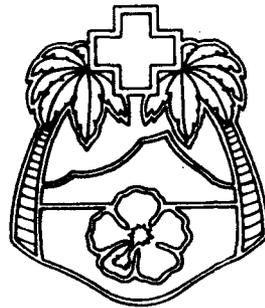


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# TRIPLER ARMY MEDICAL CENTER

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## CLINICAL INVESTIGATION PROGRAM

REPORTS CONTROL SYMBOL MED-300 (R1)

# FISCAL YEAR 1991

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ANNUAL PROGRESS REPORT

DEPARTMENT OF CLINICAL INVESTIGATION  
Reports Control Symbol MED-300(R-1)

FISCAL YEAR 1991  
1 October 1991

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DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER  
Tripler AMC, Hawaii 96859-5000

## FOREWORD

This year has been a real eye-opener for me as I finish my first year as a rookie Chief, Department of Clinical Investigation at Tripler AMC. My computer has a screen saver which randomly tosses quips at me. Either it is clairvoyant, or its random logic is stuck, as it constantly tells me 'You have the capacity to learn from your mistakes. You will learn a lot today!' I have learned an immense amount during this last year. Clinicians have no idea of the real world of medical research, finance, and politics. We (I still consider myself a clinician) blindly state that whatever is needed, our patients will get it...and usually they do. Research, unfortunately, does not generate work units for the statisticians and therefore, despite the best efforts of local commanders and Health Care Studies and Clinical Investigation Activity, does not generate its own DOD funding pot. If it were not for the excellent Chief, Resource Management (LTC John Heckert), DCCS (COL Charles Jones), DCA (COL Michael Hinton) and Commanding General (Major General Girard Seitter III), DCI at Tripler would have been in terrible condition. Adequate funds were obtained to perform significant upgrades to our outdated Animal Care Facility, including a new central air conditioning unit. Even with these upgrades, our American Association for Accreditation of Laboratory Animal Care (AAALAC) site visit would probably have failed to achieve full accreditation. However, a highly dedicated Animal Care Section led by CPT Carol Eisenhower managed to obtain just that. In its post-inspection debriefing, the AAALAC investigators made specific mention of that dedication and the concern for the health and safety of animals which was obvious in the Animal Care Section personnel.

This has been an exciting year for research, although the figures would not show this. Investigators at Tripler are beginning to formulate studies which verge on the cutting edge of medicine. The Department of Surgery at Tripler has a number of outstanding protocols which will, undoubtedly, impact heavily on general surgery throughout the world. Unfortunately, Tripler experienced the same investigator drain during the six months of Operations Desert Shield/Storm, which was reflected in the number of presentations and publications coming from Tripler for FY91. However, during that same period, there was an increase in the number of active protocols.

The first Introduction to Research for Clinical Investigators Course was held in September 1991. A large number of staff and house staff attended and received information on animal and human research, medical misconduct, and the design, execution, and publication/presentation of research. This course will be given every six months to ensure that investigators are aware of changes in rules covering research. Additionally, the Animal Care Section has instituted individual training sessions for investigators who will be involved with a particular animal model, to ensure optimal care for the study subjects.

I will close this year's Foreword with a note of Special Thanks to two individuals who have kept me on the straight and narrow road to success. First, to MAJ Donna Patterson I offer my deepest appreciation for her pulling some of my various anatomic structures out of the fire, something which seemed to happen a fair amount when I was on TDY. MAJ Patterson has served as the Chief, CMS (officially) and Assistant Chief, DCI (unofficially) for the last two years, and will be sorely missed as she moves to greener pastures in April 1992. And secondly, my reliance on Agatha Leighnor, Editorial Assistant for DCI, has been crutch-like. She has given me much advice (usually good), and despite a pitifully small staff of one, she has managed to enhance the quality of protocols leaving Tripler for HSC. Without her and the many other fine DCI personnel which bless Tripler DCI, there would be no Chief, DCI. Thank you, Agatha.



RICHARD A. BANKS  
COL, MC  
Chief, Department of  
Clinical Investigation

DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: To sponsor clinical investigation, in compliance with applicable laws, regulations and policies, to increase the academic professional stature of the MEDCEN.

B. TECHNICAL APPROACH: 1) Renew research documentation and advise the Commander and his institutional committees on matters pertaining to clinical investigation, and 2) Provide consultative and collaborative support to approved investigations.

C. STAFFING:

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Banks, Richard A.	COL	60P9B	Chief
Patterson, Donna L.	MAJ	66E9B	Assistant Chief
Mundie, Thomas G.	MAJ	68J00	Chief, Biochemistry Section
Eisenhauer, Carol L.	CPT	64C00	Chief, Animal Research Section
Tucker, Willie J.	SSG	92B30	NCOIC
Phillips, Geoffrey K.	SSG	01H30	Biological Science Asst
Anderson, Sandra J.	SGT	91T20	Animal Care Specialist
Johnson, Paula J.	SGT	91T20	Animal Care Specialist
Tostado, Mary D.	SPC	92B10	Medical Laboratory Specialist
Claybaugh, John R.	GM15	00413	Chief, Physiology Section
Uyehara, Catherine F.T.	GS12	00405	Chief, Research Pharmacology
Ichimura, Wayne M.	GS11	00802	Biomedical Engineer
Sato, Aileen K.	GS11	00644	Medical Technologist
Hashiro, Glenn M.	GS09	00404	Biological Laboratory Tech
Leighnor, Agatha M.	GS07	01087	Editorial Assistant
Parker, Dannell B.	GS05	00318	Secretary (Typing)
Freitas, Brian	WG05	05048	Animal Caretaker
Moczygamba, Darlene	WG04	05048	Animal Caretaker
Adams, Bernadette	GS03	00322	Clerk-typist
Eichinger, Mark R.*			Biological Laboratory Tech
Dice, Margaret S.**			Biological Laboratory Tech

\*MRDC Grant (Educational Contract)

\*\*NIH (Educational Contract)

Officers: 3 authorized; 4 required; 3 assigned  
Civilians: 6 authorized; 18 required; 10 assigned  
Enlisted: 6 authorized; 7 required; 5 assigned

Number of personnel funded by grants and not included in TDA: 7

D. FUNDING:

Funding Type	1991	SUNY Grant	VA Support Agreement	USAMRDC Grant
Civilian personnel including benefits	\$401,268.70	\$ 9,000.00	\$	\$14,600.00
Consumable supplies	262,801.73	1,514.95	13,971.04	6,472.95
Civilian contracts including consultants	2,180.00			
TDY	21,204.25	1,481.08	1,523.80	2,162.75
Publications	3,684.13			
OMA Total	691,138.81			
MEDCASE	753,349.67			
Military	331,788.00			
TOTAL	\$1,776,276.48	\$11,996.03	\$15,494.84	\$23,235.70

E. PROGRESS:

Number of residency and fellowship training programs that use Clinical Investigation: 19  
 28 Residents held approved protocols in 1991 with the total number of 39 protocols held by this group in 1991.  
 1 Fellow held an approved protocol in 1991 with the total number of 1 protocol held by this group in 1991.  
 62 Hospital staff members held approved protocols in 1991 with the total number of 198 protocols held by this group in 1991.

F. PROBLEMS:

Aside from the obvious problems associated with Operations Desert Shield and Storm, there are several problems which persist from year to year. The Tripler DCI is located in a sturdy building, but space is extremely limited and the utilities are unable to support electrical and plumbing needs. A new building request has been submitted and approved at the local level and current efforts at congressional funding are underway. Money for personnel and supplies was limited, and the outlook for FY92 is more bleak. However despite these concerns, the DCI team is strong and continues to be highly motivated to excel in research.

## History of Tripler Army Medical Center Protocols, Presentations, and Publications

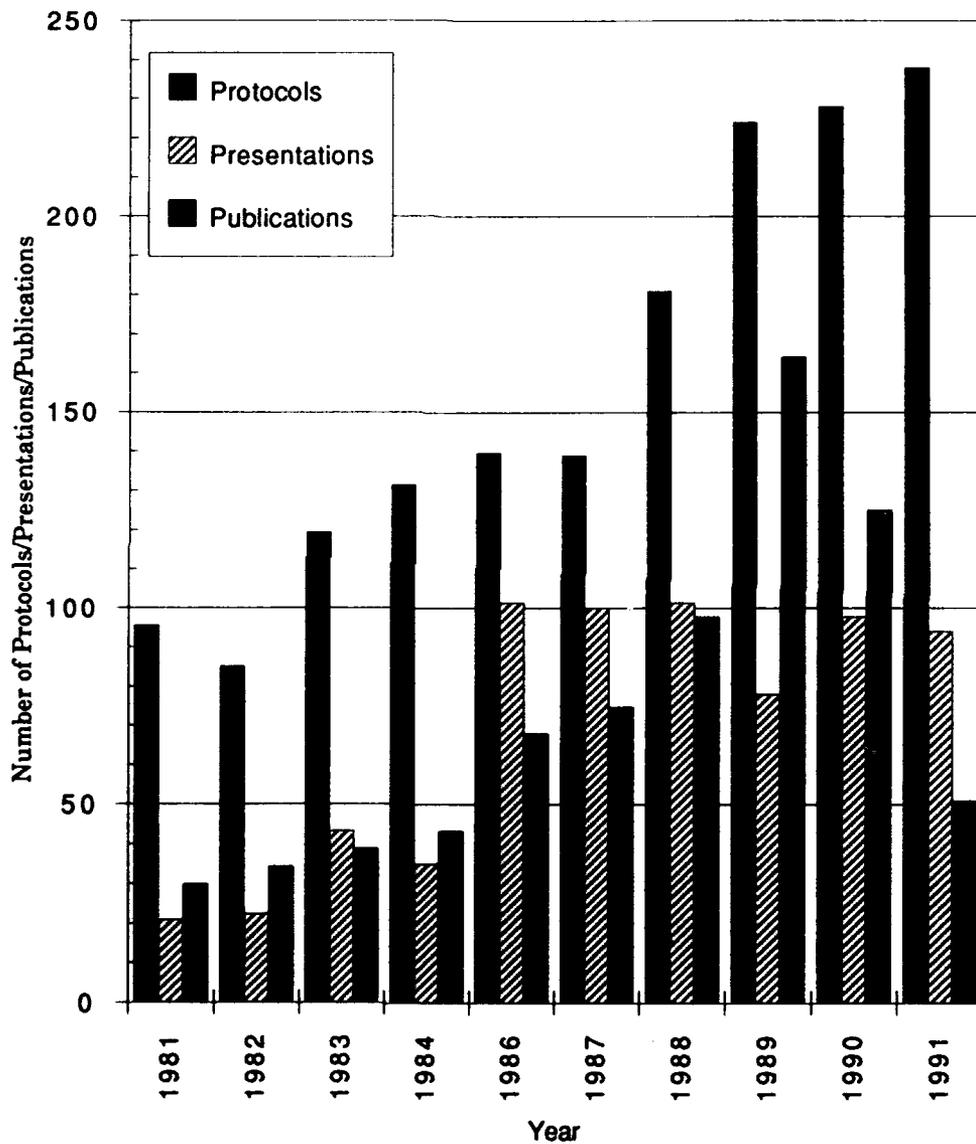




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#### DEPARTMENT OF SURGERY

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Code: SP - Submitted for Publication; C - Result of an Approved CI Protocol

PRESENTATIONS FY91

DEPARTMENT OF CLINICAL INVESTIGATION

Claybaugh JR: Vasopressin Responses to Hypoxia. Symposium, Endocrine Adaptation to Hypoxia. FASEB Meeting, Atlanta, GA, Feb 91.

Claybaugh JR: Hormonal Control of Fluid and Electrolyte Balance at High Altitude in Normal Subjects. Seventh International Hypoxia Symposium, Lake Louise, Alberta, Canada, Mar 91.

Claybaugh JR, Lin YC, Holthaus J, Schafstall HG, Bennett PB: Vasopressin, Renin, Aldosterone, and Atrial Peptide Responses to Upright Tilt at Sea Level and 450 M Sea Water. American Physiological Society Meetings, San Antonio, Texas (Abs), Oct 91. (C)

Eichinger MR, Claybaugh JR: Hypoxic Enhancement of Vasopressin Response to Hemorrhage. American Physiological Society Meetings, San Antonio, TX (Abs), Oct 91. (C)

Eichinger MR: Cardiovascular and Hormonal Responses to Hemorrhage During Hypoxia. Seventh International Hypoxia Symposium, Lake Louise, Alberta, Canada (Abs), Mar 91. (C)

Hashiro GM, McCullen AH, Claybaugh JR, Hebden RA: Effects of Ketamine Anesthesia Prior to Decapitation on the Vasopressin Responses in the Isolate Hypothalamoneurohypophyseal System (HNS) of the Rat. American Association for Accreditation of Laboratory Animal Sciences, Milwaukee, WI, Oct 90. (C)

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Rawitz EC, Tieva MH, Anderson SJ: The Use of a Harness and Tether for Continuous Intravenous Infusion in a Pig. American Association for Accreditation of Laboratory Animal Sciences, Milwaukee, WI, Oct 90.

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#### DEPARTMENT OF MEDICINE

Berenberg JL: Ethical and Medical Issues in the Treatment of a Jehovah's Witness with Gestational Trophoblastic Neoplasm Receiving Intensive Multiple Agent Chemotherapy. American College of Physicians (Abs), Honolulu, HI, Mar 91.

Finger DR, Neely ET: Ante-Mortem Diagnosis of Balo's Concentric Sclerosis Using Magnetic Resonance Imaging. American College of Physicians, Honolulu, HI, Mar 91.

Howden JK, Timmons R: Ruptured Sinus of Valsalva Aneurysms in Pacific Islanders. American College of Physicians, Honolulu, HI, Mar 91.

Jones PR, Timmons R, Hassell LH, Bornemann M: Rapid Bioprosthetic Valve Calcification in a Patient with End Stage Renal Disease and Secondary Hyperparathyroidism. American College of Physicians, Honolulu, HI, Mar 91.

Kortepeter MG, Brown JD: Malaria: A Clinical Review of 56 Cases at a Military Hospital in Hawaii. American College of Physicians, Honolulu, HI, Mar 91.

Lax DS, Hassell LH: IgA Nephropathy and Hemoglobinopathies: A New Association? American College of Physicians, Honolulu, HI, Mar 91.

Lax DS, Dworkin L, Berstein J, Tolbert E: Salt Restriction Prevents Glomerular Hypertrophy and Injury in Rats With Remnant Kidneys. American Society of Nephrologists (Abs), Washington D.C., Dec 90.

McBride CE, Bennett J, Samlaska CP: Hermansky-Pudlak Syndrome in a Guamanian Female. American College of Physicians, Honolulu, HI, Mar 91.

Narby GM, Macmillian MW, Hassell LH: Acute Anticholinergic Syndrome Due to Angel's Trumpet Ingestion. American College of Physicians, Honolulu, HI, Mar 91.

Pfanner TP, Person DA, Berenberg JL, Lockett LJ: Eosinophilia Myalgia Syndrome: A Case Report and One Year Follow-Up. American College of Physicians, Honolulu, HI, Mar 91.

#### DEPARTMENT OF NURSING

Gonzalez KA: The Effects of Supplemental Oxygen on Laboring Women as Measured Noninvasively by Pulse Oximetry. NAACOG-ACOG, Cincinnati, OH, Oct 91. (C)

Lupien AE: Efficacy of a Mentorship Program for Clinical Anesthesia Nursing Education. Nursing Research Conference (Abs), Presidio of San Francisco, CA, Oct 91. (C)

Schoneboom BA: Efficacy of Atracurium, Vecuronium, and d-Tubocurarine in the Attenuation of Post-Succinylcholine Myalgia in Patients Undergoing Minor, Lower Extremity Orthopedic Procedures. Nursing Research Conference (Abs), Presidio of San Francisco, CA, Oct 91. (C)

#### DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Chow GE, Letterie GS: Effect of Missed Oral Contraceptive Pills on Ovulation. National Meeting for American College of Gynecologists, New Orleans, LA, 91. (C)

Gililland JL, Tseng YL, Troche V, Lahiri S, Wartotsky L: Atrial Natriuretic Peptide Receptors in Human Endometrial Stromal Cells. Endocrine Society National Meeting, Jun 91.

#### PSYCHOLOGY SERVICE

Folen RA, Kellar MA, Hisert GL, Cowings P, Toscano W: Biofeedback-Assisted Self-Regulation Training and Pilot Performance During Emergency Flying Conditions. American Psychological Convention, San Francisco, CA, Aug 91. (C)

## DEPARTMENT OF SURGERY

### General Surgery Service

Fengler SA, Barcia PJ: Successful Management of a Cervical Thoracic Duct Injury With Fibrin Glue Injection. Gary P. Wratten Surgical Symposium, San Francisco, CA, Apr 91.

Roth BJ, Barcia PJ: Endoloop Repair of Electrocautery Injury to Large and Small Bowel in a Pig Model. Gary P. Wratten Surgical Symposium, San Francisco, CA, Apr 91. (C)

Tieva MH, Barcia PJ: Management of Oriental Cholangiohepatitis and Biliary Strictures: A New Approach. Gary P. Wratten Surgical Symposium, San Francisco, CA, Apr 91.

Work FT, Barcia PJ: Laparoscopic Appendectomy: Early Experience at TAMC. Gary P. Wratten Surgical Symposium, San Francisco, CA, Apr 91, & the American College of Surgeons, Honolulu, HI, Jun 91. (C)

### Orthopedic Surgery Service

Christensen, KP: Use of the Pavlik Harness in Pre-Ambulatory Infant Femur Fractures. The 6th Annual Combined Orthopaedic Spring Symposium, Honolulu, HI, Jun 91.

Cirillo RM, Christensen KP: Cost Effectiveness of Postoperative Blood Salvage in Total Hip and Knee Arthroplasty. American Orthopaedic Association, Kansas City, MO, Apr 91. (C)

Cirillo RM, Christensen KP: Post-Operative Blood Salvage in Total Hip and Knee Arthroplasties. American Orthopaedic Association - Resident's Conference, Kansas City, KS, Apr 91 & the 6th Annual Combined Orthopaedic Spring Symposium, Honolulu, HI, Jun 91. (C)

Cirillo RM, Quinlan EDC: An Unusual Enchondroma of the Femoral Head and Neck in an Adult. Society of Military Orthopedic Surgeons Meeting, Williamsburg, VA, Nov 90.

Drinhaus RR: Valgus Metatarsal Osteotomy: The Results of Treatment. The 6th Annual Combined Orthopaedic Spring Symposium, Honolulu, HI, Jun 91.

Eline E: Chronic Obturator Hip Dislocation. The 6th Annual Combined Orthopaedic Spring Symposium, Honolulu, HI, Jun 91.

Fugate DS: Osteotomy of the Coracoid Process for Evaluation of the Distal Brachial Plexus. The 32nd Annual Meeting of the Society of Military Orthopaedic Surgeons, Williamsburg, VA, Nov 90. (C)

Ono CM: Green Banks FCU Transfer in Cerebral Palsy Patients. The 6th Annual Combined Orthopaedic Spring Symposium, Honolulu, HI, Jun 1991.

Pitcher JD: Primary Benign Intraosseous Lesions of the Sacrum: Clinical Aspects. The 32nd Annual Meeting of the Society of Military Orthopaedic Surgeons, Williamsburg, VA, Nov 90, & the 58th Annual Meeting of the American Academy of Orthopaedic Surgeons, Anaheim, CA, Mar 91.

