Epps, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Lloyd Youngblood, M.D., COL, MC
Key Words: Somatosensory potentials	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine the effects of a total intravenous anesthetic technique utilizing a constant infusion of etomidate and sufentanil on the intraoperative monitoring of somatosensory evoked potentials during neurosurgical procedures.

Technical Approach: Twenty adult patients undergoing elective intracranial or spine operations will be asked to participate. Induction of anesthesia will be accomplished in the standard fashion. Somatosensory evoked potentials will be monitored with the Nicolet* CA-1000 multichannel signal averager. Sites for recording electrodes for both modalities will be measured using the International 10-20 System. A set of baseline measurements will be obtained prior to induction of anesthesia. A second set will be obtained 10 minutes post-induction and a third set 30 minutes post-induction. Each measurement will be reproduced at least once and superimposed to eliminate artifact.

Progress: Five patients currently enrolled with data collection obtained. Preliminary evidence reveals minimal changes with EP measurement.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-76-85	Status: Terminated

Title: Assessment in the Management of Patients with Transient Ischemic Attacks (TIAS) and Cerebral Infarcts with Transient Signs (CITS)

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Manuel F. Ramirez, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Vascular Surgery	Associate Investigators:
Key Words: Transient Ischemic Attack	John M. Bauman, M.D., MAJ, MC Charles F. Hales, M.D., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 10 Sep 87 Results Terminated

Objective(s): To assess the value of both the Brain Scan (BS) and Computerized Axial Tomography (CT Scan) in the management of patients with TIAS or CITs.

Technical Approach: All patients who present to the Peripheral Vascular Service with symptoms of TIAs, either hemispheric or non-hemispheric in nature, and those with ophthalmological findings of Hollenhorst plaque or retinal artery branch occlusion will be accepted into the study. Once a clinical diagnosis of TIA is made, then further non-invasive evaluation with both BS and CT scan with contrast will be performed.

Progress: This study was terminated due to lack of referral from supporting Services.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-79-85	Status: Completed

Title: Update on Routine Screening for Adenocarcinoma of the Prostate

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Edward Mueller, M.D., CPT, MC
Key Words: Adenocarcinoma of prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To review the results of the screening clinic for carcinoma of the prostate (CAP) from January 1979 to August 1985.

Technical Approach: The records of all patients who have been seen in the Urology Screening clinic will be assessed through the Urology Clinic convenience file. Records will be reviewed for results of examinations, biopsies, clinical and pathological staging, and patient follow-up.

Progress: A gradual increase in the number of cases of carcinoma of the prostate has been noted since institution of the screening clinic. Nationally, between 1974 and 1986, the nubmer of cases has increased 250%. Of the cases detected since 1979 at Brooke, an average of 30% has been detected through the screening clinic.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-1-86	Status: Ongoing

Title: Continuous Intra-Arterial Chemotherapy for Advanced Refractory Pelvic Malignancies Employing an Implantable Infusion System

Start Date 28 Oct 85	Est Comp Date:
Principal Investigator (vice Thompson) Francisco R. Rodriguez, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Walter H. Harvey, MAJ, MC
Key Words: Infusion System, implantable	Michael Hartshorne, MAJ, MC Marvin Walker, MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 15 Jan 87 Results Continue

Objective(s): To determine the efficacy of continuous infusion of intraarterial chemotherapeutic agents for pelvic malignancies utilizing an implantable infusion system (Porta-Cath)®.

Technical Approach: Patients with advanced pelvic malignancies are eligible. After analysis of feeding tumor vessels from the digital subraction angiography, a decision will be made as to which hypogastric vessel supplies the majority of the tumor. An oblique, lower quadrant incision will be made on the approriate side and the hypogastric artery and its proximal branches will be dissected extraperitoneally. The lumen will be dilated and and the catheter directed into the hypogastric artery. The tip of the catheter will be placed immediately above the highest vessel off which tumor vessels arise.

Progress: No suitable candidates have been found at this point. Would like to keep protocol active since there is always the possibility of a patient needing this mode of therapy.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-5-86	Status: Ongoing

Title: Ketamine Infusion: An Alternative Anesthetic Technique in the Morbidly Obese Patient.

Start Date 16 Jan 86	Est Comp Date:
Principal Investigator William E. Strong, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Alexander Rubin, CPT, MC
Key Words: Obese	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 24

Total Number of Subjects Enrolled to Date: 24

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): To assess the feasibility of ketamine infusion as an anesthetic technique in the morbidly obese.

Technical Approach: Morbidly obese patients (male or female) without major cardiovascular disease undergoing vertical banding gastroplasty are eligible for the study. All patients entering the study will receive ketamine anesthesia.

Progress: Ketamine by continuous infusion with nitrous oxide and atracurium was used as the primary anesthetic in 24 patients undergoing vertical bonding gastroplasty. Four patients required supplementation with other agents to control sympathetic responses. No cardiopulmonary complications were noted postoperatively but one patient complained of dysphoria. This anesthetic technique is a safe alternative with potential benefits in this unique patient population at risk for cardiopulmonary dysfunction.

Detail Summary Sheet

Date: 17 Sep 87	Proj No: C-18-86	Status: Ongoing

Title: Cephalometric Evaluation of the Sleep Apnea Patient.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator (vice Ramirez) Jesse Moss, Jr., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Donna Gibbons, CPT, MC
Key Words: Sleep apnea	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 110

Total Number of Subjects Enrolled to Date: 120

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): 1) To establish the value of a cephalogram in predicting sleep apnea.

2) To establish the value of a cephalogram in predicting the success of uvulopalatopharyngoplasty.

Technical Approach: Thirty patients will be assigned to each of four groups - 30 controls, 30 with normal cephalograms and abnormal sleep studies, 30 with abnormal cephalograms and normal sleep studies, and 30 with abnormal cephalograms and abnormal sleep studies. Based on results of cephalometry, surgical correction may or may not be recommended. Cephalogram and other pertinent data will be collected and x-ray findings will be correlated with success/failure rate of surgery.

Progress: Cephalogram is an easy inexpensive study which yields much information. It can rule in or out craniofacial abnormalities, may be predictive of sleep apnea, may assist in dictating type of surgery required, and in cases of UPPP/tonsil failure is helpful to select craniofacial surgery.

Detail Summary Sheet

Date: 17 Mar 86	Proj No: C-24-86	Status: Terminated

Title: Norfloxacin Antimicrobial Solution to Treat Acute Bacterial Infections of the External Eye.

Start Date 26 Feb 86	Est Comp Date:
Principal Investigator (vice Nevarez) Monte R. Dirks, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Eye, bacterial infection	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 154.00

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 15

Date of Periodic Review 11 Mar 87 Results Terminate

Objective(s): 1) To determine the safety and tolerability of a seven-day multiple dosing of norfloxacin ophthalmic solution as compared to tobramycin opthalmic solution.

2) To compare efficacy data of topical norfloxacin ophthalmic solution to tobramycin ophthalmic solution.

Technical Approach: This is a randomized, double-masked study design. Upon admission to the study and prior to test drug administraiton, two separate specimens for culture will be taken from the infected eye or eyes. Patients will be assigned to one of two treatment groups by means of a random allocation schedule. Half of the patients will be randomly assigned to treatment in the norfloxacin group and half will be randomized to treatment in the tobramycin group.

Progress: In six culture positive patients, all bacterial growth was suppressed by test agents. No bacterial growth on initial cultures in two of eight patients indicates probable viral etiology. No adverse reactions were encountered in any of the eight patients.

This study was terminated by the manufacturer.

Detail Summary Sheet

Date: 27 Oct 87	Proj No: C-39-86	Status: Ongoing

Title: Sympathetic Blockade and Oral Prednisone Therapy in the Treatment of Herpes Zoster and Post Herpetic Neuralgia.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator (vice Feldman) Emil Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Ava Feldman, CPT, MC J. Henneberger, CPT, MC
Key Words: Herpes zoster	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To determine if sympathetic blockade will reduce the incidence of post herpetic neuralgia in patients with herpes zoster treated with oral prednisone.