Rungee JL, Reinker K: Ossific Nucleus Eccentricity in Congenital Dislocation of the Hip. The 32nd Annual Meeting of the Society of Military Orthopaedic Surgeons, Williamsburg, VA, Nov 90, & the 24th Annual Residents Conference of the American Orthopaedics Association, Kansas City, MO, Apr 91.

Rungee JL, Fay MJ, DeBerardino TM: Biomechanical Implications of Olecranonization of the Patella. American Academy of Orthopaedic Surgeons, Anaheim, CA, Mar 91; American Orthopaedic Association - Resident's Conference, Kansas City, KS, Apr 91; International Arthroscopy Association and International Society of the Knee, Toronto, Canada, May 91; & The 6th Annual Combined Orthopaedic Spring Symposium, Honolulu, HI, Jun 91. (C)

Rungee JL: Patello-Tibial Relationship in Knee Motion: Normal Parameters and Biomechanical Implications of Olecranonization of the Patella. The 23rd Annual Henry W. Meyerding Memorial Essay Contest, Washington, DC, May 91, & Society for Sports Medicine Annual Meeting (SOSSM), Orlando, FL, Jul 91.

Willis E: Bilateral Calcaneonavicular Coalitions: Case Report. The 1991 Annual Air Force Podiatry Seminar, Hampton, VA, Mar 91.

Yanklowitz BAD: Base Sagittal V-Z Wedge Osteotomy for Metatarsus Primus Varus. The 1991 Annual Air Force Podiatry Seminar, Hampton, VA, Mar 91. (C)

#### Otolaryngology Service

Lunde KC: Nasopharyngeal Lesions Presenting as Airway Obstruction in Newborns. American Society of Pediatric Otolaryngology Meeting, Waikoloa, HI, May 91.

Lunde KC: Radiological Evaluation of a Patient With a Cervical Neuroblastoma. American Society of Pediatric Otolaryngology Meeting, Waikoloa, HI, May 91.

Lunde KC: Histiocytosis X of the Masticator Space. American Society of Pediatric Otolaryngology Meeting, Waikoloa, HI, May 91.

Zieske, LA: Dematiaceous Fungal Sinusitis-Endoscopic and Other Therapy.  
International Symposium of Contemporary Sinus Surgeons, Pittsburgh, PA,  
Nov 90.

Code: SP - Submitted for Publication; C - Result of an Approved CI Protocol

Detail Summary Sheet

Prot No: IA88 Status: Completed

TITLE: Effects of Des-leu Angiotensin I, Cortisol, and Hyperbaria on the Release of Vasopressin from the Isolated Hypothalamoneurohypophyseal System

Principal Investigator: John R. Claybaugh, Ph.D.  
Associate Investigators: Aileen K. Sato, Med Tech;  
Glenn M. Hashiro, Bio Lab Tech;  
David G. Changaris, MD; Suk Ki Hong, MD, PhD;  
Wayne Ichimura, Biomedical Engineer

Department/Section: Clinical Investigation/Physiology

Key Words: des-leu angiotensin I

Funding: FY90: \$24,604 FY91: \$1058.17 Periodic Review Date: Jan 91  
Gifts: VA-DOD Grant Decision: Completed

**OBJECTIVE:** 1) To determine if des-leu angiotensin I is able to stimulate vasopressin from the isolated hypothalamoneurohypophyseal system (HNS) in a manner similar to angiotensin II. 2) To determine if cortisol can inhibit baseline or stimulated vasopressin release from the HNS. 3) To determine if hyperbaria will inhibit the release of vasopressin from the HNS. To determine if des-leu angiotensin I stimulates vasopressin release in conscious goats and the control mechanism of the response.

**TECHNICAL APPROACH:** Two approaches to isolated hypothalamoneurohypophyseal explants have been followed, a tissue incubation (acute) and a tissue culture (chronic) approach. Both involve the surgical removal of the floor of the brain of the rat, a triangular piece of tissue approximately 1 mm thick, with a base extending parallel and anterior to the optic chiasma, and the apex approximately 2 mm posterior to the stalk of the neurohypophysis. The anterior pituitary is removed. The resulting tissue block includes the supraoptic nucleus with intact axonal projections through the stalk to the neurohypophysis. We have also begun studies on the central (intracerebroventricular) administration of angiotensin II and des-leu angiotensin I.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Acute rat HNS preparations exposed to 10-100 uM angiotensin II (AII) exhibited an increased dose-dependent release of vasopressin (AVP) over basal levels. Media osmolality of 500 mOsm/kg also significantly increased AVP release. Anesthesia prior to decapitation lowered the basal release rate of the HNS prep. In addition, the acute rat HNS prep may not be sensitive to des-leu angiotensin I. Experiments done to determine the response of the pituitary alone found the basal release was lower in the pituitary prep but AII-stimulated increments were similar to the HNS response. Osmotic stimulation was more dependent on the hypothalamus. An adjustable pressure chamber (up to 2000 psi) for the HNS was developed; preliminary data indicates that hyperbaria may affect the HNS release of AVP. Experiments with conscious goats failed to progress due to a lack of better stereo-taxic equipment (arrived this year). Due to convincing inconsistent or non-existent des-leu angiotensin I stimulation of vasopressin, this series was discontinued. Manuscripts - Hebden RA; Claybaugh JR; Hashiro GM: Comparison of Angiotensin II and Des-Leu Angiotensin I on AVP Secretion from the Hypothalamoneurohypophysis and Pituitary of the Rat. Submitted 1991.

Detail Summary Sheet

Prot No: TIA87	Status: Completed
TITLE: The Metabolic Clearance of Arginine Vasopressin in the Amniotic Sac	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Catherine F. T. Uyehara, Ph.D.; Aileen K. Sato, Med Tech	
Department/Section: Clinical Investigation/Physiology	
Key Words: arginine vasopressin;	
Funding: FY 90: \$5,381 FY 91:	Periodic Review Date: Jan 91
Gifts: None	Decision: Completed

**OBJECTIVE:** To demonstrate that the amniotic sac is a major site of fetal AVP clearance. Further, we will determine where in the amniotic sac AVP metabolism occurs (via amniotic fluid enzymes and/or via amnionic membrane receptors), explore the kinetics of this metabolic process, and characterize the metabolites produced.

**TECHNICAL APPROACH:** Vasopressin, either unlabelled or labelled with tritium is incubated with amniotic fluid, amnionic membrane, or other known vasopressin-metabolizing enzymes and chemicals (eg. vasopressinase of pregnancy serum, trypsin, thioglycolate) for biochemical identification of metabolic products. The metabolites will be characterized by their HPLC elution profiles. Guinea pig amniotic sac metabolites will be compared with metabolites produced by human amniotic fluid and amnion to determine whether the amniotic sac provides a route for fetal vasopressin clearance in humans as well.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A  
Reporting Period: N/A

One metabolite produced by both guinea pig and human amniotic fluid has been verified to be desglycinamide vasopressin and co-migrates with the metabolic product produced after vasopressin incubation with trypsin. Another as yet unidentified metabolite produced after incubation with both guinea pig and human amnionic membrane is possibly a product similar to that produced after pregnancy serum vasopressinase metabolism.

Abstract - Claybaugh JR; Uyehara CFT; Sato AK; Letterie GS: Metabolism of Vasopressin by Human Amnion and Amnionic Fluid. FASEB J, 4:A683, (Abs #2417), 1990.

Detail Summary Sheet

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Prot No: 21A89 Status: Completed

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TITLE: Effects of Hypoxia on the Vasopressin Response to Hemorrhage and its Role in the Maintenance on Blood Pressure

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Principal Investigator: John R. Claybaugh, Ph.D.  
Associate Investigators: Mark R. Eichinger, Graduate Assistant

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Department/Section: Clinical Investigation/Physiology

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Key Words: hypoxia; vasopressin;

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Funding: FY 90: \$33,453 FY 91: \$16,495.48 Periodic Review Date: Sep 91  
Gifts: MRDC Grant Decision: Completed

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**OBJECTIVE:** There is reason to believe that the maintenance of basal blood pressure and blood pressure in response to hemorrhage would be altered during conditions of hypoxemia. Similarly, pulmonary arterial blood pressure is altered during hypoxia. We propose to determine if an altered vasopressin response or vascular responsiveness is in part responsible. In addition to volume control, osmotic control of vasopressin may be altered during hypoxia. This too, will be investigated.

**TECHNICAL APPROACH:** We have chosen the conscious adult goat as our animal model. All animals to be employed in the study must first undergo surgical procedures for the construction of a carotid artery loop and tracheal fistula. The carotid artery loop allows for both blood sampling and the means of blood withdrawal during the hemorrhage studies. The fistula is used to make the animal hypoxemic by introduction of nitrogen through a tracheal catheter. The level of hypoxemia is determined through blood gas analysis, and radioimmunoassays are employed for measurement of hormonal changes.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date, six goats are actively involved in protocol 21A89. Final details of the hypoxemia gas administration as well as the hemorrhage procedure have been worked out. Five goats have participated in the normoxic and hypoxic control experiments and the hypoxic and normoxic hemorrhages. The vasopressin response to hemorrhage occurs significantly earlier during hypoxia which is partially explained by an earlier reduction in blood pressure, but also an apparent increase in baroreceptor gains on the vasopressin release. That is, the slope relating vasopressin to arterial blood pressure is steeper during hypoxia.

Manuscript - Eichinger MR; Claybaugh JR: Hypoxia Enhancement of the Vasopressin Response to Hemorrhage. Am J Physiol (submitted).

Detail Summary Sheet

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Prot No: 41H90 Status: Completed

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TITLE: Assessment of Cardiovascular Deconditioning Following Hyperbaric Exposure

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Principal Investigator: John R. Claybaugh, Ph.D.  
Associate Investigators: Peter B. Bennett, Ph.D.; Yu Chong Lin, Ph.D.

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Department/Section: Clinical Investigation/Physiology Service

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Aug 91  
Gifts: \$8,000 Tv1 & TDY by NOAA                      Decision: Completed

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OBJECTIVE: 1) One primary objective is to determine if cardiovascular deconditioning occurs during prolonged, 8 days, exposure to hyperbaria at 47 atmospheres absolute (ATA) in an oxygen-helium-nitrogen (trimix) environment; 2) A second primary objective is to assess the hormonal sensitivity to baroreceptor control; 3) Secondary objectives include the first-time assessment of basal levels of the cardiovascular and renal regulating hormonal systems, ie the catecholamines, vasopressin, renin activity, atrial natriuretic factor, cortisol, and aldosterone; 4) To provide the first confirmation of the renal responses we observed last year and increase in urine flow with both osmotic and free water components accompanied by a decrease in urinary excretion of vasopressin.

TECHNICAL APPROACH: Four experienced male saturation divers were studied in response to tilt tests at sea level and at increased atmospheric pressure. Each tilt test consisted of 10 minutes supine posture followed by 15 minutes in 90° upright passive standing posture. Blood samples were obtained immediately after the period of supine and upright postures, two times at sea level, two times at 450M, once at 360M, and two times near sea level after decompression to 50M. All hormones were successfully measured except catecholamines.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 4

Vasopressin, plasma renin activity (PRA), and aldosterone, had been previously measured in a single study at 300M. The responses observed at 450 and 360M appear to be the same. That is, the vasopressin response to tilt is obliterated while the PRA and aldosterone responses are enhanced. In addition, the atrial natriuretic factor (ANF) response was eliminated at hyperbaria, and ANF was found to be decreased at hyperbaria.

Abstract - Claybaugh JR; Lin YC; Holthaus J; Schaftstall HG; Bennett PB. Vasopressin, Renin, Aldosterone, Atrial Natriuretic Peptide Responses to Upright Tilt at Sea Level and 450M Sea Water. American Physiological Society Conference, San Antonio, TX, Sep 91.

Detail Summary Sheet

Prot No: 42H91	Status: Completed
TITLE: Hormonal and Cardio-Renal Responses to Exercise at Hyperbaria	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Peter B Bennett, Ph.D.; Richard E. Moon, MD; CPT Beau Freund, MS; Klaus Muller, MD; Justus Holthaus, MD	
Department/Section: Clinical Investigation/Physiology Section	
Key Words:	
Funding: FY 90: FY 91: Periodic Review Date: Aug 91	
Gifts: \$8,000 Tvl & TDY by NOAA	Decision: Completed

**OBJECTIVE:** The primary objectives of this study are to assess the hormonal and renal responses to maximal and submaximal exercise at 450 and 360 M depth, while in an environment of 0.5 atmospheres of oxygen, 5% nitrogen, and the remainder helium. In addition, cardiac and pulmonary responses will be determined.

**TECHNICAL APPROACH:** Two groups of subjects, three in each group, were studied at each hyperbaric depth. The original protocol outlined an experimental design allowing maximum and submaximum exercise at both sea level and at depth. Due to technical problems largely a result of attempting to do biomedical research in an industrial research institution, alterations had to be imposed. This resulted in only submaximal exercise performed two times in the group at 450M, and only one maximal exercise performance at 360M. Nevertheless, we will be able to report the first hormonal responses to exercise at hyperbaria.

**PROGRESS:** No. of Subjects Enrolled - To Date: 6 Reporting Period: 6

The study was completed 12 Jun 91. The samples arrived in Honolulu in good condition, and hormonal analysis is underway. We were able to obtain accurate oxygen consumption and ECG recording from the subjects at sea level and at depth. In Group I, a comparison of 80% maximal exercise between sea-level and 450M will be possible, and in Group II a comparison of maximal exercise at sea level and 360M will be possible.

Detail Summary Sheet

Prot No: 52A89

Status: Ongoing

TITLE: Effects of Vasopressin on Pulmonary Vascular Resistance in Hypoxia Induced Pulmonary Arterial Hypertension in Newborn and Adult Pigs

Principal Investigator: John R. Claybaugh, Ph.D.

Associate Investigators: David Easa, M.D.; Catherine F.T. Uyehara, Ph.D.  
Kenneth T. Nakamura, MD; Mark Eichinger;  
Aileen K. Sato

Department/Section: Clinical Investigation/Physiology Section

Key Words: vasopressin; hypoxia;

Funding: FY 90: \$9,089 FY 91: \$3,224

Periodic Review Date: Sep 91

Gifts: \$31,500 Leahi Trust

Decision: Continue

**OBJECTIVE:** To determine the vasopressin response of the pig to acute hypoxic exposure (i.e. 10% inspired O<sub>2</sub>) and characterize this response in pigs of ages ranging from newborn to 3 months. We will also assess the atrial natriuretic peptide responses in the same series. To determine the pulmonary arterial pressure and pulmonary vascular resistance (PVR) response of the newborn pig to hypoxia. To determine the pulmonary arterial pressure and PVR responses to vasopressin or atrial natriuretic peptide of the pig. To determine the sensitivity of the hypoxia induced pulmonary arterial hypertension and PVR to V1 and V2 receptor blockade. In addition, the effect of negative pressure respiration on the hypoxic increase in pulmonary vascular resistance will be examined.

**TECHNICAL APPROACH:** Five- thru ten-day old piglets are instrumented with cardiac catheters for measurement of mean arterial pressure, right atrial pressure, pulmonary artery pressure, left ventricular pressure and cardiac output by thermodilution. Femoral artery and vein catheters are placed for blood sampling and infusions. An endotracheal tube is placed for monitoring ventilation and administration of hypoxic gas.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Continuation of project has been seriously awaiting approval from the Secretary of the Army and receipt of continuation of funding from the Leahi Trust Grant. To date we have established that 30 minutes of eucapnic mild hypoxia (15% O<sub>2</sub>) results in significant increases in vasopressin and pulmonary arterial pressure and pulmonary vascular resistance (PVR). Subsequent experiments have shown, however, that the increase in resistance is not likely a consequence of increased vasopressin since infusion of vasopressin clearly lowers PVR and pulmonary arterial pressure.

Abstracts - Uyehara CFT; Sim HH; Eichinger MR; and Claybaugh JR. Vasopressin, Renin, Aldosterone and Pulmonary Hemodynamic Responses to Acute Eucapnic Hypoxia in Newborn Piglets. FASEB J. 5:A374 (abstract #18), 1991.



Detail Summary Sheet

Prot No: 11A91	Status: Ongoing
TITLE: Effects of Exposure to Hypoxemia on Cardiovascular Response to Drugs in the Piglet	
Principal Investigator: David Easa, M.D.	
Associate Investigators: Catherine F.T. Uyehara, Ph.D.	
Department/Section: Clinical Investigation/Physiology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To study the cardiovascular effects of certain drugs in two groups of neonatal piglets, one exposed to normoxia and another pre-exposed to hypoxia. 2) To provide alternative laboratory research opportunities for neonatal fellowship candidates in the Combined Neonatal/Perinatal Fellowship Program of the University of Hawaii School of Medicine.

TECHNICAL APPROACH: Neonatal piglets age 3-12 days are instrumented with femoral artery and vein, pulmonary artery and right atrial catheters. After stabilization, drugs are administered to the animal to determine any cardiovascular effects. The drugs are reversed when possible in order to determine whether the effects are reversible. To date we have studied 29 piglets in this project. Because of unstable cardiovascular status, problems with instrumentation or sickness in the animals, the data from one of the piglets could not be used for analysis.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

We have completed most of the pancuronium experiments with six piglets in the normoxia, five piglets in the pre-exposure to hypoxia and two piglets in the hypoxia plus pancuronium group. In addition, time controls are also being done and include five piglets in the hypoxic group and three piglets in the normoxic group. This accounts for the total number of animals successfully studied for this project except for one piglet in the fentanyl group. In terms of pancuronium, we have determined that there are no significant alterations in cardiovascular function after administration, and exposure to hypoxia did not seem to affect the response. These findings differ from previous studies on neonatal lambs.

A manuscript is in progress.

Detail Summary Sheet

Prot No: 39A91	Status: Ongoing
TITLE: The Effect of Continuous Positive or Negative Extrathoracic Pressure on the Physiological and Pulmonary Function Status of the Normal and Abnormal Piglet	
Principal Investigator: David Easa, M.D.	
Associate Investigators: Venkataraman Balaraman, M.D.;	
Catherine F.T. Uyehara, Ph.D.;	
MAJ Edward Stevens, MC; Lei Cornette-Finn, Ph.D.	
CPT Thomas G. Mundie, MS; Kenneth T. Nakamura, M.D.	
Department/Section: Clinical Investigation/Physiology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE:

1) To study the effects of continuous or intermittent positive pressure and continuous or intermittent negative extrathoracic pressure on the physiological and pulmonary function status of:

- a) the normal piglet
- b) the piglet with surfactant-deficient lungs induced by saline lavage
- c) the piglet exposed to hypoxia

2) To perform preliminary experiments to study the changes in pulmonary and physiological function during the use of high frequency ventilation, in tandem with continuous negative extrathoracic pressure (CNEP).

3) To provide alternative laboratory research opportunities for neonatal fellowship candidates in the Combined Neonatal/Perinatal Fellowship Program of the University of Hawaii School of Medicine.

TECHNICAL APPROACH: Neonatal piglets age 4-12 days are instrumented with femoral artery, pulmonary artery and right atrial catheters. They are then placed in a negative pressure chamber for equilibration. Cardiovascular and pulmonary function data are collected during varying sequences of negative pressure.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Twelve animals were surgerized and data collected for two experimental designs with negative pressure. We have completed 6 piglets in the -2, -4, -6, etc sequence and 6 piglets in the 0, -6, 0 sequence.

Abstracts were submitted to the Western Society for Pediatric Research.

Detail Summary Sheet

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Prot No: 47P91 Status: Ongoing

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TITLE: Characterization of Cardiovascular and Hormonal Responses To Hemorrhage During Hypoxia In The Conscious Goat: A Pilot Protocol

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Principal Investigator: Mark R. Eichinger  
Associate Investigators: John R. Claybaugh, PhD; CPT Carol Eisenhauer, VC;  
CPT Thomas G. Mundie, MS; Aileen K. Sato;  
Glenn M. Hashiro

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Department/Section: Clinical Investigation

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Key Words: hemorrhage; vasopressin; cardiac output; total peripheral resistance

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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**OBJECTIVE:** To determine the CV responses responsible for the earlier development of hypotension in hemorrhage with hypoxia.

**TECHNICAL APPROACH:** The cardiovascular responses to hemorrhage during hypoxia are assessed with the aid of a Swan-Ganz thermodilution catheter placed in the right heart. Cardiac output and pulmonary pressure changes can thus be monitored during hemorrhage. In addition, left atrial pressure measurements are made by use of a chronic, surgically placed catheter. Vasopressin, plasma renin activity, atrial natriuretic factor and plasma catecholamines are measured by assay technique.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A    Reporting Period: N/A

To date, left atrial catheterization has been performed in two goats. One goat continues to participate in this pilot study and is providing essential preliminary data regarding cardiovascular and hormonal responses to hemorrhage with hypoxia.

Detail Summary Sheet

Prot No: 23A91	Status: Ongoing
TITLE: Effects of Endotoxin-Induced Lung Injury and Exercise in Goats/Sheep	
Principal Investigator: CPT Thomas G. Mundie, MS	
Associate Investigators: CPT Carol L. Eisenhauer, VC	
Department/Section: Clinical Investigation/Biochemistry Section	
Key Words: goats; maximal exercise; endotoxin; ARDS	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To investigate exercise performance after endotoxin-induced acute lung injury, and 2) To investigate exacerbation of endotoxin-induced lung injury by maximal exercise.

TECHNICAL APPROACH: Goats are trained for 6-12 weeks for maximal incremental treadmill exercise using a standard protocol. Goats receive an injection of *E coli* into the pulmonary artery to induce a moderate degree of acute pulmonary injury. Goats are maximally exercised either 1, 4, or 24 hrs after injury. An appropriate number of non-exercised controls are performed. Lung injury exacerbation is evaluated by comparing the lung weights from goats receiving injury and post-exposure exercise to goats receiving lung injury alone. Exercise performance is evaluated by comparing control maximal exercise performance to post-exposure exercise performance.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Three goats have completed 4 weeks of treadmill exercise training. One goat was withdrawn from the study for uncooperative behavior.

Detail Summary Sheet

Prot No: 33A91	Status: Ongoing
TITLE: Partial Expiratory Flow During Bronchoconstriction in Goats	
Principal Investigator: CPT Thomas G. Mundie, MS	
Associate Investigators: CPT Carol L. Eisenhower, VC	
Department/Section: Clinical Investigation/Biochemistry Section	
Key Words: partial expiratory flow volume; goats; pulmonary function	
Funding: FY 90:	FY 91:
Periodic Review Date: Sep 91	Decision: Continue

OBJECTIVE:

1. To determine the feasibility of performing partial expiratory flow-volume (PEFV) maneuvers in unsedated goats.
2. To determine a PEFV dose response to inhaled histamine and methacholine.

TECHNICAL APPROACH: Partial expiratory flow volume (PEFV) maneuvers will be performed in unsedated goats using a negative pressure cylinder. Goats will be intubated transnasally using a fiberoptic bronchoscope. The procedure involves rapidly exposing the goat to 40-80 cmH<sub>2</sub>O of negative airway pressure at the beginning of expiration. The PEFV maneuver takes 1-1.5 seconds. We propose to examine the feasibility of the procedure in unsedated goats and then to perform dose-response curves using histamine and methacoline. Results from PEFV will be compared to data from resistance ( $R_L$ ) and compliance ( $C_{dyn}$ ) measurements.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Equipment is being ordered. No animals have been enrolled in this study.

Detail Summary Sheet

Prot No: 46A91	Status: Ongoing
TITLE: Pulmonary Function in Normal Piglets	
Principal Investigator: CPT Thomas G. Mundie, MS	
Associate Investigators: CPT Carol L. Eisenhauer, VC; Catherine F.T. Uyehara, Ph.D.; David Easa, M.D.; Venkataraman Balaraman, M.D.	
Department/Section: Clinical Investigation/Biochemistry Section	
Key Words: piglets; pulmonary function	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine normal pulmonary function parameters in 3 to 15-day-old piglets.

**TECHNICAL APPROACH:** Normal pulmonary function parameters are determined in 3 to 15-day-old piglets. Piglets are used 3-4 times over a two-week period allowing 2 days between determinations. Piglets are anesthetized with isoflurane and intubated. Pulmonary function parameters will be determined during spontaneously breathing and during positive pressure ventilation.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Three (3) piglets have been enrolled in the study to date.

Detail Summary Sheet

Prot No: T3A90	Status: Ongoing
TITLE: Effect of Neonatal Diet on Vascular Relaxation in Normotensive and Hypertensive Rats	
Principal Investigator: Kenneth T. Nakamura, M.D.	
Associate Investigators: Venkataraman Balaraman, M.D.; MAJ Edward Stevens, MC; CPT Bruce Pichoff, MC	
Department/Section: Clinical Investigation	
Key Words:	
Funding: FY 90:                      FY 91:	Periodic Review Date: Sep 91
Gifts: AHA \$25,000	Decision: Continue

**OBJECTIVE:** To determine if dietary alterations during the early postnatal period affect vasodilatory mechanisms and the development of hypertension in normotensive and genetically hypertensive rats.

**TECHNICAL APPROACH:** The technique of artificial rearing by gastrostomy of preweaning SHR and WKY rats will be employed to control postnatal diet to test the hypothesis that genesis of hypertension is related in part to dietary alterations effecting mechanisms controlling vascular smooth muscle relaxation during the postnatal period. The "In vitro" isometric force technique on thoracic aorta will be used to test the specific aims that high sodium intake reduces and high calcium intake augments: 1) Vascular calcium antagonist efficacy and 2) cGMP mediated vascular mechanisms of relaxation differentially in developing WKY and SHR. Studies herein will permit full control over early diet and will provide a unique opportunity to determine unequivocally the effect of milk sodium and/or calcium content on vascular vasodilatory mechanisms involved in blood pressure control.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A    Reporting Period: N/A

Experiments are almost completed. Ages studied are: 2 day, 6, 12, 18, 42, 60, and 84-day-old rats from litter SHR or WKY strain. Drugs tested at each age and for each strain are: Norepinephrine, arginine, vasopressin and angiotensin II. Data is being analyzed and an abstract will be submitted to the Western Society for Pediatric Research this calendar year.

Detail Summary Sheet

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Prot No: 24A91 Status: Ongoing

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TITLE: Role of Neonatal Diet on Vascular Responses in Normotensive and Hypertensive Rats

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Principal Investigator: Kenneth T. Nakamura, M.D.;  
Associate Investigators: LTC James Berkenbaugh, MC;  
Catherine F.T. Uyehara, Ph.D.;  
Venkataraman Balaraman, M.D.; CPT Bruce Pichoff, MC

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Department/Section: Clinical Investigation/Physiology Section

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Key Words:

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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**OBJECTIVE:** To determine if dietary alterations during the early post-natal period affect vascular responses, and the development of hypertension in normotensive and genetically hypertensive rats.

**TECHNICAL APPROACH:** The technique of artificial rearing by gastrostomy of preweaning SHR and WKY rats will be employed to control postnatal diet to test the hypothesis that genesis of hypertension is related in part to dietary alterations effecting mechanisms controlling vascular smooth muscle relaxation during the postnatal period. The "In vitro" isometric force technique on thoracic aorta will be used to test the specific aims that high sodium intake reduces and high calcium intake augments: 1) Vascular calcium antagonist efficacy and 2) cGMP mediated vascular mechanisms of relaxation differentially in developing WKY and SHR. Studies herein will permit full control over early diet and will provide a unique opportunity to determine unequivocally the effect of milk sodium and/or calcium content on vascular vasodilatory mechanisms involved in blood pressure control.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

This protocol is for year 2 of Protocol 13A90. Start date is 1 Jul 91. Thus only preliminary work has begun. Supplies have been obtained and anticipated start date for experiments is Oct 91.

Detail Summary Sheet

Prot No: 27A91	Status: Ongoing
TITLE: Determination of Methamphetamine in Meconium, Urine and Amniotic Fluid of Guinea Pigs	
Principal Investigator: Kenneth T. Nakamura, M.D.;	
Associate Investigators: CPT Carol Eisenhauer, VC;	
Catherine F.T. Uyehara, Ph.D.	
Department/Section: Clinical Investigation/Physiology Section	
Key Words:	
Funding: FY 90:	FY 91:
Periodic Review Date: Sep 91	Decision: Continue

OBJECTIVE: To determine the pharmacodynamics of methamphetamine in meconium, urine and amniotic fluid during the perinatal period in guinea pigs.

TECHNICAL APPROACH: Time bred Hartley guinea pigs will receive methamphetamine as shown below. Meconium, amniotic and urine will be assayed for methamphetamine by GC-mass spectrophotometry.

Day of Gestation	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68
Group 1	+	-						-							-				
Group 2							+	-											
Group 3															+	-			

+ = methamphetamine 1 mg/kg IP  
 - = fetuses studied

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Seventeen litters have been studied.

Abstract is being prepared for submission to the Western Society for Pediatric Research.

Detail Summary Sheet

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Prot No: 38A88 Status: Terminated

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TITLE: The Ontogeny of cGMP Mediated Relaxation in Smooth Muscle (e.g. aorta, pulmonary artery, trachea etc.,) of Developing Fetal, Newborn and Adult Guinea Pigs and Rats

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Principal Investigator: Kenneth T. Nakamura, M.D.  
Associate Investigators: John R. Claybaugh, Ph.D.;  
Venkataraman Balaraman, M.D.

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Department/Section: Clinical Investigation/Physiology

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Key Words: ontogeny;

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Funding: FY 90: \$11,832 FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Terminate

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OBJECTIVE: The objective of this study is to determine the ontogeny of cGMP mediated relaxation in smooth muscle (isolated vascular rings, tracheal rings etc.,) of developing fetal, newborn and adult guinea pigs and newborn and adult rats. We will use three different classes of pharmacological agents which stimulate cGMP by different mechanisms, viz., directly at the level of smooth muscle, receptor mediated release and endothelium dependent relaxing factor (EDRF) mediated release.

TECHNICAL APPROACH: Isolated smooth muscle structures (vascular rings, tracheal rings) are mounted in isolated organ bath and bathed in Kreb's solution aerated continuously with 95%O<sub>2</sub>, 5%CO<sub>2</sub>. Isometric relaxation responses are studied by addition of cumulative doses of drugs mediating relaxation after the tissue is precontracted with a known constricting agent. The responses are recorded using a Grass .03FT force displacement transducer attached to a Gould recording device. Thus dose response curves to the various relaxing agents are generated and differences compared using standard statistical tests.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

This study has been terminated because of protocols 63A89 and 13A90 which replaced them.

Detail Summary Sheet

Prot No: 39A90	Status: Terminated
TITLE: Determination of Methamphetamine in Meconium	
Principal Investigator: Kenneth T. Nakamura, M.D.;	
Associate Investigators: John R. Claybaugh, Ph.D.;	
CPT Carol L. Eisenhauer, VC;	
Venkataraman Balaraman, M.D.;	
Catherine F.T. Uyehara, Ph.D.	
Department/Section: Clinical Investigation/Physiology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Feb 91 Decision: Terminate

OBJECTIVE: To evaluate a commercially available radioimmunoassay kit to detect methamphetamine in meconium.

TECHNICAL APPROACH: Meconium will be collected from infants born to presumed non-drug abusing mothers determined by negative risk factors. Stool will be homogenized, filtered and the supernate tested for methamphetamine. To determine the efficiency of the method, known amounts of methamphetamine will be added to meconium and assayed. Time bred Hartley albino guinea pigs will receive single daily intraperitoneal injections of methamphetamine. Urine and meconium will be obtained for drug analysis from their fetuses after 1 to 14 days of methamphetamine administration.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

Terminated. Protocol was rewritten and resubmitted - reference 27A91.

Detail Summary Sheet

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Prot No: 58A89 Status: Ongoing

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TITLE: The Ontogeny of "Cyclic Guanosine Monophosphate (cGMP) Dependent" and "cGMP Independent" Relaxation Mediated by Sodium Nitroprusside (SNP) and Atrial Natriuretic Factor (ANF) in the Thoracic Aorta of Guinea Pigs

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Principal Investigator: Kenneth T. Nakamura, MD  
Associate Investigators: Venkataraman Balaraman, MD; Linda K. Kullama, PhD;  
Aileen K. Sato; Naomi Fujiwara;  
John R. Claybaugh, PhD; MAJ Edward Stevens, MC;  
CPT Bruce Pichoff, MC

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Department/Section: Department of Clinical Investigation

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Key Words: Cyclic Guanosine Monophosphate (cGMP)

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Funding: FY 90: \$6,448    FY 91:    Periodic Review Date: Sep 91  
Gifts:    Decision: Continue

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**OBJECTIVE:** This proposed study is designed to define the ontogeny of "cGMP dependent" and "cGMP independent" relaxation in the thoracic aorta of guinea pigs mediated by SNP and ANF. Aortae from fetal, newborn and adult guinea pigs will be studied.

**TECHNICAL APPROACH:** Relaxation responses will be measured employing the isolated vessel technique measuring isometric force. cGMP will be extracted and assayed by RIA employing a commercially available kit (New England Nuclear). Protein content will be assayed according to the technique described by Lowrey.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A    Reporting Period: N/A

Manuscript in final stage of completion. Anticipate submission in early fall 1991.

Detail Summary Sheet

Prot No: 63A89	Status: Ongoing
TITLE: Ontogeny of Airway Smooth Muscle Function	
Principal Investigator: Kenneth T. Nakamura, M.D.	
Associate Investigators: MAJ W. Michael Southgate, MC; MAJ Edward Stevens, MC; CPT Bruce Pichoff, MC; Venkataraman Balaraman, M.D.	
Department/Section: Clinical Investigation	
Key Words:	
Funding: FY 90:            FY 91: \$3756.92	Periodic Review Date: Sep 91
Gifts: \$346,226 (7/1/90 - 6/30/95)	Decision: Continue
NIH R29 HL45220	

OBJECTIVE: To define if exposure to high oxygen concentrations during the newborn period alters the normal developmental progression of airway smooth muscle function. We will examine contractile and relaxation responses of isolated newborn guinea pig airway smooth muscle rings following randomization to room air or 95% oxygen for 2 days.

TECHNICAL APPROACH: The overall hypothesis that exposure to high oxygen concentrations during the newborn period alters the normal developmental progression of airway smooth muscle function will be examined in vitro. Six groups of Hartley albino guinea pigs will be studied. Each guinea pig will contribute four airway ring segments: 2 adjacent segments of extra-thoracic trachea, right and left mainstem bronchus. Regional differences among the large airways vary with regards to histology, functional response to agonists and epithelium removal. Thus, we expect to observe differences between trachea and bronchi, with each having a paired control for experiments conducted during this study.

PROGRESS: No. of Subjects Enrolled - To Date: N/A    Reporting Period: N/A

There have been several abstracts, presentations, and publication submittals as a result of this study (listed under the Publications and Presentations Section).

Detail Summary Sheet

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Prot No: 12A91 Status: Ongoing

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TITLE: Renal Function in Hypertension: Age-related changes

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Principal Investigator: Catherine F.T. Uyehara, Ph.D.  
Associate Investigators:

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Department/Section: Clinical Investigation/Physiology Section

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Continue

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OBJECTIVE: 1) To characterize renal function during the critical developmental phase of genetic hypertension by assessing glomerular filtration and renal tubular handling of water and salt in the spontaneously hypertensive rat (SHR), a model for human essential hypertension; 2) To describe the influence of aging on renal handling of water and salt and thus determine whether premature aging of the kidneys may be involved in the development of hypertension in SHR.

TECHNICAL APPROACH: Renal clearance studies of conscious, chronically catheterized newborn rats are performed. Rats are instrumented with arterial, venous, and stomach catheters and a bladder cannula 3 to 7 days before experimentation. Water and salt handling are assessed by administering a 2% body weight water or saline load intragastrically. Urine flow, sodium excretion, glomerular filtration (inulin clearance), renal blood flow (PAH clearance) and free water clearance are assessed.

PROGRESS: No. of Subjects Enrolled - To Date: N/A  
Reporting Period: N/A

Project was not started until 8/91 due to unavailability of equipment and supplies. However, in the last six weeks, good progress has been made in establishing the neonatal conscious rat model here at DCI. 4 rats were used for teaching surgical skills to a new technician. 11 rats (3½ to 5 weeks of age) were catheterized to use for experimental purposes but 5 of the 11 did not recover from anesthesia after successful surgeries, leaving only 6 for experiments. The newborn rats are much more sensitive to the pentobarbital anesthesia (with the SHR much more so than the WKY) and drug doses have had to be greatly reduced.

The 6 remaining rats have provided good baseline water and saline load results which indicate that the younger rat at 4-6 weeks of age has a more difficult time getting rid of a water or saline load than the older rat at 8 to 11 weeks of age; this seems to hold true for both the SHR and WKY. Technically, we are finding that the rats grow too rapidly between 3 and 7 weeks to maintain the same bladder cannula throughout this entire period. Therefore, we will have to run experiments in the same animal for no longer than a 2-week period.

Detail Summary Sheet

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Prot No: 12A89 Status: Terminated

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TITLE: Evaluation of a Composite Graft (Porous Particulate Hydroxyapatite-Particulate Marrow Cancellous Bone) for Onlay Augmentation of the Atrophied Alveolar Ridge with Simultaneous Placement of Endosseous Implants in Goats

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Principal Investigator: LTC Durwood E. Bach, DC  
Associate Investigators: COL Ricney F. Newhouse, DC; MAJ Gregory Boice, DC;  
MAJ Steven Perkins, DC;  
COL Jeffrey O. Hollinger, DC

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Department/Section: Dental Activity/Tripler Dental Clinic

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Key Words: endosseous implants;

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Funding: FY 90: FY 91: Periodic Review Date: Aug 91  
Gifts: Pending HMJFAMM Decision: Terminate

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OBJECTIVE: To evaluate a composite graft system for augmentation of the atrophied alveolar ridge with simultaneous placement of 2 endosseous implant systems. Clinical evaluation to assess the degree of stability of the implant. Clinical and radiographic assessment to determine the degree of bone graft maintenance or resorption postoperatively. Histologic and histomorphometric analysis to quantitate osseointegration of the dental implants within the matrix of the graft.