Technical Approach: Patients will be randomized into two groups; one will receive nerve blocks with local anesthetic and the other injections with saline. The blocks and injections will be made appropriate to the distribution of the acute herpetic outbreak. All patients will receive oral prednisone according to the current protocol of the Dermatology Service. The following dta will be recorded: age, weight, distribution of the outbreak, onset of pain, onset of cutaneous eruption, when blocks were started, when oral prednisone was started, start of oral pain medicines, and the amount of oral pain medicine used during the herpetic eruption. Patients will be asked to fill out a short questionnaire to assess adequacy of pain relief and improvement in function.

Progress: Seven patients have been entered into the block group and five into the control group. No patients in the block group developed post-herpetic neuralgia. One of the five patients in the control group developed post-herpetic neuralgia.

Detail Summary Sheet

Date: 18 Jun 87	Proj No: C-40-86	Status: Terminated

Title: Platelet Inhibitor Drug Therapy and Coronary Bypass Graft Patency: A Comparison of Low-Dose Aspirin with Dipyridamole and Aspirin.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator (vice Moncrief) Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: James A. Ameika, CPT, MC John M. Bauman, MAJ, MC Michael J. Huggins, MAJ, MC Amram J. Cohen, CPT, MC
Key Words: Bypass graft	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To determine whether low-dose aspirin initiated perioperatively is as effective as the combinatin of Dipyridamole and higher dose aspirin in preventing early postoperative platelet deposition in coronary artery bypass grafts as detected by radioisotope labeled platelet aggregation and in preserving graft patency as demonstrated by digital subtraction angiography.

Technical Approach: Participants will be randomized to one of two treatment programs. Those assigned to program #1 will take a Dipyridamole tablet 4 times a day for two days prior to surgery and one tablet on the day of surgery. Dipyridamole will be given by nasogastric tube one hour postoperatively. Aspirin and Dipyridamole will be given per NG tube 7 hours postoperatively. On the first postoperative day and daily thereafter aspirin and Dipyridamole will be given orally three times a day.

Group 2 patients will be given aspirin per nasogastric tube 7 hours postoperatively. On the first postoperative day and once daily thereafter aspirin will be given orally.

Progress: Study terminated due to paucity of eligible patients.

Detail Summary Sheet

Date: 17 Sep 87	Proj No: C-41-86	Status: Terminated

Title: Screening for Transitional Cell Carcinoma within a Group of High-Risk Patients.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: H. Mack Blanton, MAJ, MC Lida Crooks, MAJ, MC
Key Words: Carcinoma, transitional cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To determine the utility of screening for transitional cell carcinoma within a high-risk group of patients identified by a history of smoking or a history of lung cancer.

Technical Approach: Three groups of patients will be assessed. One group will be classified as those with a 50 pack year smoking history or less. A second group will be those with a higher than 50 pack-year cigarette smoking history. A final group will be those with a history of histologically-confirmed non-small cell carcinoma of the lung. Urine specimens will be obtained and subjected to cytologic analysis.

Progress: This study was terminated following the transfer of the principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-42-86	Status: Terminated

Title: LCSG 852 - Phase II Pilot Program of Chemotherapy Before Surgery in Patients with Stage III non-Small Cell Lung Carcinoma.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Robert A. Helsel, COL, MC Joseph I. Matthews, COL, MC Glenn M. Mills, MAJ, MC Gregory G. Friess, MAJ, MC
Key Words: Carcinoma, non-small cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To determine if combined preoperative therapy with the chemotherapeutic agents 5-FU and Cisplatin and radiation therapy can produce improved resectability rates and long-term survival in patients with stage III lung cancer involving mediastinal node metastases or direct tumor extension into the mediastinum.

Technical Approach: Patients with biopsy-proven non-small cell lung cancer, and involved mediastinal (N2) lymph nodes as determined by mediastinoscopy (CME) or anterior mediastinal exploration (AME), or mediastinal invasion by primary tumor as determined by CME or AME, or with N2 status or mediastinal invasion determined at exploratory thoracotomy, will be eligible for enrollment in this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The one patient enrolled on this study died of progressive disease.

Detail Summary Sheet

Date: 19 Mar 87	Proj No: C-43-86	Status: Terminated

Title: LCSG 801 - A Clinical Investigational Trial in Completely Resected Patients with Lung Cancer Comparing Chemotherapy versus no Therapy After Surgery

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Robert A. Helsel, COL, MC Joseph I. Matthews, COL, MC Glenn M. Mills, MAJ, MC Gregory G. Friess, MAJ, MC
Key Words: Cancer, non-small cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To compare the effect of combination chemotherapy using Cytoxan, Adriamycin, and Cis-Platinum (CAP-I) versus no treatment on rates of recurrence, survival, and pattern of recurrence in patients with completely resected T_1N_1 and T_2N_0 non-small cell lung cancer.

Technical Approach: Patients with surgically resectable non-small cell carcinoma of the lung who have been fully staged at operation with sampling of bronchopulmonary, hilar, subcarinal, and mediastinal lymph nodes, and are found to have T_1N_1 or T_2N_0 disease, with the primary tumor totally resected, are eligible for entry into the study.

Therapy will follow the schema outlined in the study protocol.

Progress: Study terminated by the Lung Cancer Study Group.

Detail Summary Sheet

Date: 18 Jun 87	Proj No: C-49-86	Status: Terminated

Title: Flow Cytometry for Urologic Malignancies.

Start Date 6 May 86	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ralph Ortiz, MAJ, MC
Key Words: Malignancy, urologic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To correlate behavior of urologic malignancies with findings of flow cytometry.

Technical Approach: Patients included within this group of subjects will be those with a history of transitional cell carcinoma of the bladder, those in whom transitional cell carcinoma (or, carcinoma in situ) is suspected, or those with intact urethra who have undergone radical cystectomy and in whom followup of the urothelium is obtained with urethral washings. In all patients, specimens will be obtained at the time of routine cytology collection. An additional 60cc of bladder/urethral washings will be obtained at the time of such clinically-indicated collections.

Progress: This study was terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 15 Oct 87	Proj No: C-52-86	Status: Ongoing

Title: Correlation of Sperm ATP-dependent Bioluminescence and Sperm Motility.

Start Date 12 May 86	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Gerald Merrill, GS11
Key Words: Sperm motility	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $400.00

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To establish an association between sperm ATP concentrations as determined by bioluminescence and sperm motility.

Technical Approach: This protocol will utilize the discarded semen for bioluminescence analysis.

Progress: Using chemiluminogenic probes which are relatively specific for cellular superoxide generating oxidases (Dimethyl bis acridinium nitrate: DBA) and peroxidases (luminol), no significant chemiluminogenic probe dependent chemiluminescence was found to be associated with motile sperm. As sperm motility is dependent on utilization of ATP by Dynein ATPases of the sperm tail, the correlation of sperm ATP and motility was explored using a sensitive bioluminescent assay for ATP. Semen was washed and sedimented sperm were extracted with boiling Tris Acetate buffer containing EDTA and Triton X100. ATP and motility were not significantly correlated due to the ATP associated with nonsperm cells found in the semen of many patients. Isolation of sperm free of nonsperm

C-52-86 (continued)

cells was attempted using percoll discontinuous gradients. Nonviable sperm and most nonsperm cells had densities different than that of viable sperm, and a reasonable correlation of sperm ATP and motility was observed. However, nonsperm cells isolated in the density range of the percoll gradients where sperm were located still contributed to the ATP pool of the extracted sample. Thus vasectomy patients without sperm often had significant ATP levels. Attempts to separate sperm on immunoaffinity columns was not successful. For this reason a new extraction technique was developed. Washed semen is heated for 5 min. at 45°C in Tris Acetate EDTA buffer containing 0.04% Triton X100. Following this treatment, sperm viability is reduced to 0, while the viabilities of nonsperm cells remains unchanged. Thus ATP extracted by this technique is almost exclusively dependent on sperm ATP. Thirty three samples have been evaluated by this assay. ATP dependent bioluminescence of asectomy patients is very low. Conversely, ATP dependent bioluminescence of highly motile sperm is very high. The analysis of the correlation of motility and ATP is now being completed.