TECHNICAL APPROACH: Each animal will have an augmentation and simultaneous implant placement on the right and left side of the maxilla and the mandible. There will be 4 surgical/experimental sites per animal. One side of the mandible/maxilla will be augmented with an autogenous particulate marrow graft and the opposite side will be augmented with a composite graft of 50% hydroxyapatite and 50% autogenous particulate marrow. The sites will be randomized.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

The study hasn't really gotten off the ground. Study initiation had been pending HMJFAMM funding all this time.



Detail Summary Sheet

Prot No: 36H91	Status: Ongoing	
TITLE: Comparison of the Ease, Efficacy, and Comfort of Incisive Nerve Block Given Inside or Outside the Mental Foramen		
Principal Investigator: MAJ Anthony P. Joyce, DC Associate Investigators: LTC Jerome C. Donnelly, DC		
Department/Section: Dental Activity/Schofield Barracks Dental Clinic		
Key Words:		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Continue

**OBJECTIVE:** To evaluate the ease, efficacy, and comfort of incisive nerve anesthesia after depositing anesthetic solution either into or outside the mental foramen.

**TECHNICAL APPROACH:** Each patient will receive an anesthetic injection on the left and right side of the mandible and be placed into group A, B, or C. Group A - anesthetic injection inside the mental foramen. Group B - injection outside the foramen after failure to locate the mental foramen. Group C - injection outside the mental foramen. Two baseline vitality test readings will be taken for 3 teeth innervated by the incisive nerve on each side of the mandible. Additional readings will be taken at 2, 5, 10, 20 and 30-minute intervals after anesthesia. Patients will rate discomfort level immediately postop and 24 hours postop via questionnaire.

- Statistics A: The percentage of all teeth tested that achieve complete anesthesia.
- B: Average length of time that teeth in each group maintained complete anesthesia.
- C: The failure rate of entering the mental foramen for Group A compared to failure to obtain adequate anesthesia for Groups B and C.
- D: Average pain experience in each group during the injection and for the 24-hours post-injection.

PROGRESS:

No. of Subjects Enrolled - To Date: 15      Reporting Period: 15

Project study completion is expected in early FY92.

Detail Summary Sheet

Prot No: 62H89	Status: Completed
TITLE: Patient Controlled Analgesia in Orthognathic Surgery	
Principal Investigator: MAJ Steven J. Perkins, DC Associate Investigators:	
Department/Section: Dental Activity/Tripler Dental Clinic	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

OBJECTIVE: To evaluate efficacy and safety of patient-controlled analgesia (PCA) modality of pain control in an orthognathic surgical patient population.

TECHNICAL APPROACH: Patients will be randomly assigned to two groups. Group I will receive the current post-operative analgesic regimen; 3 - 5 mg morphine IV q3-4h prn pain in the Surgical Intensive Care Unit. Group II patients will receive an explanation of the nature of the study and instructed in the use of the "Abbot Life Care PCA Infuser"; a bolus dose of 2 - 5 mg of morphine via the infuser will be given if needed.

For comparison of the two groups, data will consist of a constant evaluation of sedation, pain, respiratory rates, side effects and the amount of narcotic given every two hours while in the SICU and every four hours while on the ward. Pain will be ranked by the patient's oral response when questioned.

PROGRESS: No. of Subjects Enrolled - To Date: 20 Reporting Period: 7

Data collection is completed; working on writing paper. There were no complications to date.

Detail Summary Sheet

Prot No: 30H91	Status: Completed
TITLE: A Comparison of Outpatient Anesthetic Techniques in the Clinic Setting (Propofol, Nitrous Oxide, and Alfentanil Verses Methohexital, Isoflurane, Nitrous Oxide, and Alfentanil)	
Principal Investigator: MAJ Michael E. Werner, DC Associate Investigators: LTC Durwood E. Bach, DC	
Department/Section: Dental Activity/ Tripler Dental Clinic	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

OBJECTIVE: To analyze two general anesthetic techniques in the outpatient oral surgery clinic setting:

- a) Diprivan, nitrous oxide, and Alfenta
- b) Brevital, Forane, nitrous oxide, and Alfenta

These modalities will be compared for: ease of administration, cost, onset of induction, length of respiratory depression, intraoperative hemodynamic stability, incidence of side effects, recovery times, and patient acceptance.

TECHNICAL APPROACH: Fifty patients presenting to the oral surgery clinic for outpatient general anesthetics for wisdom tooth removal were randomly grouped to receive either technique A or B above. They were then evaluated for the above modalities by various tests. Study completion is expected by 1 Sep.

PROGRESS: No. of Subjects Enrolled - To Date: 50      Reporting Period: 50

The results of this study have been approved for presentation at the annual meeting of the AAOMS in Chicago on 23 Sep 91.

Detail Summary Sheet

Prot No: 35H91	Status: Ongoing
TITLE: Clinical - Laboratory Correlation of Isotretinoin (13-Cis Retinoic Acid), Treatment of a Patient With Advanced Squamous Cell Carcinoma of the Skin	
Principal Investigator: COL Jeffrey L. Berenberg, MC Associate Investigators: John Bertram, Ph.D.	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To determine if isotretinoin has therapeutic benefit in a patient with advanced squamous cell carcinoma of the skin, 2) to determine if isotretinoin induces enhanced formation of gap junctions in human skin and squamous cell carcinoma of skin.

TECHNICAL APPROACH: Patients agreeing to participate will have a small skin biopsy prior to starting isotretinoin. This biopsy and another biopsy done after the patient has been on treatment at least one month will be processed for gap junction studies at the Cancer Center. The patients will receive isotretinoin by mouth daily until tumor progression.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There is no data available yet.

Detail Summary Sheet

Pret No: 64H88	Status: Ongoing
TITLE: A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvants to Opiate Analgesics in the Management of Pain in Cancer Patients	
Principal Investigator: COL Jeffrey L. Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: amitriptyline; trazodone;	
Funding: FY 90:           FY 91:	Periodic Review Date: Sep 91
Gifts: Drugs via Cancer Ctr	Decision: Continue

**OBJECTIVE:** a) Compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases. b) Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate. c) Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics, in the treatment of pain associated with malignant disease.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will first be titrated to a dose of morphine sulfate that controls their pain satisfactorily. They will then be randomized to receive an additional drug (either 1. amitriptyline, 2. trazodone, or 3. placebo). This will be double-blinded. When this additional drug is started, their morphine dose will be decreased by 25% and the patients will be monitored closely for their pain level. The patients will have constant access to additional morphine if and when they need it for breakthrough pain. The physician following the patient will be expected to adjust the regularly scheduled morphine based on any regularly occurring breakthrough pain. Patients will be followed for 60 days minimum.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Multi-institutional study to continue until study objective met. Status is ongoing. No patients have been entered at Tripler and no data is available yet.

Detail Summary Sheet

Prot No: 19H84	Status: Ongoing
TITLE: Treatment of Graves' Ophthalmopathy with Cyclosporin	
Principal Investigator: COL Michael Bornemann, MC	
Associate Investigators:	
Department/Section: Medicine/Endocrine-Metabolic	
Key Words: Graves' ophthalmopathy;	
Funding: FY 90:      FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

OBJECTIVE: To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' disease.

TECHNICAL APPROACH: This is a random crossover study comparing Cyclosporin therapy of Graves' ophthalmopathy versus the standard of current therapy, high-dose oral Prednisone. Because of potential toxicity, this is not a double-blind study. The drugs will be administered for three weeks each, and then the patient will be crossed over with clinical response measured by an ophthalmopathy index. There will be a pretherapy clinical assessment and the usual laboratory testing pre-, post-, and during therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This Walter Reed collaborative protocol remains open anticipating any patients that might meet the study population criteria. No (new) enrollees from this institution. Recommend on-going status. This is part of an Army-wide project with centralized support WRAMC.

Detail Summary Sheet

Prot No: 33H86	Status: Ongoing
TITLE: The Natural History of HTLV-III Infection and Disease in a United States Military Population	
Principal Investigator: COL Joel D. Brown, MC Associate Investigators: Arthur Johnson, III, M.D.	
Department/Section: Medicine/Infectious Disease Service	
Key Words: HTLV-III; AIDS; infection;	
Funding: FY 90:           FY 91:           Periodic Review Date: Sep 91	Gifts: None                           Decision: Continue

OBJECTIVE: To assess the impact of HTLV-III infection on military readiness by defining the natural history of infection in the general military population and to form a study cohort upon which subsequent studies can be built.

TECHNICAL APPROACH: Personnel with confirmed HTLV-III infection who agree to participate will receive standard evaluation, counseling, and referral of contacts. Information will be centralized in a common data base. Serum and CSF samples will be stored at WRAIR for future testing. Follow-up studies will be performed every six months.

PROGRESS: No. of Subjects Enrolled - To Date: 197  
Reporting Period: 26

This study enrolls volunteer HIV infected patients for epidemiologic and periodic clinical evaluation to determine the course of their disease over time. A total of 197 patients entered the study to date; twenty-six patients were enrolled in 1991. No publications were submitted by TAMC since it is a multi-centered study.

Detail Summary Sheet

Prot No: 45H91	Status: Ongoing
TITLE: What is the Value of Fecal Occult Blood Tests Performed at the Time of Digital Rectal Examination?	
Principal Investigator: MAJ Charles F. Cohan, MC Associate Investigators: MAJ Kent C. Holtzmueller, MC	
Department/Section: Medicine/Gastroenterology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91 Decision: Continue

OBJECTIVE: The purpose of this study is to objectively determine the clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult method) discovered at the time of routine digital rectal examination.

TECHNICAL APPROACH: Comparing the positive results found on digital rectal examination to Hemoccult results on properly collected spontaneously passed stool specimens, simultaneous hemoglobin quantitation by the Hemoquant assay, and endoscopic evaluation of the gastrointestinal tract for possible sources of blood loss.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Unable to start project until funds are available during the next fiscal year.

Detail Summary Sheet

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Prot No: 8L87 Status: Completed

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TITLE: Noncompliant Behavior Among Hemodialysis Patients: Relationship to Disturbances of the Renin-Angiotensin-Aldosterone, Antidiuretic Hormone, and Atrial Natriuretic Hormone Axes

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Principal Investigator: LTC L. Harrison Hassell, MC  
Associate Investigators: John R. Claybaugh, Ph.D.; Arnold Siemsen, M.D.;  
Jon Streltzer, M.D.

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Department/Section: Medicine/Nephrology

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Key Words: hemodialysis patients;

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Funding: FY 90:           FY 91:           Periodic Review Date: Sep 91  
Gifts: none                   Decision: Completed

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OBJECTIVE: Designed to compare levels of plasma renin activity (PRA), aldosterone (PA), antidiuretic hormone (ADH), and human atrial natriuretic peptide (hANP) in compliant and noncompliant hemodialysis patients to those in both humans and experimental animals associated with stimulation of thirst and salt appetite. Abnormalities of these hormonal axes may provide inferential evidence of disturbances of thirst and salt appetite which may underlie noncompliant behavior.

TECHNICAL APPROACH: Hemodialysis patients have blood drawn before and after two consecutive hemodialysis treatments. Urine is collected in the interim to calculate residual renal function. Patients have been categorized according to pre-defined criteria of compliance as assessed by interhemodialytic weight gain. The study will evaluate relationships of hormonal abnormalities to compliant and noncompliant behavior.

PROGRESS: No. of Subjects Enrolled - To Date: 9  
Reporting Period: 0

No adverse effects have occurred. Manuscript preparation in progress.



Detail Summary Sheet

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Prot No: 10H89 Status: Terminated

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TITLE: Double Blind Trial of Sucralfate in the Treatment of Minor Aphthous Stomatitis

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Principal Investigator: CPT James K. Howden, MC  
Associate Investigators:

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Department/Section: Medicine

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Key Words: sucralfate; aphthous stomatitis;

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Funding: FY 90:           FY 91:           Periodic Review Date: Jun 91  
Gifts:                    Decision: Terminate

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OBJECTIVE: Recurrent aphthous stomatitis, commonly known as canker sores, is estimated to affect 20 percent of the general population. Effective therapy of the common idiopathic aphthous ulcerative type is not available. Because of promising results in the therapy of chemotherapy associated oral mucositis, a therapeutic trial with sucralfate is proposed.

TECHNICAL APPROACH: After being assessed through questionnaire, short physical exam and complete blood count, patients are randomly assigned, in blinded fashion, to either the treatment or placebo group. The patient's consent is obtained and he is given a prescription. The patient is instructed to begin therapy on the initiation of symptoms and to call the Internal Medicine Clinic to arrange follow up within one day. The patient is thereafter seen every two days for a total of ten days to assess for subjective and objective improvement.

PROGRESS: No. of Subjects Enrolled - To Date: 30 Reporting Period: 0

Investigator requested termination due to inability to enroll the required number of subjects (50) and a large number of patients lost to follow-up.

Detail Summary Sheet

Prot No: 6H91	Status: Ongoing
TITLE: A Randomized Controlled Study of the Efficacy and Safety of Maintenance Treatment with Oral Ganciclovir for Newly Diagnosed Cytomegalovirus Retinitis in People with AIDS	
Principal Investigator: Arthur C. Johnson, III, MD Associate Investigators: COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: To evaluate the efficacy of oral ganciclovir maintenance therapy for newly diagnosed CMV retinitis by comparison to intravenous maintenance treatment.

TECHNICAL APPROACH: Patients must meet the inclusion criteria of this treatment protocol. CMV retinitis may progress if maintenance therapy with ganciclovir is not undertaken. This study is designed to evaluate the safety and efficacy of an oral ganciclovir maintenance therapy compared to intravenous maintenance therapy. Ganciclovir stops CMV from multiplying. It does not destroy existing viruses, but stops them from reproducing and invading healthy cells. This is a 23-week study which begins with a three-week course of IV ganciclovir given bid over one week for 14 days then daily for seven days. If CMV retinitis is stable, patients will be randomized to receive maintenance treatment with either oral ganciclovir or IV ganciclovir for 20 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Have not had the opportunity to enroll patients in this study because no subjects meet the inclusion criteria.



Detail Summary Sheet

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Prot No: 8H91 Status: Ongoing

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TITLE: An Open-label Safety Study of Dideoxycytidine (ddC) in Patients with AIDS or Advanced ARC who cannot be Maintained on Zidovudine (ZVD) Therapy

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Principal Investigator: Arthur C. Johnson, III, MD  
Associate Investigators: COL Joel D. Brown, MC

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Department/Section: Medicine/Infectious Disease

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Key Words:

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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OBJECTIVE: To demonstrate that ddC can be used to treat patients with HIV infection who experience intolerable side effects with AZT (zidovudine) or AZT treatment failures, and to evaluate the toxicity of ddC in these patients.

TECHNICAL APPROACH: Treatment protocol; patients must meet inclusion criteria. Dideoxycytidine is an antiviral drug which in laboratory and early clinical studies was shown to be effective against HIV infection. Patients agreeing to participate will be randomly assigned to one-of-two treatment groups. Patients are monitored very closely through physical exams and laboratory tests, on a monthly basis or more often if needed.

PROGRESS: No. of Subjects Enrolled - To Date: 2            Reporting Period: 2

We have enrolled two patients on the study. To date, both are doing well with no adverse reactions and tolerating the drug well. This protocol is closed to further patient accrual. A new protocol (1H92 - pending final approval) has been submitted for further patient access to ddC.

Detail Summary Sheet

Prot No: 9H91	Status: Terminated
TITLE: A Randomized Controlled Prophylactic Study of Clofazimine to Prevent Mycobacterium Avium Complex Infection in HIV Disease	
Principal Investigator: Arthur C. Johnson, III, MD Associate Investigators: COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Feb 91 Decision: Terminate

**OBJECTIVE:** To examine the efficacy of clofazimine in prophylaxing mycobacterium avium complex infection in HIV infected patients who are at risk to develop this untreatable opportunistic disease.

**TECHNICAL APPROACH:** Treatment protocol. In the absence of truly effective antiretroviral therapy, a potential mode of treatment for patients with HIV infection is to prevent the development of the life-threatening opportunistic infections. Clofazimine has been shown to have a good in vitro activity against MAC. Since clofazimine is easy to administer and is well tolerated for a long periods of administration, it is a good candidate for a prophylactic treatment of MAC.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No subjects were enrolled in this study due to fulfillment of patient numbers soon after approval for study implementation was received.

Detail Summary Sheet

Prot No: 29H90	Status: Ongoing
TITLE: A Treatment IND Protocol for the Use of ddI (2'3'-dideoxyinosine) in Patients With AIDS or ARC Who Are Intolerant of AZT	
Principal Investigator: Arthur C. Johnson, III, MD Associate Investigators: COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To make ddI available to patients with HIV infection who have developed intolerance to AZT (zidovudine), and to evaluate the toxicity of ddI in these patients.

**TECHNICAL APPROACH:** Treatment Protocol: ddI is an antiviral drug which in laboratory and early clinical studies was shown to be effective against HIV infection. This drug has less toxicity than AZT. Patients must meet the eligibility criteria. Patients are given one of three doses based on Kg weight. Patients are monitored very closely through physical exam and laboratory tests, on a monthly basis or more frequently if warranted.

**PROGRESS:** No. of Subjects Enrolled - To Date: 12      Reporting Period: 12

We have enrolled 12 patients in this protocol. Seven patients are still currently on drugs. Of the five that are not on drugs, two have died of their HIV disease; one is off because he is on IV chemotherapy for Kaposi's Sarcoma and had been experiencing peripheral neuropathy probably due to the vincristine (chemotherapy); one is off due to extrapulmonary pneumocystis that involves the pancreas, spleen and liver, causing the patient to have pancreatitis; one is off due to pancreatitis, etiology unknown.

Detail Summary Sheet

Prot No: 30H90	Status: Ongoing
TITLE: An Open Study of Foscarnet Treatment of CMV retinitis in AIDS Patients Who Demonstrated DHPG (Ganciclovir) Treatment Failure or Toxicity	
Principal Investigator: Arthur C. Johnson, III, MD Associate Investigators: COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words: Foscarnet, cytomegalovirus (CMV) retinitis	
Funding: FY 90:           FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

OBJECTIVE: To make Foscarnet available to patients with CMV retinitis who have failed Ganciclovir and to evaluate the safety and toxicity of Foscarnet in these patients.

TECHNICAL APPROACH: Treatment protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0           Reporting Period: 0

Have not had the opportunity to enroll patients in this study because subjects do not meet the inclusion criteria.

Detail Summary Sheet

Prot No: 3TH90	Status: Terminated
TITLE: Evaluation of Autopsy Results of AIDS Autopsies in Hawaii; 1981 to Date	
Principal Investigator: Arthur C. Johnson, III, MD Associate Investigators: Lee Ann Mullen	
Department/Section: Medicine/Infectious Disease	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Terminate

**OBJECTIVE:** The purpose of this study will be to see how data from a Hawaii Autopsy series compares to national data. It is possible that because of Hawaii's unique ethnic makeup and geographic location that this might contribute to the understanding of the pathophysiology and treatment of AIDS, if not presently, then at some later date.

**TECHNICAL APPROACH:** Autopsy reports and medical records of all patients with AIDS autopsied on Oahu will be reviewed. Data will then be collated and used to establish a computerized database which will be analyzed for the variables listed in the objectives.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0            Reporting Period: 0

Study was never implemented due to administration reasons. Request termination of this study.

Detail Summary Sheet

Prot No: 32H90	Status: Terminated
TITLE: Stool Survey of Persons with HIV Disease	
Principal Investigator: Arthur C. Johnson, III, MD	
Associate Investigators: Al Katz, MD; David Morens, MD; COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Terminate

OBJECTIVE: To evaluate possible changes which occur over time, in the amount and kinds of bacteria and parasites living in the lower gastrointestinal tract of patients who are infected with HIV.

TECHNICAL APPROACH: Patients agreeing to participate in this study will provide stool specimens for examination upon regular checkups and whenever ill with a gastrointestinal illness.

PROGRESS: No. of Subjects Enrolled - To Date: 2            Reporting Period: 2

This study had a hard time getting off the ground due mainly to a lack of participant enlistment. Of the two patients entered in the study, stool specimens were negative for bacteria, parasites and MAI.

Detail Summary Sheet

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Prot No: 43H89\* Status: Completed

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TITLE: Clinical Utility of Post-Thoracentesis Chest Roentgenography

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Principal Investigator: CPT Mark G. Kortepeter, MC  
Associate Investigators: CPT William D. Holland, MC; MAJ John D. Olsen, MC  
CPT Oleh Hnatiuk, MC

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Department/Section: Medicine

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Key Words: post-thoracentesis; roentgenography

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Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 91  
Gifts: None Decision: Completed

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OBJECTIVE: The purpose of this study is to prospectively assess whether the routine use of post-thoracentesis chest roentgenography in asymptomatic patients without clinically apparent complications is warranted. This prospective study hopes to provide unbiased, well documented evidence needed to calculate an accurate negative predictive value for the parameters identified in our retrospective review.

TECHNICAL APPROACH: No alteration from basic standards of medical practice. Follow up of patient's thoracentesis will involve reviewing the thoracentesis form and reviewing CYR.

PROGRESS: No. of Subjects Enrolled - To Date: 23 Reporting Period: 0

Study completed and data now being analyzed.

\*Exempt from committee protocol (retrospective study).

Detail Summary Sheet

Prot No: 48H91	Status: Ongoing
TITLE: TriSodium Citrate Versus Normal Saline Flushes In Arterial Lines	
Principal Investigator: CPT Mark Kortepeter, MC	
Associate Investigators: LTC Ney Gore, MC; Ms. Cindy Kortepeter, RPH	
Department/Section: Medicine	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: To determine if trisodium citrate is a safe, effective, and viable alternative to normal saline as a flush solution in maintaining the patency of arterial lines when heparin is contraindicated.

TECHNICAL APPROACH: Patients in the intensive care unit with the ability to consent to the study will be randomized to receive normal saline or trisodium citrate as a flush solution for their arterial line.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Patients matching the criteria thus far have not been capable of giving consent.

Detail Summary Sheet

Prot No: 11H88	Status: Terminated
TITLE: Efficacy of Steroids in the Acute Treatment of Asthma: Are Duration of Symptoms Important?	
Principal Investigator: LTC Marcia L. Muggelberg, MC Associate Investigators: MAJ T. R. Vaughan, MC	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: efficacy of steroids; asthma;	
Funding: FY 90:      FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Terminate

OBJECTIVE: To determine whether the efficacy of steroids for the treatment of asthma in the acute setting is related to the duration of the patients' symptoms for that episode of asthma.

TECHNICAL APPROACH: Prospective data collection; standard patient care.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

This study is terminated. Investigator was sent as part of 'Desert Storm' and has PCS'd.

Detail Summary Sheet

Prot No: 12H88	Status: Terminated
TITLE: Multicenter Clinical Evaluation of Penicillin Skin Testing Materials	
Principal Investigator: LTC Marcia L. Muggelberg, MC	
Associate Investigators:	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: penicillin allergy;	
Funding: FY 90:      FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Terminate

OBJECTIVE: 1) To determine whether there is a difference in the incidence of skin test positivity to the different skin testing reagents prepared by different methods in patients with a history of penicillin allergy as well as in subjects with no previous history of an adverse reaction to a penicillin-like drug. 2) To study the comparative potency, as determined by cutaneous endpoint titration skin testing, of reagents prepared by different methods in skin test positive patients. 3) To compare skin test reactivity to freshly reconstituted reagents with that produced by aged reagents.

TECHNICAL APPROACH: Test-arm trials.

PROGRESS: No. of Subjects Enrolled - To Date: 17    Reporting Period: 0

This study is terminated. Investigator was sent as part of 'Desert Storm' and has PCS'd.

Detail Summary Sheet

Prot No: 32H89	Status: Ongoing
TITLE: The Effect of Cancer Chemotherapy on the Reactivation of Chronic Hepatitis B Infection	
Principal Investigator: CPT Rickey C. Myhand, MC	
Associate Investigators: COL Jeffrey Berenberg, MC; COL Charles C. Jones, MC; COL Joseph Woods, MC; LTC Bruce A. Cook, MC	
Department/Section: Medicine	
Key Words: chronic hepatitis B;	
Funding: FY 90:            FY 91:	Periodic Review Date: Jun 91
Gifts: None	Decision: Continue

**OBJECTIVE:** Cases of reactivation of chronic hepatitis B infection with resultant acute hepatitis and death have been described in the literature. The changing status of hepatitis B infection in patients who receive cancer chemotherapy has not been evaluated in a prospective study. Specific questions to be addressed by this study are: 1) Does hepatitis B reactivation and subsequent liver damage occur frequently in chronic carriers who receive cancer chemotherapy for malignancy? 2) Should candidates for cancer chemotherapy be routinely screened for chronic hepatitis B infection? 3) Is there a morphologic/histopathologic distinction between chemotherapy induced hepatotoxicity and viral induced liver disease?

**TECHNICAL APPROACH:** Screen patients receiving or about to receive chemotherapy (screen for positive HBsAg). If positive, obtain consent to enter study. When consent is obtained, obtain baseline studies of HBsAg, Delta Ag and Ab, HBcAB (IgM, IgG), HBeAg, HBeAb, HB serum DNA probe, HAV Ab, SGOT, SGPT, GGT, T bili, Alkaline Phosphatases, T-Helper/Suppressor ratio, cytotoxic T-cell. Liver biopsy (excluding pediatric patients) upon entrance of study and at the completion of chemotherapy regimen. Follow baseline studies monthly.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5    Reporting Period: 2

Two liver biopsies were done, both without complications. No subjects have been dropped or withdrawn. Preliminary findings were presented to the Cancer Center, Honolulu, Hawaii, in May 91. With PCS of CPT Myhand, CPT Neal Shparago will become the new principal investigator.

Detail Summary Sheet

Prot No: 55H88	Status: Terminated
TITLE: A Direct Comparison Between the Cholesterol Lowering Effects of Psyllium Mucilloid and Bile Sequestering Agents	
Principal Investigator: CPT Timothy Pfanner, MC	
Associate Investigators: CPT Steven E. Hill, MC; CPT Gary Gazenski, MC; MAJ Suzanne Chiang, RD	
Department/Section: Medicine	
Key Words: psyllium mucilloid;	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Jun 91 Decision: Terminate

OBJECTIVE: To show that psyllium mucilloid is more efficacious than the bile sequestrant cholestyramine in reducing total serum cholesterol and low density lipoprotein.

TECHNICAL APPROACH: Two arm outcome study of approved medications.

PROGRESS: No. of Subjects Enrolled - To Date: 77 Reporting Period: 0

No significant changes to report. What we thought we would have time for never materialized and precluded entry of more patients into the study. Therefore request termination of the study.



Detail Summary Sheet

Prot No: 22H90	Status: Ongoing
TITLE: Effects of Aspirin vs. Coumadin on the Prevention of Calf-Vein DVT Progression to Proximal DVT	
Principal Investigator: CPT Howard Zimring, MC	
Associate Investigators: CPT William J. Thomas, MC	
Department/Section: Department of Medicine	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91 Decision: Continue

OBJECTIVE: 1) Can aspirin provide protection equivalent to Coumadin in: preventing the progression of calf vein DVT to Proximal DVT 2) Is Aspirin a safer treatment option for calf vein DVT compared to Coumadin and placebo.

TECHNICAL APPROACH: Patients will be randomized in blocks into the treatment groups after a diagnosis of DVT confined to the calf has been made by venogram. Patients will then be assigned in blocks of three to one-of-three groups and further classified with regard to the type of calf-vein DVT initially found on the venogram. Patients will undergo clinical exam and duplex ultrasound to assess compressibility of popliteal vein/femoral vein system upon diagnosis and then again at specified intervals. Compliance with drug therapies will be evaluated by interviews with the patients, pill counts, prothrombin-time monitoring and testing of urinary salicylate levels.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

Study still ongoing - incomplete data secondary to sparcity of cases recently. CPT William J. Thomas will assume role of principal investigator upon PCS of CPT Zimring.

Detail Summary Sheet

Prot No: 21H91	Status: Ongoing
TITLE: The Effects of Supplemental Oxygen Administration on Maternal Arterial Oxygen Saturation During Labor and Delivery as Measured by Pulse Oximetry	
Principal Investigator: 1LT Kelly Gonzalez, AN Associate Investigators: Nursing Staff of Labor and Delivery at TAMC	
Department/Section: Nursing/Maternal - Child Health Nursing Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: To determine the effects of supplemental oxygen administration on maternal arterial saturation as measured noninvasively by pulse oximetry initiated in the active phase of labor.

TECHNICAL APPROACH: The purpose of the study is to demonstrate the need to monitor maternal oxygen saturation during the active phase of labor and to determine the effects of supplemental maternal oxygen administration on the arterial oxygen saturation as measured noninvasively by pulse oximetry comparing two groups, one receiving oxygen and one breathing room air.

PROGRESS: No. of Subjects Enrolled - To Date: 37      Reporting Period: 37

The findings imply that mother and fetus have the ability to tolerate insult and return to a self-directed homeostasis. The study established relevance for pulse oximetry as a valuable observation tool capable of providing assistance to the nurse in maintaining maternal/fetal stability. The oximeter has real value when designing nursing goals, outcomes and assessments for patients in their charge.

Detail Summary Sheet

Prot No: 18H90	Status: Completed
TITLE: Parental Facilitated Guided Imagery and Relaxation For Reducing Chemotherapy Associated Nausea and Vomiting in Children With Cancer	
Principal Investigator: Florence Kerfoot, RN, MS	
Associate Investigators: Deborah LaFond, RN	
Department/Section: Nursing/Pediatric Oncology	
Key Words: Anxiety; nausea; vomiting; lifestyle disruptions; guided imagery	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Completed

**OBJECTIVE:** Investigate the effectiveness of parental facilitated guided imagery (muscle relaxation program) in reducing chemotherapy associated nausea and vomiting in pediatric oncology patients -- ages 3 to 10.

**TECHNICAL APPROACH:** Parents and child view video tape (no fears no tears), complete questionnaire, intervention (distraction with blowing and books--initially done by investigator then by parent). Parent and child then do a self report questionnaire.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 0

Study was completed December 1990. Lafond completing her graduate work. There were no adverse effects noted on the children. Guided imagery did not appear to have an effect on controlling nausea and vomiting in the population sampled. But as a result of the study we found that the guided imagery approach was useful in decreasing patient and parental anxieties. Many of the families continue to use the techniques learned when their child is to undergo a painful procedure.

Detail Summary Sheet

Prot No: 51S91	Status: Ongoing
TITLE: The Relationship Between Family History and Infantile Apnea	
Principal Investigator: LTC Frances Krom, AN	
Associate Investigators: Mary S. Sheridan, PhD	
Department/Section: Nursing/Clinical Nursing Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** The question of a relationship between infantile apnea in a given patient and a family history of various sleep disorders has been raised, but not studied extensively. For research purposes, the null hypothesis (i.e., that no relationship exists) will be examined through questionnaire administration to parents and later comparison with infants' charts.

**TECHNICAL APPROACH:** Incidence of infant apnea and family history of sleep disorders will be examined per questionnaire administration and comparison with infants' charts.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

New start. Data collection was initiated in Aug 91 and is expected to continue for 6-to-9 months in order to obtain sample size of 75-100 surveys.

Detail Summary Sheet

Prot No: 37H90	Status: Completed
TITLE: Efficacy of a Mentorship Program for Clinical Anesthesia Nursing Education	
Principal Investigator: MAJ Alfred E. Lupien, AN Associate Investigators: MAJ Harold S. Booker, AN	
Department/Section: Nursing/Nursing Education and Staff Development	
Key Words: mentor, protege	
Funding: FY 90: FY 91: Gifts: None	Periodic Review Date: Sep 91 Decision: Completed

**OBJECTIVE:** To determine the efficacy of a mentorship program in clinical anesthesia nursing education. Statistical hypotheses to be tested:

- There is no difference between protege (student) performance and AHS performance standards
- There is no difference between overall protege (student) stress level and the stress level of the previous class of students

**TECHNICAL APPROACH:** Participants were 5 students entering the clinical phase of anesthesia nursing education. Performance was compared to Academy of Health Science standards and responses from a previous class. Matching of protege (student) and mentor (clinical staff) was done randomly.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5 Reporting Period: 5

Mean clinical performance scores were significantly greater than the Academy of Health Science standard. Self-reported stress levels for this group were no different from the previous class (without a mentorship program), however, the lack of correlation between stressor rankings for the two classes suggested that the preception of stressors in this investigational group differed from the previous class. The implementation of a mentorship program appears to be an effective technique for clinical anesthesia nursing education.

**Presentation:** The findings of this investigation will be presented at The Fourth Annual Bridgeway to Research Symposium, Letterman Army Medical Center, on 24 Oct 91.



Detail Summary Sheet

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Prot No: 5H91 Status: Completed

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TITLE: Attenuation of Succinylcholine-induced Myalgias: A comparison of the Efficacy of Pretreatment with Atracurium, Vecuronium and d-Tubocurarine

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Principal Investigator: CPT Bruce Schoneboom, AN  
Associate Investigators: CPT David Butler, AN

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Department/Section: Nursing/Anesthesia Nursing Service

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Aug 91  
Gifts:    Decision: Completed

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**OBJECTIVE:** To determine if atracurium pretreatment is effective in attenuating postoperative muscle pain caused by succinylcholine in ASA I and II minor lower extremity orthopedic patients, and if so, is atracurium pretreatment superior to pretreatment with vecuronium or d-Tubocurarine.

**TECHNICAL APPROACH:** A convenience sample of healthy adult males who had chosen a general anesthetic were counseled about the purpose of the study and informed consent was obtained. They were then randomized in a double-blind fashion into three treatment groups. The pretreatment drug was administered by the investigator and general anesthesia was induced and maintained with a standard technique. On the first postoperative day, following ambulation, the participant completed a visual analog scale evaluating the degree of discomfort in eleven regions of the body by marking on a 10 centimeter line representing specific body regions. Summed myalgia scores for each subject were analyzed using Analysis of Covariance.

**PROGRESS:** No. of Subjects Enrolled - To Date: 94                      Reporting Period: 94

Subjects included in data collection: 74. Subjects excluded from data collection: 20. One was excluded due to a postoperative complication unrelated to the study and 19 were excluded due to incomplete data collection. No statistical difference were demonstrated among the three groups.

**Presentations:** Results were presented to the 5th Annual Tripler Army Medical Center Nursing Research Conference on 6 Sep 91 and is scheduled to be presented to the Letterman Army Medical Center Nursing Research Conference on 24 Oct 91.

Detail Summary Sheet

Prot No: 52H91	Status: Ongoing
TITLE: Dental Liquid Ration Evaluation	
Principal Investigator: MAJ Suzanne S. Chiang, AN	
Associate Investigators: Simone O. Adams, PhD; Dianne Engell, PhD	
Department/Section: Nutrition Care Division/Clin Dietetics Branch	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** Acceptance and consumption of a new 5-day dental liquid diet will be compared to the dental liquid diets currently being served in 20 military hospitals and service institutions. Subjects will consist of approximately 150 patients with maxillofacial and oral injuries, 25 cancer and 25 geriatric patients who require a dental liquid or pureed diet. Subjects will be asked to rate the appearance, flavor, texture, consistency, ease of sipping, temperature, portion size and overall acceptability of each liquid product served. Estimates of fluid consumption will be collected and subjects' nutrient intakes will be evaluated. A questionnaire will be filled out by dietitians/dietetic technicians to obtain opinions about the two diets.

**TECHNICAL APPROACH:** All oral surgery inpatients will be served a dental liquid diet (prepared inhouse) for one day and the national dental liquid diet on the second day. These patients will evaluate every meal and nourishment using NATICK developed questionnaires. At least twelve patients will be requested to participate in this test project.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This project will begin in Oct 91, when technician and dietician staff are available to support it.

Detail Summary Sheet

Prot No: 34H88	Status: Completed
TITLE: A Prospective Evaluation of Laparoscopic Techniques Verres Needle Insufflation vs. Direct Trocar Insertion	
Principal Investigator: CPT John W. Byron, MC	
Associate Investigators: CPT Glenn R. Markenson, MC; LTC Milo L. Hibbert, MC; COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: laparoscopic techniques;	
Funding: FY 90: FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Completed

OBJECTIVE: To compare the efficiency and safety between two laparoscopic techniques in a prospective manner. Determine if direct insertion technique offers benefits of decreased time of surgery and reduction in amount of pneumoperitoneum required.

TECHNICAL APPROACH: Patients for the proposed study will come from those undergoing laparoscopic procedures through any of the gynecologic teams: GYN Oncology Team, GYN Team, Family Planning or Infertility Service. Informed consent will be obtained prior to the procedure. Patients will then be randomized into one of the two groups with the procedure to be performed located on the surgeon data sheet. The data sheet will remain sealed until immediately prior to surgery. A data sheet will be completed by the operating surgeon in conjunction with the anesthetist. Data sheets will then be collected by an author who will check them for accuracy and completeness.

PROGRESS: No. of Subjects Enrolled - To Date: 200+  
Reporting Period: 0

Study has been completed and results presented.

Detail Summary Sheet

Prot No: 23H90	Status: Terminated
TITLE: A Prospective Randomized Blinded Trial of Indomethacin in Conjunction with Conventional Tocolytics as an Adjunct in the Treatment of Premature Labor	
Principal Investigator: CPT Mark T. Lau, MC	
Associate Investigators: MAJ Albert P. Sarno, MC; MAJ Jerome Kopelman, MC; COL Larry L. Morgenstern, MC	
Department/Section: Department of Obstetrics & Gynecology	
Key Words:	
Funding: FY 90:                      FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Terminated

**OBJECTIVE:** To assess the safety and efficacy of indomethacin as an adjunct to conventional tocolytics in the treatment of premature labor in patients who have failed first line therapy.

**TECHNICAL APPROACH:** Candidates for study will be selected from women admitted to the TAMC and MAMC labor and delivery suites with the diagnosis of premature labor who fail conventional intravenous tocolytic therapy. Premature labor will be defined as documented cervical change with uterine contractions greater than 6 per hour. Conventional intravenous tocolytic therapy consists of ritodrine hydrochloride or magnesium sulfate. Patients eligible for study entry will be counseled regarding potential risks and benefits of participation as well as available alternatives. The gestational age range acceptable for the study will be 20 - 34 weeks.

**PROGRESS:** No. of Subjects Enrolled - To Date:                      Reporting Period: FY 91

Changing clinical trends in the treatment of preterm labor have made this study difficult to initiate since other, potentially safer therapies, have begun to be used making the need for Indocin less likely. We, therefore, would like to terminate this protocol.