AD-A190 939 ANNUAL RESEARCH PROGRESS REPORT FISCAL YEAR 1987 VOLUME 1(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX F H GOLDNER 01 OCT 87 4/4

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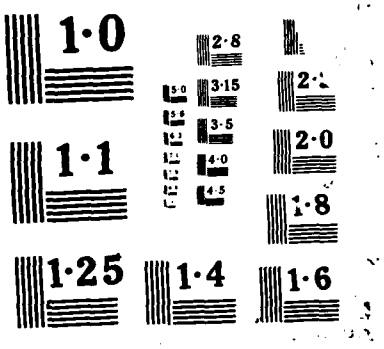
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Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-57-86	Status: Ongoing

Title: Porous Polysulfone Coated Titanium Alloy (Ti-6Al-4V) Hip Prosthesis.

Start Date 10 Jun 86	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators:
Key Words: Hip prosthesis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 32

Total Number of Subjects Enrolled to Date: 32

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biological fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: The Porous Polysulfone Coated Titanium Alloy Hip Prosthesis is intended to serve as the femoral component of a two component system used in total hip arthroplasty. This femoral component will differ from other femoral components in that it does not rely on polymethylmethacrylate (PMMA) bone cement for stabilization within the femoral canal. The criteria used in this evaluation to determine safety will be removal rate. The type and incidence of all complications will be tabulated for analysis along with the removal rate. The criteria for determining efficacy will be pain relief, range of motion and the ability to walk.

Progress: No adverse side effects and no major complications have been encountered. All patients (32) and hips (33) are doing "excellently" by assessment of the modified Harris Hip Score.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-62-86	Status: Ongoing

Title: Efficacy of Endotracheal Tube Cuff Palpation in Distinguishing Endotracheal from Esophageal Intubation.

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator Robert G. Knight, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Intubation, endotracheal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To determine if palpation of the endotracheal tube cuff in the sternal notch is a sensitive and specific means of quickly assessing correct placement of the endotracheal tube.

Technical Approach: At the time of surgery, participants will be assigned to one of two groups. Group I patients will be anesthetized and have an endotracheal tube inserted. Group II patients will be anesthetized, but the esophagus will be intentionally intubated. In both groups, the pilot balloon will be inflated to a prssure of 20 mm Hg. A anesthesia resident will then assess endotracheal vs esophageal intubation in both groups by palpation of the suprasternal notch. Then, a single breath will be given and the endotracheal tube will be observed for condensation of moisture during exhalation. AT the end of this time, the Group II patients will be quickly extubated and a new endotracheal tube appropriately placed in the trachea.

Progress: OR responsibilities during the past year have been with pediatric, obstetric and ICU patients or patients undergoing neurosurgical or cardiac procedures who are not appropriate candidates. Completion is anticipated later this year.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-64-86	Status: Completed

Title: Incidence of Colonization and Lower Respiratory Tract Infections Between Conventional and Endotracheal Suctioning versus Trach Care Suction System$_{TM}$

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator Scott A. Deppe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery	Associate Investigators: Ann Halliday, CPT, AN Jeanne H. Chudy, MAJ, AN William Kelly, CPT, MC Robert N. Longfield, LTC, MC S. Vern Juchau, COL, MC
Key Words: Suctioning, endotracheal Suction system, Trach Care	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): To evaluate the incidence and time of colonization and the incidence and timing of lower respiratory infections in endotracheally intubated patients dependent on the type of tracheal suctionig used.

Technical Approach: The study will be conducted in two major groups. Group I will be patients hospitalized less than 72 hours and an endotracehal tube expected to be in place for at least 24 hours after entry into the study. Patients will be randomized to Group IA (control) or Group IB. Group IA will have their endotracheal suctioning performed by open system, and Goupr IB will have their endotracheal suctioning performed by closed multiple use suction system. Objective data regarding positive sputum cultures, CXR changes, and positive catheter tips will be collected.

Group II patients will be differentiated only from Group I by being in the hospital for greater than 72 hours prior to entry into the study.

Progress: This study has been completed but the data has not been analyzed due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-69-86	Status: Terminated

Title: LCSG 85Q - Quality of Life Survey

Start Date 6 Aug 86	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Robert A. Helsel, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To measure quality of life assessment by patients and to determine the usefulness of such a measure in comparing efficacy of different treatment regimens.

Technical Approach: Patients considered for this protocol will be patients with lung cancer. Prior to their first protocol treatment (LCSG 801 or LCSG 852), patients will be asked to complete the FLIC questionnaire.

Progress: Eight hundred and fifty patients continue to be followed at prescribed intervals by LCSG data manager. This study will be utilized for patients entered into protocol C-87-86 and will no longer be conducted as a separate protocol.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-73-86	Status: Ongoing

Title: Comparison of External Pneumatic Compression Boots and Embolex in Prophylaxis Against Deep Vein Thrombosis

Start Date 12 August 1986	Est Comp Date:
Principal Investigator (vice Thompson) Kurt L. Hansberry, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Oncology	Associate Investigators: John M. Bauman, MAJ, MC Kurt L. Hansberry, CPT, MC Scott Deppe, MAJ, MC Francisco Rodriguez, COL, MC Michael F. Hartshorne, MAJ, MC
Key Words: Thrombosis, deep vein	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 24

Total Number of Subjects Enrolled to Date: 37

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To compare the efficacy and complication rates of external pneumatic compression (EPC) boots and the drug Embolex in preventing lower extremity venous thrombosis in patients undergoing open urologic procedures.

Technical Approach: Adult male patients 40 years of age and older scheduled for open urologic procedures are eligible. Patients will be assigned to one of three treatment groups according to a table of random numbers. Group I will receive Embolex 2 hours before and every 12 hours during the post-operative period. Group II will have external pneumatic compression of the calves achieved by inflatable boots. EPC will be applied during induction of anesthesia and continued until the patient is ambulatory at least three times a day. Controls will wear Ted hose pre- and post-operatively.

Progress: Five patients were found to have DVT's by labelled platelet scanning and one had a PE. All findings were subclinical and asymptomatic at time of discovery. Of the DVT's, one was in the Embolex group, two were in the pneumatic compression stocking group, and two on TED hose. Complications have arisen from the anticoagulation as treatment for DVT's including excessive bleeding from the wound or urinary tract. Consequently, we have submitted a change to the protocol to monitor subclinical DVT below the calf with nuclear scan and treat those above the knee or that are symptomatic otherwise. Plans are to continue the study to completion and have 90 patients enrolled.

Detail Summary Sheet

Date: 3 Dec 87	Proj No: C-76-86	Status: Ongoing

Title: Incidence of Spinal Headache After SAB as Related to Needle Bevel Relationship to Dural Fibers, and Position of Patient During SAB.

Start Date 12 Aug 86	Est Comp Date:
Principal Investigator Robert D. Culling, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: J. Culclasure, CPT, MC Jerry Epps, CPT, MC
Key Words: Headache, spinal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 10 Sep 87 Results 10 Sep 87

Objective(s): To determine if the incidence of spinal headache is increased in patients when the bevel of the spinal needle is inserted perpendicular to the dural fibers versus parallel insertion of the needle.

Technical Approach: Patients will be divided randomly into four groups: I) seated with bevel inserted perpendicular to dural fibers, II) seated with bevel inserted parallel to dural fibers, III) lateral decubitus with bevel inserted perpendicular to dural fibers, and IV) lateral decubitus with bevel inserted parallel to dural fibers. Patients will be followed for 72 hours post-op.

Progress: Data are being analyzed.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-79-86	Status: Ongoing

Title: Tissue Vitamin A Levels in the Oral Mucosa of Head and Neck Cancer Patients

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Roger J. Simpson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Michael Peek, GS-9 Otolaryngology Staff
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To compare the tissue level of retinol in the oral mucosa of head and neck cancer patients with a control population.

2) To determine if there is a correlation between the tissue retinol level of the cancer patient and the degree of differentiation of the tumor.

Technical Approach: The study group will include head and neck cancer patients admitted with a diagnosis of epithelial carcinoma of the head and neck. All patients and controls will be biopsied with cupped biopsy forceps. The left retromolar trigone will be biopsied except those involved with tumor in which case the opposite side or another oral site will be used. The control and patient groups will be analyzed by the difference in mean tests; and the correlation between the degree of differentiation of tumor and the level of vitamin A will be examined.

Progress: The principal investigator reported that he has been unable to get the paperwork done on the control subject (cadavers) side of the study. According to pathology and PAD, there may be insurmountable administrative problems in attempting to obtain informed consent from the next of kin. A new protocol will be submitted with a different control group.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-87-86	Status: Ongoing

Title: LCSG 853 - A Clinical Trial in Patients with Stage II and III Completely Resected Non-Small Cell Lung Cancer Comparing Chemotherapy (CAT) versus No Therapy Following Surgery...

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words: Cancer, non-small cell lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): 1) To compare combination chemotherapy (CAP given at 4-week intervals for 4 cycles) as an adjuvant to surgery to prolong disease-free interval and survival with no immediate adjuvant treatment following complete resection of stage II and III non-small cell cancer of the lung.

2) To compare combination chemotherapy (CAP) administered immediately postoperatively in prolonging survival in these patients with delayed combination chemotherapy administered at the time of systemic recurrence in the no-treatment control group.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient eligible to enter the study refused to participate.

Detail Summary Sheet

Date: 11 Aug 86	Proj No: C-88-86	Status: Terminated

Title: Efficacy of Serum PSA as a Marker for Prostate Cancer

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Mary Wilson, MAJ, MC
Key Words: Cancer, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the effiacy of Tandem-R PSA as a marker for prostate cancer.

Technical Approach: All patients in the following categories will undergo both PAP and Tanem-R PSA: follow-up prostate cancer, newly-diagnosed prostate cancer, and BPH (admitted for TURP). The two assays will be compared with the clinical status of the disease (in categories one and two) and with final pathologic report and further staging, if appropriate, for category three.

Progress: This study was terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-89-86	Status: Ongoing

Title: Kennedy Ligament Augmentation Device in Reconstruction of the Unstable Knee for Anterior Cruciate Instability

Start Date 12 Sep 86	Est Comp Date:
Principal Investigator Allan L. Bucknell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To demonstrate the effectiveness of the Kennedy LAD as a perioperative facilitator and as an augmentation device for repair or reconstruction of the anterior cruciate ligament.

Technical Approach: As outlined in the 3M Company protocol.

Progress: Prior to actual Center entry into this study, "investigational" status terminated, and second or tertiary phases of investigations commenced. No patients enrolled at BAMC because of inability to assure "follow-up" criteria.

Detail Summary Sheet

Date: 11 Aug 87	Proj No: C-93-86	Status: Ongoing

Title: Sphenopalatine Ganglion Blocks for Treatment of Nicotine Addiction

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator vice Henneberger Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Addiction, nicotine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 17

Total Number of Subjects Enrolled to Date: 17

Date of Periodic Review _____ Results _____

Objective(s): Treatment of the nicotine abstinance withdrawal syndrome associated with acute cessation of tobacco with sphenopalatine ganglion blocks.

Technical Approach: Subjects will be randomly assigned to one of three study groups. The 1st group will receive topical 4% cocaine, a 2nd group will receive .75% Bupivicaine with 1:100,000 epinephrine, and a 3rd group will receive saline. Subjects will be cigarette smokes who demonstrate a desire to quit smoking. All subjects will be required to complete a "tolerance questionnaire" which measures the degree of physical dependence.

Progress: Seventeen patients have completed a treatment course involving daily intra-nasal application of local anesthetic (cocaine or bupivacaine) or saline over the sphenopalatine ganglion. The data demonstrates a significantly lower association of physical symptoms with patients undergoing sphenopalatine ganglion bock. Additionally, significantly ($p < .05$) fewer physical symptoms of withdrawal were reported in patients receiving the longer acting local anesthetic bupivacaine as compaired with cocaine. Considered together, patients in the nonplacebo groups demonstrated a lower relapse rate at 30 days ($p < .05$) to smoking than did patients in the placebo groups.

Detail Summary Sheet

Date: 11 Aug 87	Proj No: C-95-86	Status: Ongoing

Title: Capnometry During the Administration of Supplemental Oxygen

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator (vice Shipman) Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Robert E. Middaugh, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 38

Total Number of Subjects Enrolled to Date: 38

Date of Periodic Review _____ Results _____

Objective(s): To evaluate noninvasive methods of capnometry while administering supplemental oxygen to patients during surgery.

Technical Approach: One hundred and fifty patients will be routinely given oxygen and monitored using nasal cannula, venti mask, and a semi-closed anesthesia circuit. Three sets of end tidal CO_2 values will be recorded for each oxygen apparatus.

Progress: System Three (nasal cannula) recorded the highest average value of 36.7 $\pm$ 3.9 followed by System One (semiclosed circuit) at 34.8 $\pm$ 3.9 and System Two (nonrebreathing mask) at 25.3 $\pm$ 6.5. Comparison of the average end tidal carbon dioxide values with a one way analysis of variance demonstrated a statistically significant difference between the three groups.

Detail Summary Sheet

Date: 7 Dec 87	Proj No: C-1-87	Status: Ongoing

Title: The Effect of External Electrical Stimulation on Spine Fusions (Lumbar)

Start Date 19 Nov 86	Est Comp Date:
Principal Investigator Gerald Q. Greenfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Allen L. Bucknell, COL, MC Michael Haak, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review_____ Results_____

Objective(s): To determine whether the Spinal Stim-System will increase the success rate and decrease the healing time in patients having undergone a lumbar fusion.

Technical Approach: The study group at BAMC will become part of a large multi-center project. Patients will be assigned to groups in a randomized double blind fashion as each patient will have a "stimulator" applied, but activity of each determined by a code at the company. Patients will be followed by clinical evaluation as well as serial radiographs. Since current data incidates that fusion takes four to six months, all patients will use the external stimulator for a minimum of eight hours daily over three to nine months.

Progress: To date we have enrolled two subjects in this study though many possible candidates (15-20) have not needed the operation. Our evaluation of potential candidates continues.

Data is submitted to the multicenter tabulation center; however, the tabulation center has not provided any data as yet.

Detail Summary Sheet

Date: 14 Oct 87	Proj No: C-3-87	Status: Ongoing

Title: Radical Retropubic Prostatectomy and Orchiectomy for Stage C Carcinoma of the Prostate

Start Date 19 Nov 87	Est Comp Date:
Principal Investigator John Brizzolara, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Prostate Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review _____ Results _____

Objective(s): To determine the efficacyof combined hormonal and surgical therapy for carcinoma of the prostate.

Technical Approach: Patients eligible for entry into the study will either be placed on Leupron theapy, one injection per day for two months, or undergo bilateral simple orchiectomy. Eight weeks following orchiectomy, radical prostatectomy will be performed.

After post-hormonal maniulation studies are obtained, patients will undergo staging pelvic lymphadenectomy. Postoperative treatment shall be in accordance with standard procedures.