Detail Summary Sheet

Prot No: 17H87	Status: Completed
TITLE: Comparison of Pregnancy Rates Using Oil-based and Water-based Contrast Medium in the Evaluation of Tubal Patency	
Principal Investigator: LTC Gerard S. Letterie, MC Associate Investigators: COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: tubal patency;	
Funding: FY 90:      FY 91:	Periodic Review Date: Aug 91
Gifts: None	Decision: Completed

OBJECTIVE: To determine if the use of oil-based contrast medium in the evaluation of tubal patency enhances fertility when compared to water-based solutions.

TECHNICAL APPROACH: Sixty patients fulfilling the study criteria will be entered into one of two random study groups. Group I patients will have an oil-based contrast medium injected during the intra-operative tubal insufflation and a water based contrast medium will be used in an identical fashion on Group II patients. Effectiveness will be determined by the conception rates for the two groups at the end of a three month period.

PROGRESS: No. of Subjects Enrolled - To Date: 22      Reporting Period: 14

Thirty patients have been entered, fifteen into each of two groups (as described above). Six pregnancies in the oil-based group and one patient in the water-based group have been observed. This difference was statistically significant (Fisher's Exact Test). No adverse effects were noted. This protocol is completed and published.

Detail Summary Sheet

Prot No: 27H90	Status: Terminated
TITLE: Microheterogeneity of Human Chorionic Gonadotropin (hCG) in Ectopic Pregnancies	
Principal Investigator: LTC Gerard S. Letterie, MC	
Associate Investigators: John R. Claybaugh, PhD; Catherine F.Y. Uyehara, PhD	
Department/Section: Obstetrics and Gynecology	
Key Words: serum human chorionic gonadotropin (hCG); ectopic pregnancies	
Funding: FY 90:      FY 91:	Periodic Review Date: Aug 91
Gifts: None	Decision: Terminate

OBJECTIVE: To determine if unique variants of serum hCG exist in association with ectopic pregnancies (EP).

TECHNICAL APPROACH: An analysis of serum hCG concentrations and hCG microheterogeneity will be made on a single serum sample obtained during the first trimester from patients fulfilling the study criteria.

PROGRESS: No. of Subjects Enrolled - To Date:      Reporting Period:

Study terminated due to interference by Desert Shield/Storm and now due to the ETS of the principal investigator, Dr. Letterie.

Detail Summary Sheet

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Prot No: 29H87 Status: Completed

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TITLE: Evaluation of Missed Pills on the Effectiveness of Oral Contraception

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Principal Investigator: LTC Gerard S. Letterie, MC  
Associate Investigators: LTC James Wilson, MC

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Department/Section: Obstetrics and Gynecology

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Key Words: oral contraception;

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Funding: FY 90:                      FY 91: \$4,719                      Periodic Review Date: Aug 91  
Gifts: None    Decision: Completed

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OBJECTIVE: To determine if missed pills in an oral contraceptive cycle result in the sequence of follicular maturation and eventual ovulation.

TECHNICAL APPROACH: Ten patients will be assigned to each group on a rotating basis for a total of 20 patients. The study population will consist of volunteers drawn from these patients referred to the Reproductive Endocrinology Service, Department of Obstetrics and Gynecology for tubal reanastomosis. The use of this specific population will enable a manipulation of an oral contraceptive regimen without the risk of pregnancy.

PROGRESS: No. of Subjects Enrolled - To Date: 8      Reporting Period: 0

Eight patients were entered. Completed, presented ACOG May 91 and submitted for publications.



Detail Summary Sheet

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Prot No: 37R91 Status: Completed

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TITLE: The Association Between Race and Risk of Preterm Labor Among Enlisted Women in the Army

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Principal Investigator: MAJ Albert Sarno, MC  
Associate Investigators: CDR Melissa M. Adams, MC

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Department/Section: Obstetrics & Gynecology/Antepartum Diagnostic Center

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Completed

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**OBJECTIVE:** We propose a retrospective cohort study of the association between maternal race (black or white) and preterm delivery among the relatively homogeneous population of enlisted Army women who delivered at the four Army medical centers with the greatest number of deliveries. This study presents a unique opportunity to assess the relationship between race and a preterm delivery in a healthy, relatively homogeneous population for whom no financial barriers to prenatal care exist and in which the providers of and content of prenatal care are consistent across racial groups.

**TECHNICAL APPROACH:** We plan to abstract data at four medical centers: Beaumont, Madigan, Walter Reed, and Tripler. A sample size calculations will be computed assuming that data from the four centers will be combined in the analysis. A two-sided test with alpha equal to 0.05. We will assume a 10% preterm delivery rate.

**PROGRESS:** No. of Subjects Enrolled - To Date:                      Reporting Period:

Four hundred ninety seven (497) charts reviewed during July and August 1991. Data currently being analyzed by CDR Melissa Adams at CDC in Atlanta. Chart review process totally completed. No manuscript anticipated for publication prior to Jan 92.

Detail Summary Sheet

Prot No: 50R91	Status: Ongoing
TITLE: Unexplained High Maternal Serum Alpha-Fetoprotein: Obstetrical and Neonatal Outcomes	
Principal Investigator: MAJ Albert Sarno, MC	
Associate Investigators: Cynthia S. Hartwell, BSN	
Department/Section: Obstetrics & Gynecology/Antepartum Diagnostic Center	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date:
	Decision: Continue

OBJECTIVE: This study will utilize chart review to explore unexplained elevated MSAFP test results and possible relationships with obstetrical and neonatal outcomes. The study asks what are the obstetrical and neonatal outcomes of a group of women with abnormally high maternal serum alpha-fetoprotein (MSAFP) test results which are unexplained by ultrasonography and/or amniocentesis? How do these maternal and neonatal outcomes compare to those of a group of pregnant women whose MSAFP results are within normal limits? Also are there associations between unexplained high MSAFP and certain obstetrical and neonatal factors? If so, to what degree are these factors associated with unexplained elevated MSAFP?

TECHNICAL APPROACH: This retrospective study will review the prenatal, labor and delivery, and neonatal records of at least 252 women who received antepartum care from Tripler Army Medical Center from Dec 1988 through Aug 1990. Women's records included in the control group had a Down syndrome risk less than or equal to that of a 35 year (1/365) and/or an adjusted MSAFP less than 2.5 MoM. The control group mothers will be identified by review of the delivery room records.

PROGRESS: No. of Subjects Enrolled - To Date:                      Reporting Period:

Chart review ongoing and more than 50 charts reviewed to date. Statistic consultation completed. Data for analysis will be available in next three months.

Detail Summary Sheet

Prot No: 16L91	Status: Ongoing
TITLE: A Comparison of the BACTEC NAP/Conventional Biochemical-Physiological Tests and the SNAP Culture Test (Syngene, Inc.) for Identification of the Mycobacterium tuberculosis and M. avium Complex	
Principal Investigator: Bardwell Eberly, MT	
Associate Investigators: CPT Steve Adams, MC; LTC Bruce A. Gunn, MS; COL Robert Hill, MC; COL Joseph C. Woods, MC	
Department/Section: Pathology/Microbiology-RIA-Immunology-Virology	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To compare the cost, accuracy and speed of our conventional BACTEC NAP/conventional Biochemical-Physiological with the rapid SNAP DNA probe method for identification of the M. tuberculosis and M. avium complexes.

**TECHNICAL APPROACH:** Approximately 100 BACTEC (TB) culture bottles have been collected and saved for this study. Mycobacteria have been isolated from each of these bottles and the NAP and conventional tests have been performed. The bottles are frozen in preparation for the rapid SNAP DNA probe testing.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A      Reporting Period: N/A

Due to personnel shortages, we have not had the opportunity to begin this study. We anticipate that it will be started and finished during the months of October and December 1991.





Detail Summary Sheet

Prot No: 19L91	Status: Completed
TITLE: The Use of Rapid L-Pyrrolidonyl-b-Naphthylamine (PYR) and Esculin (ESC) Hydrolysis Tests for Identification of b-Hemolytic Streptococci Cultured from Throat Cultures and Enterococci Cultured from Urine	
Principal Investigator: LTC Bruce A. Gunn, MS	
Associate Investigators: CPT Bruce Britton, MC; Bardwell Eberly, MT; LTC Frank Gress, MC; COL Robert Hill, MC	
Department/Section: Pathology/Microbiology-RIA-Immunology-Virology	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

OBJECTIVE: To compare the cost, accuracy and speed of our conventional tests for identifying enterococci/b-hemolytic streptococci with rapid spot identification tests using PYR and ESC discs.

TECHNICAL APPROACH: 500 strains of b-hemolytic streptococci will be collected and identified and tested for PYR and ESC reactions. The usefulness of testing for PYR reaction from colonies of b-hemolytic strains growing on SBA plates will be assessed.

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

This project has been completed and we are awaiting analysis of results and writing the manuscript for potential publication.

Detail Summary Sheet

Prot No: 20L91	Status: Ongoing
TITLE: Rapid Identification of Lactose-Fermenting Gram-Negative Bacilli from Urine Cultures Using Indol and Nitrophenyl-B-Glucopyranosiduric Acid (PGUA) Tests	
Principal Investigator: LTC Bruce A. Gunn, MS	
Associate Investigators: CPT Vicky Rholl, MC; Bardwell Eberly, MT; MAJ Mark Pitt, MC; COL Joseph Woods, MC	
Department/Section: Pathology/Microbiology-RIA-Immunology-Virology	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: To compare the cost, accuracy and speed of our conventional identification system with the rapid *E. coli* Screen Test (Indole/PGUA) of Carr Scarborough Microbiologicals Inc. for identifying lactose-fermenting gram-negative bacilli cultured from urine. And, to use antibiograms to confirm the results of the rapid screen test.

TECHNICAL APPROACH: The Indole/PGUA tests will be done on fresh clinical isolates of gram-negative bacilli cultured on MAC and XLD agars. The organisms will be definitively identified with the VITEK system and these results will be compared to the rapid test results.

PROGRESS: No. of Subjects Enrolled - To Date: N/A      Reporting Period: N/A

Due to personnel shortages, we have not had the opportunity to begin this study. We anticipate that it will be started and finished between October 1991 and May 1992.

Detail Summary Sheet

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Prot No: 38L91 Status: Ongoing

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TITLE: Characterization of Mouse Monoclonal Antibodies to Human Chondrocytes

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Principal Investigator: CPT Matthew Plymyer, MC  
Associate Investigators: Lucille H. Kimura, Ph.D.

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Department/Section: Pathology and Area Laboratory Services

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Ongoing

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OBJECTIVE: To determine the tissue reactivities of five mouse anti-human chondrocyte monoclonal antibodies for possible use in chondrocyte differentiation studies and differential diagnosis of chondrosarcomas.

TECHNICAL APPROACH: Methodology includes two basic types of analyses of tissues harvested intraoperatively at Queen's Medical Center, tissues obtained from autopsies at Tripler Army Medical Center, and archival sarcoma tissue from both institutions. Such tissues are being studied by one or both techniques, namely an avidin-biotin immunoperoxidase procedure and flow cytometric analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 15      Reporting Period: 15

There have been no adverse effects or subjects dropped/withdrawn from this study.

- A) Avidin-biotin immunoperoxidase studies on paraffin-embedded archival autopsy material has been completed on a wide variety of tissues; the five mouse monoclonal antibodies have shown an interesting and varied array of reaction characteristics. Additionally, the avidin-biotin method has been used to date to study cartilage removed during surgery from several patients, examination of which shows that the five antichondrocyte antibodies vary in their degree of reactivity and their reaction substrates. As an accessory study, a similar technique was used to characterize the reactivities of four monoclonal antibodies generated against mycobacterial proteins (heat-shock proteins) to human chondrocytes. Frozen sections prepared with the avidin-biotin immunoperoxidase technique found only one such antibody, ML30, to have reactivity with chondrocytes.
- B) Chondrocytes from cartilage of several patients harvested at the time of surgery have also been analyzed by flow cytometric analysis. Reactivities of the five monoclonal antibodies differ quantitatively as a function of time of tissue culture, correlating with prior studies showing chondrocyte morphologic changes over time.

One publication, Reaction of Antibody to Mycobacterial 65kD Heat-shock Protein with Human Chondrocytes is being submitted for publication to the Journal of Autoimmunity.

Detail Summary Sheet

Prot No: 33H89	Status: Completed
TITLE: Prevalence of Hantavirus	
Principal Investigator: CPT Glenn Sandberg, MC Associate Investigators:	
Department/Section: Pathology and Area Laboratory Services	
Key Words:	
Funding: FY 89:	FY 90:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

OBJECTIVE: To determine the prevalence of Hantavirus antibody in human population groups located in the Pacific region.

TECHNICAL APPROACH: Serologic testing (EIA) for serum antibodies to the hantavirus (KHF).

PROGRESS: No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

This project has been completed and is awaiting analysis of results.



Detail Summary Sheet

Prot No: 9A89	Status: Ongoing	
TITLE: Pediatric Intubation Training Utilizing the Feline Model		
Principal Investigator: COL Richard A. Banks, MC		
Associate Investigators: COL John D. Roscelli, MC		
Department/Section: Pediatrics		
Key Words: intubation training;		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Continue

**OBJECTIVE:** This training is designed to teach physicians and other health care professionals the basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

**TECHNICAL APPROACH:** Initially the cats will be anesthetized with ketamine HCL (22 mg/kg intramuscularly) with atropine (0.04 mg/kg, subcutaneously). Additional doses of ketamine may be given if necessary by the Veterinarian staff. The administration and monitoring of the anesthesia will be directly performed by the Veterinarian staff. The students will then visualize the larynx and perform endotracheal intubation using the larynx scope and endotracheal tubes. Anesthesia will be maintained throughout the procedure. Examination gloves will be worn by the students. Animals not suffering significant trauma may be retained for future sessions. If euthanasia is required (determined by the Veterinarian staff), the animals will be euthanized with T-61 given IV, 0.3 ml/kg.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

This needs to be continued. Currently, no plans for Pediatric Advanced Life Support (PALS). The last course was held in March 1989.

Detail Summary Sheet

Prot No: 31H85	Status: Terminated
TITLE: Treatment of Kawasaki Syndrome with Intravenous Gamma Globulin	
Principal Investigator: COL James W. Bass, MC Associate Investigators: Marian E. Mellish, M.D.	
Department/Section: Pediatrics	
Key Words: Kawasaki syndrome	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: IV Gamma Globulin	Decision: Terminate

OBJECTIVE: To evaluate the use and establish the proper dose of intravenous Immuno Globulin for the treatment of children with Kawasaki Syndrome.

TECHNICAL APPROACH: Children with Kawasaki Syndrome seen at Tripler Army Medical Center will be offered the opportunity to participate in the study after informed written consent is obtained from the parents. The intravenous immuno globulin will be supplied by Dr. Mellish. It will be administered in two different doses as outlined in the protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0    Reporting Period: 0

This study has been in operation over the past 4 - 5 years and no patients have presented that could be entered into this study. Recommend the study be terminated.

Detail Summary Sheet

Prot No: 33H87	Status: Ongoing
TITLE: Ceftriaxone vs. Augmentin for Initial Empirical Therapy of Occult Bacteremia	
Principal Investigator: COL James W. Bass, MC	
Associate Investigators:	
Department/Section: Pediatrics	
Key Words: occult bacteremia;	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: To evaluate the efficacy of a single intramuscular injection of ceftriaxone (75 mg/kg) versus augmentin suspension administered three times a day (40 mg/kg/day divided into three equal doses) in preventing or alleviating the acute infectious morbidity of occult bacteremia in febrile children.

TECHNICAL APPROACH: Children 3-36 months of age with documented rectal or tympanic temperature  $\geq 103.0$  and no source of infection by physical exam, chest x-ray, and lab (urinalysis) with informed consent will be randomized to receive empirical therapy of either oral Augmentin or one injection of IM Ceftriaxone. Patients are then followed up in 12-36 hours for evidence of focal infection and blood culture results.

PROGRESS: No. of Subjects Enrolled - To Date: 492 Reporting Period: 10

Four-hundred ninety-two patients have been enrolled in this study as of 31 August 1991. There have been 55 (11.2%) positive blood cultures. All children have done well. It is anticipated that we will need over 1,000 patients entered into this study with approximately 100 positive blood cultures to prove or disprove our hypothesis - that Ceftriaxone will prove superior to Augmentin for patients with occult bacteremia. This will probably take another 1 - 2 years.

Detail Summary Sheet

Prot No: 28H91	Status: Terminated
TITLE: North American Multicenter Trial of the Effects of Two Dosing Regimens of EXOSURF Neonatal on Alveolar-Arterial Oxygen Tension Gradient Improvement in Larger Infants With Established Respiratory Distress Syndrome	
Principal Investigator: LTC James T. Berkenbaugh, Jr., MC Associate Investigators: MAJ W. Michael Southgate, MC	
Department/Section: Pediatrics/Newborn Medicine Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91 Decision: Terminate

OBJECTIVE: The objectives of this study in premature infants with birth weight greater than or equal to 1250 grams and established RDS is to compare the effect of dosing based on the clinical status of the patient to the effect of dosing on a fixed time schedule on:

- a) alveolar-arterial oxygen gradient
- b) time to permanent cessation of mechanical ventilation
- c) time to permanent cessation of supplemental oxygen
- d) safety

TECHNICAL APPROACH: This study is a multicenter, randomized, parallel, open, comparison of two dosing regimens of EXOSURF Neonatal. Each dosing regimen consists of 5.0 cc/kg intratracheal doses of EXOSURF Neonatal administered to infants with birth weights  $\geq$ 1250 grams and with established Respiratory Distress Syndrome (RDS).

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol was terminated since Burroughs-Wellcome was not interested in our participation in the study.

Detail Summary Sheet

Prot No: 23H88	Status: Ongoing
TITLE: Predicting Responsiveness to Methylphenidate	
Principal Investigator: Dr. Thomas E. Gallagher, M.D. Associate Investigators: Dr. David S. Weiss, Ph.D.	
Department/Section: Pediatrics//Exceptional Family Member Program	
Key Words: methylphenidate (ritalin);	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

OBJECTIVE: To identify the variables which predict the responsiveness of Attention Deficit Disorder children to treatment with methylphenidate (Ritalin).

TECHNICAL APPROACH: Multivariant prospective data collection of patient care.

PROGRESS: No. of Subjects Enrolled - To Date: 34      Reporting Period: 5

Study is ongoing and there are now 34 subjects enrolled, although data collection is not complete on all of them.

Detail Summary Sheet

Prot No: 40H90	Status: Ongoing
TITLE: Serum Endothelin Measurement in Pediatric Asthmatic and Control Patients	
Principal Investigator: MAJ Louis H. Guernsey, Jr., MC	
Associate Investigators:	
Department/Section: Pediatrics	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** This study will follow-up the hypothesis that serum endothelin (ET) levels are elevated in asthmatic patients during episodes of status asthmaticus. Prior work by this investigator has established a statistically significant increase in serum endothelin levels in pediatric patients in status asthmaticus when compared to healthy non-asthmatic children seen prior to elective surgery (unpublished data). This study would expand on the earlier work by investigating serum levels during the course of therapy and at a non-wheezing baseline after hospital discharge. It would attempt to correlate serum levels with measurements of pulmonary function and expand the control group to include hospitalized patients with pulmonary disease but without a reactive airways component. It would also attempt to establish baseline values for healthy, non-wheezing children who have a past history of reactive airway problems. This information will help us to better understand the role that endothelin might play as a bronchoreactive mediator in status asthmaticus.