Progress: To date, there has been only one patient who has met the criteria to be entered into the protocol. This patient, after treatment with leupron, showed a down staging of his prostate size and subsequent uneventful surgical removal of the prostate. Persently there is no evidence of recurrent disease.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-21-87	Status: Terminated

Title: A Pilot Study to Evaluate the Efficacy of Intra-Pleural Chemotherapy in the Management of Malignant Pleural Effusions (LCSG 861)

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator (vice Friess) Brent O. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Thoracic Surgery	Associate Investigators: Robert A. Helsel, COL, MC
Key Words: Effusion, pleural	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): To evaluate the efficacy of an intrapleural combination chemotherapy regimen (Cisplatin and Cytarabine) in the treatment of malignant pleural effusions caused by metastatic solid neoplasms; to further asses the toxicities of the two drugs, and consequently, the possibility of administering this treatment on an outpatient basis; to generate informatin about which solid tumors may be most sensitive to this regimen; and to assess the impact of this regimen on the patient's quality of life.

Technical Approach: Patients with histopathologically proven diagnosis of cancer involving the pleura, as demonstrated by pleural fluid cytology or pleural biopsy positive for carcinoma or lymphoma will be eligible. The patient's malignant pleural effusion must be refractory to standard systemic therapy, or the patient's tumor must have no known effective standard therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been terminated. Only patients already entered into the protocol will continue to be followed.

Detail Summary Sheet

Date: 20 Mar 87	Proj No: C-31-87	Status: Completed

Title: A Comparison of Tear Breakup Time (TBUT) Obtained Using Fluor-I-Strip vs Fluress.

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator Stuart Farris, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Tear breakup time (TBUT)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 16

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review _____ Results _____

Objective(s): To determine if there is a significant difference in TBUT Using Fluor-I-Strip versus Fluress.

Technical Approach: TBUT is determined by placing fluorescein stain on the cornea and measuring the time it takes for the flurescein marked tear film to break up after a blink. The literature recommends the use of only Fluor-I-Strips, but without really giving any reasons. Since Fluress is commonly used for examination of the cornea and applanation tonometry, this study was designed to see if Fluress can be accurately used for TBUT determination.

Tear break-up time was obtained in 30 eyes of 16 patients using Fluor-I-Strips first and then Fluress. Five measurements of TBUT were obtained with each dye.

Progress: There is a statistically significant ($p > 0.05$) increase in TBUT using Fluress as compared to Fluor-I-Strips.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-32-87	Status: Ongoing

Title: LCSG 821 - A Randomized Comparative Trial of Lobectomy versus Limited Resection for Patients with Cancer of the Lung

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words: Lobectomy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review_____ Results_____

Objective(s): 1) To determine if limited pulmonary resection (wedge resection or segmental resection) for peripheral $T_{1NO}MO$ non-small cell lung cancer is as effective as lobection in preventing recurrence of disease.

2) To compare morbidity and mortality of imited resection with that of standard lobectomy.

3) To compare postoperative pulmonary funciton with regard to type of procedure employed.

Technical Approach: Eligible patients must have a presumed diagnosis of non-small cell carcinoma of the lung (squamous cell, adenocarcinoma or large cell). The patient must be a candidate for lobectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been randomized to lobectomy and one to limited resection. No acute morbidity has been noted.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-33-87	Status: Ongoing

Title: Morbidity Associated with Pelvic Lymphadenectomy

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Thompson) Francisco R. Rodriguez, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Doug Corrie, CPT, MC
Key Words: Lymphadenectomy, pelvic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the morbidity associated with pelvic lymphadenectomy.

Technical Approach: The inpatient records of all patients undergoing pelvic lymphadenectomy during the period 1978 to 1986 will be reviewed. In addition, outpatient records will be reviewed for any evidence of long term sequelae of the operation.

Progress: Review of the records continues. No reportable data are available at this time.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-34-87	Status: Ongoing

Title: Bowel Obstruction Secondary to Carcinoma of the Prostate

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Thompson) Francisco R. Rodriguez, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To discern the natural history of patients developing rectal obstrction secondaryt o carcinoma of the prostate. To further determine the effect of treatments given to patients with this extensive disease.

Technical Approach: All cases of bowel obstruction secondary to carcinoma of the prostate will be retrieved from records of the Urology Oncology data registry at BAMC.

Progress: This is a chart review. No data are available at this time.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-46-87	Status: Ongoing

Title: LCSG 862 - Immunohistochemical Analysis of Lung Cancer

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Robert A. Helsel, COL, MC Lida A. Crooks, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review_____ Results_____

Objective(s): 1) To ascertain the predictive value of a series of immunohistochemical markers for response and survival in a previously studied patient population on whom data on routine prognostic factors, response, survival and toxicity is known.

2) To ascertain whether patterns of disease prsentation are correlated with specific markers for cell surface and cytoskeletal proteins.

3) To ascertain if thepattern of loss of markers used to define the small cell "variant" cell lines and specimens is predictive of improved response in non-small cell patients.

Technical Approach: Data collection and registration are as outlined in the study protocol.

Progress: One patient entered in LCSG 853 which is requisite for tissue analysis for this protocol.

Detail Summary Sheet

Date: 22 Oct 87	Proj No: C-50-87	Status: Ongoing

Title: Chromosomal Analysis of Genitourinary Neoplasms

Start Date 11 May 87	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric J. Zeidman, MAJ, MC Kurt L. Hansberry, CPT, MC Isidoro Chapa, GS-7
Key Words: Karyotype	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1,462.38

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To correlate tumor karyotypes with patient data, tumor stage and grade, and clinical course of the disease.

Technical Approach: At the time of removal of a genitourinary tumor, a small piece of tumor tissue will be sent for karyotyping. The technique for karyotyping will employ the coverslip method. Chromosomal banding will include standard techniques for G-banding, Q-banding (fluorescence), and C-banding. Photographs will include intact banded metaphase plates. Karyotyping will be performed by cutting individual chromosomes from photographs and identifying according to standard nomenclature.

Progress: Data are being accumulated.

Detail Summary Sheet

Date: 28 Sep 87	Proj No: C-55-87	Status: Ongoing

Title: The Effect of Combined Low Dose Dopamine and Furosemide on Urine Production and Renal Function in Acute Oliguric Renal Failure

Start Date 13 May 87	Est Comp Date:
Principal Investigator (vice Cushner) Joseph P. Ducey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Intensivist	Associate Investigators:
Key Words: Renal failure Dopamine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the effectiveness of furosemide and low dose dopamine in patients with established acute renal failure (ARF) in order to see if these agents favorably alter the patient's course.

Technical Approach: Patients meeting the criteria for inclusion will be assigned to one of the trial groups via a random numbers table. Group I will receive low dose dopamine plus furosemide by continuous infusion. Patients in Group II will receive saline-placebo as substitution for both continuous dopamine and intermittent furosemide infusion. Therapy and data collection will follow the schema outlined in the study protocol.

Progress: No patients have met entry criteria to date. We hope to expand to additional Military Medical Centers in order to increase study population.

Detail Summary Sheet

Date: 16 Oct 87	Proj No: C-65-87	Status: Ongoing

Title: Trauma Score

Start Date 2 Jul 87	Est Comp Date:
Principal Investigator R. Duane Cook, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Eugene Kwong, CPT, MC
Key Words: Trauma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To compare the Trauma Score and CRAMS (Circulation, Repiration, Abdomen, Motor, Speech) Scale as predictors of outcome and triage instruments in major trauma and to document the present state of trauma care at BAMC.

Technical Approach: The study population will be comprised of all patients brought to BAMC Emergency Department because of major trauma who are either admitted, transferred to another hospital or die prior to admission. Each patient will undergo standard emergency evaluation and treatment. After stabilization of the patient a checklist will be completed by the physician regarding the patient's prehospital and emergency department condition and care. Each patient will be scored according to the Trauma Score and CRAMS scale.

Progress: This study has been temporarily suspended.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-68-87	Status: Terminated

Title: Intrathecal and Epidural Calcitonin for Intractable Pain Due to Malignancy

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review_____ Results_____

Objective(s): To determine the analgesic effectiveness and duration of analgesia after subarachnoid injection of calcitonin.