**TECHNICAL APPROACH:** After a delay incurred by increased clinical responsibilities during Operations Desert Shield/Desert Storm, the infrastructure of my experiment has been established. A contract is pending to provide for the required number of RIA kits. Serum for intra- and inter-assay controls have been obtained and frozen. The mechanics of protein elution and specimen drying have been established and performed in a dry run. Sufficient reagent is on hand for the processing and storage of the initial 50 blood specimens. I have coordinated with the outpatient phlebotomy lab and pediatric clinic to enroll both control and study patients. Equipment is now on hand to calibrate the spirometer that will be used to monitor each study patient's pulmonary function.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Patient enrollment can begin as soon as the RIA kit contract is finalized.

Detail Summary Sheet

Prot No: 61H89	Status: Completed	
TITLE: Clinical Application of Orthostatic Measurements in Adolescents		
Principal Investigator: CPT William Joseph Horam, MC		
Associate Investigators: COL John D. Roscelli, MC; CPT Linda M. Brantner, MC		
Department/Section: Pediatrics		
Key Words: orthostatic measurements in adolescents		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Completed

**OBJECTIVE:** Establish normal standards of measurement for orthostatics in healthy adolescents and evaluate utilization of orthostatic measurements for ill adolescents.

**TECHNICAL APPROACH:** Prospective clinical study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 127 Reporting Period: 0

Enrollment of subjects has been completed. All three investigators have now PCS'd.

Presented at the Pediatric Tri-Service Conference, March 1991.

Detail Summary Sheet

Prot No: 4H9T	Status: Completed
TITLE: Presence and Persistence of Antigenuria in Infants following H. Influenzae Type b Oligosaccharide Conjugate (HbOC) Vaccine	
Principal Investigator: MAJ Ronald G. Jones, MC Associate Investigators: COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91 Decision: Completed

**OBJECTIVE:** To test whether and for how long HbOC vaccine given to infants will produce H. influenzae antigenuria.

**TECHNICAL APPROACH:** Infants will be randomly recruited from the well-baby clinic. Urine samples will be obtained and tested for Hemophilus antigen using the Directogen latex particle agglutination materials. Data will be tabulated and reported as to incidence of antigenuria at various times (1, 3, 6, and 9 days) after vaccination.

**PROGRESS:** No. of Subjects Enrolled - To Date:                      Reporting Period:  
Study completed.

Detail Summary Sheet

Prot No: 44H89*	Status: Completed
TITLE: National Survey of Pediatric Sedation Procedures	
Principal Investigator: CPT Simone Nomizu, MC	
Associate Investigators: COL James W. Bass, MC; CPT Mark Alexander, MC	
Department/Section: Pediatrics	
Key Words: sedation;	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91
	Decision: Completed

OBJECTIVE: To collect data from institutions across the country through questionnaire form regarding the procedures used in the sedation of pediatric patients for diagnostic procedures.

TECHNICAL APPROACH: Questionnaires will be sent to various medical centers in order to collect the following data:

- a. selection, route, and dosage of premedication
- b. procedures for which sedation routinely used
- c. age at which sedation routinely used
- d. monitoring procedures
- e. type of health care facility and practice
- f. existence of written guidelines for pediatric sedation
- g. approximate incidence of adverse side effects due to sedation

The data collected will be combined, analyzed and summarized; appropriate conclusions will be made in regards to a national consensus (if one does exist) as to the procedures used in the sedation of pediatric patients for diagnostic procedures. Also, further recommendations will be made for improving currently followed sedation protocols.

PROGRESS: No. of Subjects Enrolled - To Date: 82 Reporting Period: 0

This study has been completed. Results have been written and a paper has been accepted for publication in Clinical Pediatrics.

\*Exempt cmte/HUC review

Detail Summary Sheet

Prot No: 38H90	Status: Completed
TITLE: "Compassionate Clearance Protocol for the Treatment of Recurrent Hemiplegia of Childhood with Flunarizine"	
Principal Investigator: COL Donald A. Person, MC Associate Investigators: COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Aug 91
Gifts:	Decision: Completed
OBJECTIVE: Research to determine whether a new experimental drug, flunarizine, is effective in the treatment of a disease called Recurrent Hemiplegia.	

TECHNICAL APPROACH: This is an individual request for the continued compassionate use of the investigational new drug (IND), flunarizine in the treatment of a child with recurrent hemiplegia/recurrent stroke syndrome.

PROGRESS: No. of Subjects Enrolled - To Date: 1    Reporting Period: 0

The patient experienced no recurrence of hemiplegia nor did he suffer from any flunarizine attributable side effects. This protocol was terminated/completed as the patient moved from Hawaii to Germany.

Detail Summary Sheet

Prot No: 16H89	Status: Ongoing	
TITLE: Urinary C-peptide Response to Umbilical Arterial Catheter Position in Neonates		
Principal Investigator: CPT Ronald D. Prauner, MC		
Associate Investigators: LTC Robert V. Jarrett, MC; COL Richard A. Banks, MC		
Department/Section: Pediatrics		
Key Words: umbilical arterial catheter (UAC)		
Funding: FY 90: NA	FY 91: NA	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** To determine if umbilical Arterial Catheter (UAC) position, (high vs low) results in different rates of insulin production in neonates.

**TECHNICAL APPROACH:** All infants in which a UAC is to be placed will be eligible for enrollment in the study. The decision to place a UAC will be made based solely on the infant's clinical condition. Informed consent will be obtained prior to enrollment of all infants. After enrollment, UAC placement will be allocated to either high or low position. The patients will be stratified based on weight. The first child in any weight group will have a high UAC tip placement. Subsequent UACs in each weight group will be alternated sequentially in order to maintain equal numbers of high and low UACs in each weight group. Each child will receive IV fluid (D10W) at 80 cc/kg/day (5.55 mg of glucose/kg/min). At 24 hours following placement of the catheter, a 4-6 hour collection of urine will be assayed for C-protein. The urine will be obtained by passive collection with a container placed to catch the urine as the child voids. Capillary dextrosticks will be obtained at a minimum of eight hour intervals during the first 24 hours following placement (as per NICU protocol). The study group will consist of 10 children with low UACs, 10 children with high UACs and 10 children receiving IVF through peripheral veins. Children enrolled in the study will be at no additional risk based on the study. Benefits of being enrolled in the study include prompt-recognition of problems involving glucose metabolism, as well as catheter related complications.

**PROGRESS:** No. of Subjects Enrolled - To Date: 10 Reporting Period: 0

We plan to enroll 20 patients. No new subjects were enrolled in the study this past year.

Detail Summary Sheet

Prot No: 14H91	Status: Ongoing
TITLE: Perinatal HIV Infection: Epidemiology and Natural History	
Principal Investigator: MAJ Judy M. Vincent, MC	
Associate Investigators:	
Department/Section: Pediatric/Infectious Disease Section	
Key Words:	
Funding: FY 91:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To develop a standardized procedure for diagnosis and management of pregnant women who are infected with human immunodeficiency virus (HIV) and their newborn infants; 2) To systematically collect clinical, laboratory, and epidemiologic data describing the course and natural history of perinatal HIV infection.

TECHNICAL APPROACH: Pregnant women who are HIV positive will be approached by the principal investigator and asked for permission to follow them for the effect of their pregnancy over the course of their HIV infection and also to follow their infant with physical exams and lab tests (HIV culture and PCR) to determine whether the infant has acquired the infection.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Only one HIV positive woman has given birth since this study started. She has not developed progression of HIV infection and the infant has had negative HIV cultures three times and appears to not be infected. The active duty sponsor is getting out of the Army and the family is moving to Las Vegas where they will receive civilian care.

Detail Summary Sheet

Prot No: 25H90	Status: Terminated
TITLE: A Prospective Controlled Trial of Trimethoprim-Sulfamethoxazole versus Cephalexin for Treatment of Cat Scratch Disease in Children	
Principal Investigator: MAJ Judy Vincent, MC	
Associate Investigators: LTC Bruce Cook, MC; CPT Martin Weisse, MC; CPT Cheryl Sisler, MC; MAJ Ronald Jones, MC; Debora Schotik, B.S.; COL Donald Person, MC; COL James W. Bass, MC	
Department/Section: Department of Pediatrics	
Key Words:	
Funding: FY 90:                      FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Terminate

OBJECTIVE: To determine whether trimethoprim-sulfamethoxazole accelerates the resolution of symptoms and/or physical findings in cat scratch disease in children compared to cephalixin.

TECHNICAL APPROACH: Patients will be enrolled if they meet certain criteria predetermined by the principal investigator. A history and physical exam, laboratory, and radiologic exams will be performed. Patients will be randomized to receive one of two drug therapies and will be seen in the pediatric clinic once a week for a follow-up exam by either the principal investigator or one of the associate investigators as well as an ultrasound to assess the patient's lymph nodes. TAMC will process all lab specimens except for the antibody serology. CSD antibody serology will be performed by the CDC in Atlanta.

PROGRESS: No. of Subjects Enrolled - To Date: 20      Reporting Period: 20

About twenty patients have been enrolled to date. The CDC was able to get the cat scratch organism from samples sent by us and were able to determine that it was resistant to both cephalixin and trimethoprim-sulfamethoxazole. Therefore this study will be terminated. CSD serology is pending.

Detail Summary Sheet

Prot No: 3H90	Status: Ongoing
TITLE: The Prevention of Amphotericin B Nephrotoxicity With Intravenous Saline	
Principal Investigator: CPT Martin Weisse, MC Associate Investigators: CPT Kevin M. Creamer, MC	
Department/Section: Pediatrics	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91 Decision: Continue

OBJECTIVE: To assess onset, severity and incidence of renal toxicity in patients receiving amphotericin. Treatment group will receive NS bolus before and after amphotericin. Control group will receive standard therapy.

TECHNICAL APPROACH: Two groups, one control, one treatment with NS. Patients randomly assigned. Urine and serum electrolytes, creatinine, BUN assessed.

PROGRESS: No. of Subjects Enrolled - To Date: 8      Reporting Period: 3

There will be a change in principal investigator upon PCS of Dr. Weisse. The new PI will be MAJ Judy Vincent.

Detail Summary Sheet

Prot No: 14H90	Status: Terminated
TITLE: Efficacy of Cholestyramine in Acute Diarrhea in Children	
Principal Investigator: CPT Martin E. Weisse, MC	
Associate Investigators: Debora Schotik, RPH	
Department/Section: Pediatrics	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91
	Decision: Terminate

OBJECTIVE: To assess cholestyramine vs. placebo in young children with diarrhea. Weight loss/gain, duration of diarrhea will be assessed.

TECHNICAL APPROACH: Two groups of patients will be assessed; treatment and placebo. Patients will be randomly assigned.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Only one patient was enrolled in this study, probably because the entrance eligibility requirements were too narrow. Therefore request termination of this project.

Detail Summary Sheet

Prot No: 43A91	Status: Completed
TITLE: Virulence of Mucoïd and Nonmucoïd Pseudomonas Aeruginosa in a Rat Model of Sepsis	
Principal Investigator: MAJ Martin E. Weisse, MC Associate Investigators: LTC Bruce A. Gunn, MS	
Department/Section: Pediatrics/Pediatric Infectious Disease	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Aug 91 Gifts:                            Decision: Completed

**OBJECTIVE:** To determine the in vivo virulence of a strain of mucoïd Pseudomonas aeruginosa before and after the suppression of its mucoïd characteristic by passage in TMP/SMX enriched agar.

**TECHNICAL APPROACH:** Sixty rats divided into three groups will receive either injections (SQ) of Psae in rough form or mucoïd form or they will receive saline injections as a control. Animals will be weighed daily and sacrificed on day 10. If all tests show that only the rough form was present in vivo at the end of the experiment it will be halted. If the rough strain does revert back to mucoïd and expected differences in weight gains are not noted, the experiment will be repeated with 60 more rats that have been pretreated with TMX/S in their drinking water. Animals will be sacrificed at 10 days post injection.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A    Reporting Period: N/A

The study was to be done in two phases - with and without antibiotics.

Phase I results: There was no statistically significant difference between the infected animal groups.

Phase II was not pursued because the non mucoïd Pseudomonas was much more resistant to the phase II antibiotic (Trimethoprim/Sulfa) than was the mucoïd.

Detail Summary Sheet

Prot No: 26D84	Status: Ongoing	
TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients With No Therapeutic Alternative		
Principal Investigator: CPT Scott C. Martin, MS Associate Investigators: COL Jeffrey L. Berenberg, MC; LTC Bruce A. Cook, MC; LTC William J. Uphouse, MC; CPT Paul Fishkin, MC		
Department/Section: Pharmacy Service/Hem-Onc Pharmacy Section		
Key Words: hyperuricemia; allopurinol;		
Funding: FY 89:	FY 90:	Periodic Review Date: Sep 91
Gifts: Allopurinol		Decision: Continue

**OBJECTIVE:** To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

**TECHNICAL APPROACH:** This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 1-2 patients a year will be treated on this protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 12 Reporting Period: 1

No patients were enrolled in FY91. Protocol to continue as a "convenience protocol" for use on an as-needed basis. Status is ongoing. PI change is requested to LTC Cook, Department of Pediatrics.

Detail Summary Sheet

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Prot No: 53L91 Status: Ongoing

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TITLE: Stability of Extemporaneously Compounded Captopril 0.1% and 1% Oral Solution Under Two Storage conditions

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Principal Investigator: Debora A. Schotik, RPH  
Associate Investigators: John R. Claybaugh, PhD; COL James Bass, MC;  
Aileen Sato

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Department/Section: Pharmacy Services/

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Continue

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**OBJECTIVE:** The objective is to determine the stability of captopril 0.1% and 1% solution in sterile glass evacuated containers under the following conditions 1) storage under refrigeration ( $4 \pm 4$  degrees C) in a dark environment and 2) storage at room temperature ( $25 \pm 4$  degrees exposed to light) by using high performance liquid chromatography (HPLC) and spectrophotometry in an attempt to determine guidelines for an acceptable expiration date.

**TECHNICAL APPROACH:** In the process of determining the optimum wavelength of adsorption to measure the amount of degradation product (captopril Disulfide) in relation to the parent compound (captopril) at given point in time.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A      Reporting Period: N/A

Determined rate of degradation of four solutions of captopril at wavelength equals 205 nm days 0, 4, 12, 14, 26, 30 and 42 if in fact degradation peak (9-10 minutes) is captopril Disulfide. This still needs to be determined.

Detail Summary Sheet

Prot No: T3S91	Status: Ongoing
TITLE: Assessment of Procedures for Measuring Pinch Strength in Army Occupational Therapy Clinics	
Principal Investigator: ILT Vanessa M. Larsen, SP Associate Investigators: MAJ Melissa W. Sinnott, SP	
Department/Section: Physical Medicine Service/Occupational Therapy Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** This study will assess the procedures used in Army Occupational Therapy Clinics for measurement and interpretation of pinch strength. Data collected will determine if there are inconsistencies in the pinch strength procedures among clinics, and discrepancies among procedures used for evaluation and interpretation of pinch strength within Occupational Therapy Clinics.

**TECHNICAL APPROACH:** Survey

**PROGRESS:** No. of Subjects Enrolled - To Date:                      Reporting Period:

The survey has been distributed with approximately half being returned. A second/follow-up survey will be sent out and results will be tallied upon return.

Detail Summary Sheet

Prot No: 15H89	Status: Completed	
TITLE: A Study of the Relationship Between the Topography of Herniated Lumbar Disks, Lumbar List, and the Side of Pain		
Principal Investigator: LTC Richard C. Schreck, SP		
Associate Investigators: MAJ Kevin Foley, MC; MAJ Douglas Fellows, MC; Mark Laslett, N.Z.R.P.; Maynard Williams, M.S.C.		
Department/Section: Physical Medicine		
Key Words: herniated lumbar disks;		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Completed

OBJECTIVE: 1) To test the hypothesis that the relationship between an entrapped lumbar nerve root and a herniated lumbar disk will determine whether a lumbar list will be towards or away from the side of pain. Specifically: that a herniated disk that lies medial to the nerve root will cause a list to the same side as the pain, and a herniated disk that lies lateral to the nerve root will cause a list away from the side of pain.  
2) To test the reliability and specificity with which therapists observe a lumbar list.

TECHNICAL APPROACH:

- A. INCLUSIONS:
- 1) Consecutive patients diagnosed as having a herniated lumbar disk.
  - 2) Those patients who are scheduled to undergo surgery for removal of the herniated lumbar disk.
- B. EXCLUSIONS:
- 1) Those who will not sign a standard informed consent form.
  - 2) Those patients who are unable (for whatever reason) to complete the study procedures.
  - 3) Those whose pain is too severe for them to be subjected to the study procedures.

PROGRESS: No. of Subjects Enrolled - To Date: 47 Reporting Period: 0

The number of subjects enrolled in the study as of 30 Sep 90 is 47. No other subjects have been enrolled. Fifty subjects were asked to participate in the study, with three patients electing not to participate. Of the 47 patients in the study, all have completed the procedures with no adverse response. Early statistical analysis indicates that there is no correlation between the side of pain, lumbar list, and the location of the disk herniation. Statistical analysis is being completed. A rough draft of the article to be submitted for publication has been completed.

Detail Summary Sheet

Prot No: 37H89	Status: Ongoing	
TITLE: The Effectiveness of a Community Health Nursing Outreach Program on Reducing the Effect of High-Risk Factors Associated with Child Abuse/Neglect		
Principal Investigator: Teena Edwards, RN, MS		
Associate Investigators: COL Lucille A. Smith, AN		
Department/Section: Preventive Medicine Service/Community Health Nursing		
Key Words: child abuse/neglect		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

OBJECTIVE: This study will determine the correlation between a community health nursing outreach program and the effects of high-risk factors predisposing to child abuse/neglect within a military community.

TECHNICAL APPROACH: The technical approach has been modified due to changes in staffing patterns within the program. A modification will be requested in order to continue the study using professional staff and compare to former protocol of using paraprofessional/professional staffing patterns. The protocol has remained the same.

PROGRESS: No. of Subjects Enrolled - To Date: 150 Reporting Period: 50

To date, 150 subjects enrolled/completed services in the sample. Completion of study is projected for May 1992 with analysis of data August 1992.

Detail Summary Sheet

Prot No: 17H90	Status: Ongoing
TITLE: A Psychophysiological Study of Chronic Post Traumatic Stress Disorder in Vietnam Veterans	
Principal Investigator: MAJ Charles S. Milliken, MC	
Associate Investigators:	
Department/Section: Psychiatry	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: Validate the effectiveness of psychophysiological methods in diagnosing PTSD in combat veterans.

TECHNICAL APPROACH: Vietnam theatre male combat veterans who are presenting for mental health care will be assessed by extensive proven standards, methods, and pathophysiological methods. PTSD diagnoses arrived at by standard methods will act as the control against which comparisons will be made. The pathophysiologic method involves exposure to (1) vivid audiovisual scenes and (2) individually tailored narrative descriptions while monitored by standardized polygraph equipment.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

The study is still ongoing with patients being recruited from the VA Mental Health clinic and studied at the VA.