Technical Approach: Fifteen patients with intractable pain from terminal cancer will be included. The patient will mark a visual analog scale and will be taken to the Pain Clinic and 100 units of Calcitonin in 6 cc of saline will be injected into the subarachnoid space. Patients will mark a visual analog scale at 15, 30, and 60 minutes post injection. Those patients who obtain at least 50% reduction in pain will continue in the study.

Progress: One patient was entered into this study from BAMC. There was significant pain relief x 5 days after intrathecal Calcitonin; however, there was severe nausea and vomiting x 36 hours. The IND and the investigation have been terminated with the FDA.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-69-87	Status: Terminated

Title: Pilot Study of the Topical Use of Capsaicin in Neuralgia

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review _____ Results _____

Objective(s): To determine the analgesic effectiveness and duration of analgesia of the topical use of capsaicin in neuralgia.

Technical Approach: Ten patients with the diagnosis of peripheral neuritis or post herpetic neualgia will be studied. Gauze sponges saturated with Lidocaine, 4%, will be placed over the area marked. After 15 minutes, these gauzes will be removed. At that time, capsaicin 1% in ethyl alcohol will be applied with a sponge applicator by passing the applicator over the marked area. The visual analog scale, Lidocaine application and capsaicin application will be done on the first three days. On the fourth and fifth day, patients will not receive Lidocaine, but will complete the visual analog and receive capsaicin. Subjects will be seen one week after the fifth treatment and then at two week intervals for three more visits. At each visit, subjects will be asked to mark the visual analog scale.

Progress: Two people were entered into the study at BAMC. There was no benefit seen in the use of capsaicin in post-herpetic neuralgia by visual analog scales. The IND and the investigation has been terminated with the FDA.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-90-87	Status: Ongoing

Title: Opti-Fix^{tm} Hip Prosthesis (Multicenter Study)

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Allen L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators:
Key Words: Prosthesis, hip	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biologic fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: Patients requiring total hip replacement will be asked to participate in this study. If they agree, the Opti-Fix^{tm} will be implanted as outlined in the study protocol.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-93-87	Status: Ongoing

Title: The Relative Roles of the Lacrimal Canaliculi in Tear Drainage

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator William L. White, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Tear drainage	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine the rate at which the superior and inferior canaliculi transport tears relative to each other.

Technical Approach: Each potential test subject will be evaluated for punctal patency and position by slit lamp exam. The cornea will also be examined for evidence of dry eyes and a dye disappearance test will be done to insure normalcy of the test subject's lacrimal drainage system. Dacyroscintillography will be performed with each punctum occluded.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 29 Oct 87	Proj No: C-94-87	Status: Ongoing

Title: Correlation of the Bacterial Colonization of the Adenoidal Tissue and Middle Ear Effusion

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator John T. Fraker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Jesse Moss, Jr., LTC, MC Hugh M. Gelston, Jr., MAJ, MS Sheila Jones, SSG
Key Words: Adenoidectomy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To compare the bacterial content of the adenoid tissue and middle ear effusion in children.

Technical Approach: All patients ages 2 to 18 undergoing adenoidectomy and myringotomy with PE tube placement will be asked to participate. At the time of surgical removal of the adenoids, a small portion of the tissue will be taken and sent for anaerobic culture and identification. At the same time, using an anaerobic transport swab, culture will be taken of the middle ear effusion for identification of the organisms present.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 13 Nov 87	Proj No: C-32-85	Status: Terminated

Title: Benzodiazepine Drug Monitoring Program.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator John R. Downs	Facility Brooke Army Medical Center
Dept/Svc Pharmacy Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): To observe the use and effects of benzodiazepine anxiolytic medications in a customary use situation.

Technical Approach: The study population will consist of outpatients enrolled in participating pharmacies. Individuals in the study population will have had a prescription filled in the participating pharmacy for one of the eligible benzodiazepine anxiolytic medications.

Progress: This study was terminated due to lack of progress.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-92-86	Status: Terminated

Title: Comparison of Two Conservative Treatments in the Management of Dequervain's Tenosynovitis: Splinting versus Splinting and Ultrasound

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator Dominick C. Aretino, CPT, SP	Facility Brooke Army Medical Center
Dept/Svc Occupational Therapy	Associate Investigators: Steven D. Hunte, CPT, SP Deborah M. Stetts, CPT, SP Marc S. Willey, 1LT, SP William Milnor, COL, MC
Key Words: Tenosynovitis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 10 Sep 87 Results Terminate

Objective(s): To determine if ultrasound in conjunction with splinting is a more effective therapeutic modality than splinting without ultrasound in the treatment of De Quervain's tenosynovitis.

Technical Approach: Patients will be randomly assigned to two groups. Group A will be treated with splinting alone. Each patients will be treated with an orthoplast thumb spica splint to be worn 24 hours per day for one month. Group B patients will be treated with splinting and ultrasound with 10% hydrocortisone. Each patient will also be placed in the same splint as in Group A.

Progress: This study was terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 3 Dec 87	Proj No: C-77-85	Status: Completed

Title: Nitrogen Balance in Pediatric Patients Undergoing Autologous Bone Marrow Transplantation

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Cheryl Walton, 2LT, SP	Facility Brooke Army Medical Center
Dept/Svc Directorate of Nutrition Care	Associate Investigators: Paul Thomas, COL, MC Lewis, MAJ, AN Walter H. Harvey, M.D., MAJ, MC
Key Words: Bone Marrow Transplantation, Autologous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): 1) To determine N balance in pediatric patients receiving autologous bone marrow transplantation.

2) To assess changes in body composition.

3) To correlate the above with recovery and transition from parenteral to enteral feeding.

Technical Approach: 72 hour urine collections will be obtained weekly during hospital course to determine optimum versus negative nitrogen balance. SMAC 20 for serum albumin, BUN and creatinine will also be done.

Progress: This study has been completed. However, due to change of investigators and subsequent transfer of the principal investigator, no data are available.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-80-86	Status: Completed

Title: The Effect of Verbal and Recorded Instruction on Work Produced by the Quadriceps Femoris Muscle in Isokinetic Exercise

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator J. Kim Albany, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Branch	Associate Investigators: Tim Gangel, 2LT, SP Leanne Pentland, 2LT, SP Glen D. Stobaugh, 2LT, SP
Key Words: Exercise, isokinetic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 42

Total Number of Subjects Enrolled to Date: 42

Date of Periodic Review_____ Results_____

Objective(s): To investigate the effects of verbal and recorded instruction with positive motivation on quadriceps femoris muscle force as measured on the Cybex II isokinetic dynamometer.

Technical Approach: The subjects include 42 active duty personnel - 21 male and 21 female. Participants were seated in a standard position for knee extension and flexion on the Cybex II® dynamometer. Each subject was tested at 60°/sec and performed 10 maximal knee extension contractions as a pretest (used for group assignment), and as the actual testing procedure with either positive recorded motivation, positive verbal motivation or no motivation (the control).

Progress: This study indicates that 1) positive recorded motivation may improve isokinetic work output generated by the quadriceps femoris muscle group, 2) verbal positive motivation does not statistically improve work output, and 3) males improve their motor performance in response to positive motivation more than females. Possible explanations for these findings include individual and gender differences, audience effects, varying reactions to the mode of motivation, sensory input differences, and difficulty in assessing maximum effort.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-81-86	Status: Completed

Title: Effects of Varying Electrode Site Placements on the Torque Output of an Electrically Stimulated, Involuntary Quadriceps Femoris Muscle Contraction

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Mark W. Blackley, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Jim P. Ferguson, 2LT, SP Ron D. Knight, 2LT, SP Thomas G. Sutlive, 2LT, SP
Key Words: Muscle, quadriceps femoris	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review _____ Results _____

Objective(s): To investigate the effects of varying electrode site placement on the torque output produced by involuntary quadriceps femoris contraction.

Technical Approach: Twenty subjects were divided into five groups based on treatment order. The five stimulation strategies used were: femoral nerve and vastus medialis (VM), rectus femoris (RF), vastus lateralis (VL), or opposite quadriceps (OQ), and ipsilateral vastus medialis and vastus lateralis (VM/VL). The peak torque of three cycles of electrical stimulation for each placement was measured as a percentage of maximum voluntary isometric contraction (MVIC). Electrical stimulation utilizing the Electro-Stim 180-2 will be applied to the level of subject tolerance at each site.

Progress: The results indicated the mean percent (%) MVIC of the VM, VL, and RF sites was significantly ($p \leq 0.05$) different from the mean of the OQ and VM/VL sites. Post hoc testing did not reveal a difference in the mean % MVIC between the VM, VL, and RF sites. Either the VM, VL, or RF distal electrode site placement may be used clinically to produce a maximum involuntary isometric contraction of the quadriceps femoris muscle when stimulated electrically.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-82-86	Status: Completed

Title: Effects of Ice Massage, Ultrasound and the Combination of Ice Massage/ Ultrasound on Blood Flow

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Nancy R. Brown, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Michael R. Leachman, 2LT, SP Paul Stoneman, 2LT, SP
Key Words: Massage, ice Ultrasound	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine whether the combination treatment of ice massage and ultrasound is more effective in increasing the blood flow in the brachial artery than ultrasound or ice treatment alone.

2) When using the ice/ultrasound combination treatment, does the ordering of the combination treatment have an effect.

Technical Approach: Five males and five females were randomly ssigned to one of the following treatment groups: 1) rest/rest, 2) ice/rest, 3) ultrasound/rest, 4) ice/ultrasound, or 5) ultrasound/ice. Photoplethysmography was used to measure blood flow. Measurements were taken pre-treatment, after the first treatment phase (5 minutes) and following the second phase (10 minutes).

Progress: One-way ANOVA and Duncan's procedure showed that the two combinations of ice massage and therapeutic ultrasound did not significantly change blood flow ($p < .05$). Ice treatment alone decreased blood flow while ultrasound had no significant effect ($p < .05$). Results did not support the use of combination treatments to significantly change blood flow.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-83-86	Status: Completed

Title: Age and Gender as Determinants of Post-Rotary Nystagmus Duration

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Robert C. McFarland, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Mary A. Somers, 2LT, SP Margaret J. Weatherson, 2LT, SP Wendy A. Wight, 2LT, SP
Key Words: Nystagmus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 80

Total Number of Subjects Enrolled to Date: 80

Date of Periodic Review _____ Results _____

Objective(s): To determine and correlate differences or similarities in duration of post-rotary nystagmus in the healthy adult active duty military population.

Technical Approach: The sample consisted of 80 normal active duty military personnel ages 17-36 years, 40 males and 40 females. The subject is seated in the Barany chair with the head placed at a 30° angle from the vertical. The subject is then passively rotated to the left and the chair abruptly stopped. At this time the subject is asked to generally gaze up at the blank wall and nystagmus duration is timed. After one minute rest, the subject is passively rotated to the opposite direction. Nystagmus duration is again measured while the subject gazes at the blank wall.

Progress: Duncan's multiple range test revealed a significant increase ($p<.05$) in mean nystagmus duration with increasing age. Though not statistically significant, a trend was noted towards decreased nystagmus duration time with increased exercise frequency. No significant relationship between postrotary nystagmus duration (PRND) and gender, balance, or coordination was noted. These findings suggest that medical personnel should be aware that increased PRND in older adults may not indicate a pathological condition, but rather may be due to the effects of age.

Detail Summary Sheet

Date: 21 Oct 87	Proj No: C-15-87	Status: Ongoing

Title: Electroanalgesia as it relates to electrically induced quariceps femoris muscle contraction.

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Frank B. Underwood, CPT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: LCDR Gary L. Kremser, MS, USN LTC David G. Greathouse, SP
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 19

Total Number of Subjects Enrolled to Date: 19

Date of Periodic Review_____ Results_____

Objective(s): To investigate the effect of a 20 minute application of high frequency, low-amplitude electrical current on involuntary torque production by the quadriceps femoris muscle group.

Technical Approach: Maximum voluntary isometric torque production of the quadriceps femoris muscle group is determined via the Cybex dynamometer. One of the two muscle groups (left or right) receives low-amplitude current from the Electrostim 180-2 electrical stimulator, followed by a maximal tolerated current to produce torque. The opposite muscle group receives the maximal tolerated current without the preceding low-amplitude current. The mean of the torque production and the maximal tolerable current will then be compared using the t-test.

Progress: Currently, adequate data has been collected to demonstrate that the low-amplitude current increases the tolerable current, but does not increase the amount of torque produced with a maximal tolerable current. A gross trend analysis indicates movement toward statistical significance regarding torque produciton - therefore, data from additional subjects will be collected.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-81-87	Status: Ongoing

Title: A Comparison of Actual and Apparent Lumbar Lordosis and the Validity of the Flexible Rod as a Noninvasive Measure of Lordosis in Black vs White Females

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Eileen Mosner, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Jean M. Bryan, MSJ, SP Margaret A. Stull, MAJ, MC
Key Words: Lordosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review n/a Results _____

Objective(s): To study the effects of racial group of origin upon the dependent variables of actual and apparent measures of lumbar lordosis. This study will also investigate the validity of the flexible rod as a noninvasive measure of lumbar lordosis in both black and white adult females.

Technical Approach: Subjects will be assigned to one of two groups consisting of 30 members in each group. Group I will consist of 30 black females, and Group II will consist of 30 white females. Height and weight of volunteers will be measured using a standard height/weight scale, and the subject's weight must comply with AR 600-9 standards. Bony areas around the hip and low back will be identified and marked for the following measurements: one right lateral low back x-ray, a tape measure recording out to the mark on right greater trochanter, a flexible rod measure where a flexible rod is molded against the curve of her low back, lateral photograph from the chest down, and hamstring length measurement.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-82-87	Status: Ongoing

Title: The Effects of Transcutaneous Electrical Nerve Stimulation (TENS) on Neural Conduction of the Superficial Radial Nerve

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Steven H. Bullock, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Stephen P. Layman, 2LT, SP Rebecca D. Nowlin, 2LT, SP
Key Words: TENS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To investigate the effect of various intensities of TENS upon the dependent variable of neural conduction of the superficial radial nerve in normal subjects.

Technical Approach: Three study groups will be required consisting of four individuals per group. Participants will receive an application of TENS on the forearm that is either imperceptible (feel nothing), minimal (intensity turned up until a slight muscle contraction is visible, then turned back down) or contractile (intensity turned up to a slight visible muscle contraction). All applications of TENS will be preceded by 10 minutes of rest. The length of time for the TENS application will be 20 minutes. Neural conduction will be recorded just before the application and at 0, 1, 3, and 5 minutes after.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-83-87	Status: Ongoing

Title: An Operational Definition of Lower Limb Dominance

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Garn T. Loveland, 2LT, SP	Facility Academy of Health Scineces
Dept/Svc Physical Therapy Section	Associate Investigators: Robert L. Matekel, 2LT, SP William G. Sumsion, 2LT, SP
Key Words: Dominance, lower limb	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To establish a consistent and reliable procedure for determining lower limb dominance.

Technical Approach: At least 50 normal subjects, 25 male and 25 female, between the ages of 18 and 35 years will be studied. Four different methods of predicting the dominant lower extremity will be conducted in the following order: 1) preferred leg for kicking, 2) girth measurements, 3) handedness, and 4) isokinetic measurements using the Cybex II dynometer.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 28 Oct 87	Proj No: C-84-87	Status: Ongoing

Title: Effects of Gender and Handedness on Neural Conduction in Human Subjects

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Gerald Harkins, 2LT SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Daniel Jayne, 2LT, SP Lawrence Masullo, 2LT, SP Kelly Norton, 2LT, SP
Key Words: Conduction, neural	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To investigate the effects of gender and handedness upon the dependent variable of neural conduction (NC).

Technical Approach: Twenty subjects will be used for this study and grouped according to their gender and handedness. The physical examination will consist of the following: 1) muscle stretch reflexes of the upper extremities; 2) gross motor strength evaluation of both upper extremities; and 3) sensation testing of both upper extremities. Neural conduction latencies and amplitudes will be measured using a Cadwell 5200A electromyograph and stimulator. During the NC examintion the subject will be placed in a supine position on the examining table. The median nerve, ulnar nerve, and radial nerve will be measured according to procedures outlined by Braddon and Schuchman.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 17 Sep 87	Proj No: C-48-85	Status: Transferred

Title: Treatment of Mammalian Bites.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Daniel J. Dire, M.D., CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators: Steve Walker, D.O., MAJ, MC
Key Words: Bite, mammalian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review 18 Jun 87 Results Continue

Objective(s): 1) To show whether there is a statistically significant difference in the infection rate of mammalian animal bite wounds that require suturing among those wounds which are closed immediately in the Emergency Room and those utilizing delayed primary closure.

2) To show whether there is a statistically significant difference in the infection rate of mammalian bite wounds that are treated with good wound cleaning and debridement compared to those also treated with a prophylactic course of oral antibiotics (excluding puncture type wounds and wounds of the hands and feet).

Technical Approach: All patients 1-year-old and up with mammalian bits who present to the Emergency Room are eligible. Those with wounds not requiring stitches will be randomly assigned to either receive or not receive a 7 day course of antibiotics. Those with wounds requiring stitches will be randomly assigned to either have the wound immediately sutured or will be required to return in 3 days for suturing. Patients in this latter group will either receive or not receive a 7 day course of antibiotics.

Progress: Data has been collected on over 1000 patients with 200 of these having been prospectively randomized into treatment groups.

This study is being transferred to William Beaumont Army Medical Center for completion.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-25-86	Status: Completed

Title: A Retrospective Review of Mammalian Bite Wound Infection Rates.

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator John J. Lorette, Jr., CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators: Daniel J. Dire, CPT, MC William Dice, MAJ, MC
Key Words: Bite, mammalian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 11 Mar 87 Results Continue

Objective(s): 1) To show whether there was a statistically significant difference in the infection rates of mammalian bite wounds among patients who were or were not prescribed a prophylactic course of antibiotics.

2) To collect epidemiological statistics on patients who were treated at a US Army Community Hospital for all animal bite wounds from May 1983 to June 1985.

Technical Approach: All mammalian bites treated at Darnall Army Community Hospital from May 1983 to June 1985 will be reviewed.

Progress: Data collection has been completed, but has not been analyzed. Consider the project completed.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-47-86	Status: Terminated

Title: The Plastic Fracture and Its Incidence in the Pediatric Population

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Jose Aponte, Jr., CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Fracture, plastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To prospectively and retrospectively study a large population of pediatric patients to determine the incidence of this injury and alert physicians who initially come into contact with this population to the mechanism of this fracture.

Technical Approach: This study will cover a six month period or until enough cases have been accumulated as determined by Mendenhall's sample size formulation. During this time a retrospective study will include all patients between the ages of six months and fourteen years of age who present to the Emergency Department with the complaint of an upper extremity injury. Children with a clinical forearm deformity without a fracture, an angulated shaft fracture of either the radius or ulna, or a dislocation of one bone at the wrist or elbow will be suspect for a plastic deformity. Their x-rays will be obtained and reviewed by a radiologist.

Progress: The study was terminated due to lack of support.

Detail Summary Sheet

Date: 20 Oct 87	Proj No: C-68-86	Status: Terminated

Title: Utility of Liquid Crystal Thermography in IV Cannulation

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator Dennis M. Plante, CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____Results_____

Objective(s): To determine if the use of liquid crystal thermography strips will aid in IV cannulation in the Emergency Department.

Technical Approach: After eligibility is determined, the patient will be randomly assigned to either a control or test group. The control group will have their IV's started in the routine manner. The test group will have their IV's started using the Vena Vue (V.V.) system. The following data will be compared: attempts/successful IV start in the V.V.; time to start the IV in each group; age of each group; number of complications; and comparison of subjective difficulty in starting the IV in both groups.

Progress: No patients were enrolled on this study. The project was terminated at the request of the principal investigator.

Detail Summary Sheet

Date: 18 Sep 87	Proj No: C-22-87	Status: Terminated

Title: Use of Serum Myoglobin in the Evaluation of Acute Visceral Chest Pain in the Emergency Room

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator Robert L. Patterson, CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Emergency Medicine	Associate Investigators:
Key Words: Myoglobin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To confirm or refute reports regarding the positie and negative predictive values of serum myoglobin for AMI in an emergency room setting, using a rapid latex agglutination test for serum myoglobin.

Technical Approach: None.

Progress: Study terminated due to inability to obtain the Rapitex Myoglobin procedure from Behring Institute.

Detail Summary Sheet

Date: 11 Mar 87	Proj No: C-28-86	Status: Completed

Title: Efficacy of Routine Gastric Aspiration in Normal Newborns.

Start Date 11 Mar 86	Est Comp Date:
Principal Investigator (vice Meidell) Samuel A. Mujica, CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Aspiration, gastric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 75

Total Number of Subjects Enrolled to Date: 150

Date of Periodic Review 11 Mar 87 Results Completed

Objective(s): To determine the efficacy of routine gastric emptying by aspiration in normal newborns.

Technical Approach: At random determine which normal newborns will be aspirated or nonaspirated for stomach contents right after birth. Compare data (HR, RR, Temperature, change in weight during hospital stay, vomiting [+ or -])

Progress: Results show there is no statistical difference in overall behavior or incidence of vomiting between the aspirated vs not aspirated group. No difference noted on HR, RR, temperature or change in weight. No difference in feeding tolerance.

Detail Summary Sheet

Date: 21 Sep 87	Proj No: C-27-87	Status: Transferred

Title: Hospital Liquid Diet Evaluation

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Hirsch) Katie Boyd, LTC, SP	Facility DArnall Army Community Hospital
Dept/Svc Chief, Nutrition Care Division	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 16

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review n/a Results

Objective(s): To determine the acceptability of commercially produced menu items for patients with jaw injuries and/or dental problems.

Technical Approach: The study will be conducted in 12 military hospitals. Hospitals participating in the evaluation will be asked to provide support from dietitians and/or diet technicians who will be responsible for the following: 1. briefing patients; 2. obtaining patients' signatures on volunteer agreement forms; 3. preparing the liquid products according to instructions provided by NATICK; 4. measuring liquid product and beverage intake according to the protocol; 5. providing a description of the currently used liquid diet products; 6. providing information regarding each patient's hospitalization; 7. obtaining the attending physicians' written permission for eligible patients to participatpate; 8 distributing and collecting the questionnaires; and 10. forwarding completed questionnaires to NATICK.

Progress: This study has been transferred to William Beaumont Army Medical Center.

Detail Summary Sheet

Date: 22 Jul 87	Proj No: C-27-86	Status: Terminated

Title: Tine Test versus Mono-vacc Screening for Tuberculosis.

Start Date 22 Mar 86	Est Comp Date:
Principal Investigator Robert A. Calder, CPT, MC	Facility Reynolds Army Community Hospital
Dept/Svc Preventive Medicine Service	Associate Investigators:
Key Words: Test, tine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review 18 Jun 87 Results Terminate

Objective(s): To determine whether or not the Tine and Mono-vacc tests are equivalent in their ability to detect PPD reactions in a healthy population.

Technical Approach: Tests were administered to 20 volunteers as outlined in the study protocol and read 72 hours after application.

Progress: The principal investigator reported that they were only able to recruit 20 subjects. It was rare to find a person who was first noted to react to tuberculin after getting a PPD. Most often, reactivity to tuberculin is first discovered by a positive tine test, since that is what is used to screen basic trainees. In order to avoid selection bias, prior knowledge of persons known to react to tine were not included in the study.

Another reason for termination of the study is that it has become rather common knowledge that tuberculin potency of different lots of multiple puncture devices is quite variable.

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