Detail Summary Sheet

Prot No: 49H91	Status: Ongoing
TITLE: Frontal Lobe Functioning, In Borderline Personality Disorder	
Principal Investigator: CPT David B. Dameron, MS	
Associate Investigators: SGT Donna Tamura-Wageman	
Department/Section: Psychology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** The present study looks at frontal lobe functioning of patients with Borderline Personality Disorder utilizing standardized neuropsychological testing. Borderline subjects are compared to matched controls for frontal lobe neuropsychological deficits.

**TECHNICAL APPROACH:** An experimental/control group design matching 20 borderline and 20 normals is utilized in this study. Each subject is given several neuropsychological tests sensitive to frontal lobe involvement. The borderline subjects are selected from the Department of Psychiatry patients identified as meeting the DSM III-R criteria for Borderline Personality Disorder. All subjects are volunteers. The study is conducted in accordance with applicable regulations.

**PROGRESS:** No. of Subjects Enrolled - To Date: 14      Reporting Period: 14

SGT Donna Tamura-Wageman will become the new principal investigator upon PCS of CPT Dameron.

Detail Summary Sheet

Prot No: 6H90	Status: Completed
TITLE: The Effects of Biofeedback-Assisted Self Regulation Training on Pilot Performance in Emergency Flying Conditions	
Principal Investigator: Raymond A. Folen, Ph.D. Associate Investigators:	
Department/Section: Psychology Service/Health Psychology Section	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91 Gifts:                            Decision: Completed

**OBJECTIVE:** The purpose of this study is to determine the effects of biofeedback-assisted self-regulation (BASR) in a new application: pilot reactivity and performance during emergency flight situations. Specifically, the study addresses the effects of BASR on pilot performance and physiologic response to stressful emergency aircraft simulations.

**TECHNICAL APPROACH:** A pre-test/post-test control group design was used in this study. Subjects were volunteer active duty USCG HC-130 and HH-65 aircraft pilots. Subjects were randomly assigned to either the control or BASR group. Subjects in the BASR group received 12 BASR treatment sessions. Physiologic responses and pilot performance were measured during 'check rides' pre- and post- treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 17            Reporting Period: 0

The study has been completed. Analysis of the data indicates that BASR has a significant positive effect on pilot performance in emergency conditions. Findings of the study were presented at the 1991 Annual Meeting of the American Psychological Association. Additional statistical analyses are currently being run.

### Detail Summary Sheet

Prot No: 41H89	Status: Terminated
TITLE: The Effects of a Multicomponent Smoking Cessation Program	
Principal Investigator: Raymond A. Folen, Ph.D.	
Associate Investigators: LTC Federico M.V. Tamayo, MS	
Department/Section: Psychology Service	
Key Words: smoking cessation;	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Terminate

**OBJECTIVE:** To assess the effects of a weight control component in a smoking cessation program versus smoking cessation alone on recruitment of participants, attrition rates, cessation rates, and body weight changes.

**TECHNICAL APPROACH:** All individuals expressing an interest in the on-going smoking cessation program are contacted and, as a possible alternative, offered enrollment in one of the two experimental arms of the project. Subjects expressing an interest in the study are, after giving informed consent, placed in a) the six week behavioral-cognitive smoking cessation arm or b) the six week behavioral-cognitive and weight control component arm of the project. Participants not electing to participate in the study are provided with standard TAMC smoking cessation treatment. No adverse effects are to be reported, and no subjects have been withdrawn or dropped from the study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 26      Reporting Period: 0

The study is terminated due to the fact that, at this point in time, the limited success in recruitment is far below the 100 subjects required for the study. Very few of the potential subjects were willing to enroll in the study given the standard alternative treatment at TAMC which includes a pharmacologic component (Nicorette).

Detail Summary Sheet

Prot No: 44S91	Status: Ongoing
TITLE: Impact of Anger and Blame on Emotions and Conflict Tactics of Spouses in Abusive Relationships	
Principal Investigator: CPT Patti L. Johnson, MS	
Associate Investigators: Edward S. Kubany, PhD	
Department/Section: Psychology Service/Neuropsychology	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: The overall objective of the proposed study is to assess different styles of interpersonal communication for their potential to evoke anger and counterproductive conflict tactics during marital interaction. More specifically, we will attempt to assess the social impact of different kinds of negative feeling statements--assertive and aggressive statements of distress and anger. A secondary purpose will be to assess the effects of marital distress and trait anger on the impact of communicating negative feelings.

TECHNICAL APPROACH: Paper and pencil questionnaires assessing communication style and related behavioral variables are administered to subjects willing to participate in the study.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

We have not yet begun recruiting subjects. We plan to begin in Oct or Nov 1991.

Detail Summary Sheet

Prot No: 31H88	Status: Ongoing	
TITLE: Stimulant Drug Response in Attention Deficit Disordered Preschoolers		
Principal Investigator: Dr. David S. Weiss, Ph.D.		
Associate Investigators: Dr. Thomas E. Gallagher, M.D.		
Department/Section: Psychology Service		
Key Words: attention deficit disorder; Ritalin;		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** To determine the efficacy and side-effects of Ritalin (methylphenidate) and Dexedrine (dextroamphetamine) with preschool children (3-5 years of age) diagnosed as having an Attention Deficit Disorder.

**TECHNICAL APPROACH:** Children diagnosed with Attention Deficit Disorder, aged 3-5 years, will be given Ritalin, Dexedrine, and placebo in a counter-balanced, double-blind, crossover design (3 weeks in each condition). Ratings will be obtained from parents as well as direct tests of attention and impulsivity on the children, prior to entry in the study and in the last week of each condition. A side effects questionnaire will also be completed by the parents.

**PROGRESS:** No. of Subjects Enrolled - To Date: 12 Reporting Period: 10

We currently have 12 children enrolled in the study. The study was adjusted, with CI approval, so that each condition would last for only one week.

Detail Summary Sheet

Prot No: 31S91	Status: Completed
TITLE: Sibling Aggression	
Principal Investigator: CDR Elisabeth N. Wright, MC Associate Investigators: David S. Weiss, Ph.D	
Department/Section: Psychology/Child, Adolescent Psychology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Jun 91 Decision: Completed

OBJECTIVE:

a) To determine the prevalence of sibling aggression in both a general pediatric clinic population as well as in a mental health clinic population;

b) To test the hypothesis that sibling aggression will be higher in a mental health clinic population than in a general pediatric population;

c) To test the hypotheses that sibling aggressors have an increased incidence of conduct disorder diagnoses while sibling victims have an increased incidence of anxiety disorder diagnoses.

TECHNICAL APPROACH: Questionnaires were completed by children aged 9-17 years and their parents, at the Child Psychiatry and Child Psychology Clinics, as well as a control group at Pediatrics. The samples (experimental and control) were compared on their response rates.

PROGRESS: No. of Subjects Enrolled - To Date: 69      Reporting Period: 69

The study was completed, with a total of 69 subjects. Results were presented to the Department of Psychiatry in June 1991. We are planning to submit the study for publication sometime in the future.

Detail Summary Sheet

Prot No: 41H91	Status: Ongoing
TITLE: NCOG 6G-90-2: A Phase II Study of External Beam Radiation Therapy Followed by Temporary Radioactive Implant Boost With or Without Hyperthermia for Primary Glioblastoma Multiforme	
Principal Investigator: CPT Daniel Fram, MC	
Associate Investigators:	
Department/Section: Radiology/Radiation Therapy Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** Evaluate response to concurrent hydroxyurea and external beam radiation therapy followed by temporary radioactive implant boost with or without hyperthermia for primary glioblastoma.

**TECHNICAL APPROACH:** External beam radiation is delivered in the normal fashion with concurrent with oral Hydroxyurea chemotherapy administered in Hematology-Oncology. The Iodine 125 brain implant procedure ± hyperthermia is conducted at the University of California in San Francisco.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

Basically, this protocol was developed for compassionate, one-time use, for a particular patient. Request that the protocol be kept ongoing in the event that a subject fulfills the inclusion criteria.

Detail Summary Sheet

Prot No: 32H83	Status: Ongoing
TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen	
Principal Investigator: COL Peter J. Barcia, MC Associate Investigators: CPT Vik Zadoo, MC	
Department/Section: Surgery/General Surgery	
Key Words: urinary D-lactate; acute abdomen;	
Funding: FY 90:           FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

OBJECTIVE: To determine the usefulness of serum D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D-lactate and creatinine specimens collected every 12 hours from the initial evaluation until four collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, ten preoperatively to serve as controls.

PROGRESS: No. of Subjects Enrolled - To Date: 100      Reporting Period: 35

No changes to protocol. Waiting for lab tech to run samples. Approximately 100 patients run to-date.



Detail Summary Sheet

Prot No: 35H90	Status: Ongoing
TITLE: Closed Unreamed Intramedullary Nailing Versus External Fixation in Open Tibia Fractures	
Principal Investigator: CPT Richard M. Cirillo, MC	
Associate Investigators: MAJ Kevin P. Christensen, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To compare the outcome of patients with open tibia fractures treated by two different treatment regimens.

**TECHNICAL APPROACH:** Currently gathering data for accumulation with AAOS study on this subject.

**PROGRESS:** No. of Subjects Enrolled - To Date: 9 Reporting Period: 9

Of the nine patients entered in this study, six were treated with unreamed nails and three had external fixations. This study will require more time to accumulate data. Change in principal investigator to MAJ Kevin P. Christensen is requested.

Detail Summary Sheet

Prot No: 14H89	Status: Completed
TITLE: A Randomized Prospective Comparison of Operative Versus Non Operative Treatment of Third Degree Acromioclavicular Separation	
Principal Investigator: CPT Rolf R. Drinhaus, MC	
Associate Investigators: COL Michael J. Fay, MC; MAJ Kevin P. Christensen, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: acromioclavicular separation;	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

**OBJECTIVE:** To gain further insight into shoulder function after operative versus nonoperative treatment of third degree Acromioclavicular separations; specifically by comparing the strength of the two shoulders in various motions. This should provide data to help the clinician better determine in which patients open repair should be performed.

**TECHNICAL APPROACH:** Patients with third degree acromioclavicular separations who agree to participate are randomized into operative and nonoperative groups. Operative treatment consists of a Weaver-Dunn acromioplasty with the addition of coracoclavicular suturing when possible. Nonoperative treatment currently consists of a sling or shoulder immobilizer until the discomfort subsides. Patients are evaluated subjectively with a questionnaire, objectively with shoulder strength testing and radiographically. There have been no operative infections, neurovascular complications, problems with screw breakage or other adverse effects to date.

**PROGRESS:** No. of Subjects Enrolled - To Date: 20      Reporting Period: 0

There are no new patients being enrolled in this study. The data is currently being interpreted and should be ready for publication/presentation in a few months.

Detail Summary Sheet

Prot No: 3H91	Status: Ongoing
TITLE: Unreamed Intramedullary Tibial Nails for Treatment of Delayed Union of Tibial Stress Fractures	
Principal Investigator: MAJ Eugene A. Eline, MC	
Associate Investigators: MAJ Kevin P. Christensen, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To demonstrate the efficacy of unreamed intramedullary tibial nails as a treatment for nonunions of tibial stress fractures, and to demonstrate the advantages of intramedullary fixation in the treatment of tibial stress fracture nonunions.

**TECHNICAL APPROACH:** Patients with stress fractures of >1 years duration are selected for the study. They self-randomize into surgical or nonsurgical (control) treatment. Intramedullary nail fixation of the tibial fractures are then performed and followed according to the protocol guidelines.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4 Reporting Period: 4

Four subjects are enrolled; two self-randomized to nonoperative care, and two self-randomized to operative care. Four surgical procedures on four limbs (one each) have been performed. At present our early results have shown healing of the stress fractures and relief of pain. We feel that continuation of the study to enroll significant numbers of patients to gather meaningful results is necessary. No complications to report since study inception.

Detail Summary Sheet

Prot No: 5H90	Status: Ongoing
TITLE: Analysis of Multiple Risk Factors and Their Effect on Troop Readiness	
Principal Investigator: MAJ Scott A. Fengler, MC	
Associate Investigators: CPT Vik Zadoo, MC; CPT Mark Catterson, MC	
Department/Section: Surgery/General Surgery Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Jun 91
	Decision: Continue

OBJECTIVE: To evaluate the various risk factors (tobacco, alcohol, obesity, age) on troop readiness.

TECHNICAL APPROACH: Initial survey gathered for baseline data, then data was gathered for all clinic visits for approximately three months. The numbers of visits and the diagnoses are to be evaluated for possible significance of risk factors.

PROGRESS: No. of Subjects Enrolled - To Date: 1,700 Reporting Period: 0

Paper being written. With PCS of MAJ Fengler, CPT Vikram Zadoo will become the new principal investigator.

Detail Summary Sheet

Prot No: 46A89	Status: Terminated
TITLE: Use of Fibrin Glue to Achieve Hemostasis in Solid Organ Injury	
Principal Investigator: MAJ Scott A. Fengler, MC	
Associate Investigators: LTC Lawrence Runke, MC	
Department/Section: Surgery/General Surgery Service	
Key Words: fibrin glue; hemostasis;	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Jun 91
	Decision: Terminate

**OBJECTIVE:** To evaluate the efficacy and safety of the use of Fibrin glue (concentrated human fibrinogen and clotting factors) as a hemostatic agent in solid organ injury.

**TECHNICAL APPROACH:** An injury will be created of the spleen and fibrin glue will be injected intraparenchymally in an attempt to control bleeding.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

The animal model was not found suitable to investigate this area. Project will be terminated upon PCS of principal investigator.

Detail Summary Sheet

Prot No: 36H90	Status: Completed
TITLE: MRI Evaluation of Symptomatic Glenoid Labral Pathology: Comparison to Arthroscopic Findings	
Principal Investigator: CPT Michael R. Green, MC Associate Investigators:	
Department/Section: Surgery/Orthopedic	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

OBJECTIVE: To Determine the effectiveness of MRI in the diagnosis of symptomatic glenoid labral pathology.

TECHNICAL APPROACH: All patients scheduled for shoulder arthroscopy for suspected glenoid labral pathology will have a preoperative MRI. The results will be compared to arthroscopic findings in a double blind fashion.

PROGRESS: No. of Subjects Enrolled - To Date:                      Reporting Period:

Study is complete.

Detail Summary Sheet

Prot No: 50H85	Status: Terminated
TITLE: Arthroscopic Evaluation of Acute Primary Shoulder Dislocations	
Principal Investigator: CPT Michael Green, MC	
Associate Investigator: COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedics	
Key Words: shoulder dislocation; arthroscopy;	
Funding: FY 89:	FY 90:
Gifts: None	Periodic Review Date: Sep 91
	Decision: Terminate

**OBJECTIVE:** To evaluate arthroscopically the lesions associated with shoulder dislocations and correlate these lesions with prognostic indicators relative to recurrent dislocations.

**TECHNICAL APPROACH:** Patient referral requests will be sent to all outlying clinics requesting referral of all patients with initial shoulder dislocations documented by radiographs. Patients entered into the study will be admitted to TAMC Orthopedic Service and placed on the surgery schedule. Arthroscopy will be performed as soon as possible after the injury. Intra-articular pathology will be documented on operative findings data sheets and photographs of pathology will also be maintained in the data file for each patient. Postoperatively, patients will be placed in shoulder immobilizers for three weeks, followed by physical therapy with range of motion and shoulder bridle strengthening program for four weeks. Patients will then be progressed to full duty over a four-week period, and will be followed monthly in Sports Medicine Clinic for six months to one year, documenting clinical progress. Subsequent clinical progress and recurrent dislocation will be correlated with initial pathology documented by arthroscopy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 50 Reporting Period: 0

No report/response (no indication that study is continuing).

Detail Summary Sheet

Prot No: 40A87	Status: Terminated
TITLE: Emergent Initiation of Cardiopulmonary Bypass in a Swine Model	
Principal Investigator: CW3 David L. Hahn	
Associate Investigators: COL Arthur W. Larson, MC; SFC Sam Morgan	
Department/Section: Surgery/Cardiothoracic Surgery Svc	
Key Words: emergent cardiopulmonary bypass;	
Funding: FY 90: \$5,062	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Terminate

**OBJECTIVE:** To introduce and familiarize personnel with the initiation of emergent cardiopulmonary bypass (ECPB) procedure using the swine model.

**TECHNICAL APPROACH:** Identify problems associated cardiopulmonary bypass e.g., aspiration pneumonia, cardiac damage, and implement appropriate actions, i.e., stabilization, cannulation, heparinization and performance of cardiopulmonary bypass.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Because of Desert Storm, only one case was done, during April, with replacement surgeons and surgical residents. This project is terminated until required re-write & resubmittal.

Detail Summary Sheet

Prot No: 15T85	Status: Terminated
TITLE: Animal Models for Advanced Trauma-Life Support Provider and Instructor Courses	
Principal Investigator: LTC Eric A. Johnson, MC Associate Investigators: COL Donald W.S. Yim, MC;	
Department/Section: Surgery/General Surgery	
Key Words: advanced trauma life support;	
Funding: FY 90:\$4,663	FY 91:
Gifts: None	Periodic Review Date: Dec 90 Decision: Terminate

**OBJECTIVE:** To fulfill the requirement of ATLS Provider and Instructor courses, i.e., to teach physicians a standardized approach to trauma care in the early hours of trauma patient assessment and to teach life-saving skills using animal models.

**TECHNICAL APPROACH:** Goats or pigs are deeply anesthetized with sodium pentobarbital and prepared for surgery. Participants then perform cricothyroidotomy, peritoneal lavage, chest tube placement, pericardiocentesis, and venous cutdown procedures under the close supervision of certified instructors. Animals are euthanized at the end of the surgery laboratory.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

There have been no adverse effects. This study was rewritten and resubmitted; the new protocol (22T91) was initiated in Feb 91.

Detail Summary Sheet

Prot No: 22T91	Status: Ongoing
TITLE: Surgical Skill Practicum for the Advanced Trauma Life Support Course of the American College of Surgeons Utilizing Anesthetized Goats	
Principal Investigator: LTC Eric A. Johnson, MC Associate Investigators: COL Donald W.S. Yim, MC	
Department/Section: Surgery/General Surgery Service	
Key Words: Advanced Trauma Life Support	
Funding: FY 90: \$4,663	FY 91: Periodic Review Date: Sep 91
Gifts:	Decision: Continue

**OBJECTIVE:** 1) To comply with and meet the requirements of the American College of Surgeons to conduct an accredited Advanced Trauma Life Support course at TAMC, and 2) To train and/or enhance the professional trauma care skills of physicians and similar health care professionals in the initial resuscitation and care of the injured trauma victim.

**TECHNICAL APPROACH:** Goats are deeply anesthetized with sodium pentobarbital and prepared for surgery. Registered ATLS course participants then perform cricothyroidotomy, peritoneal lavage, chest tube placement, pericardiocentesis, and venous cutdown procedures under the close supervision of certified instructors. Animals are euthanized at the end of the surgery laboratory.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

**Adverse effects:** None. The course is conducted once or twice per year with sixteen participants utilizing four goats per course.

Detail Summary Sheet

Prot No: 38A89	Status: Ongoing
TITLE: "Use of Auto Suture Co. (U.S. Surgical Corp.) Surgical Stapling Instruments in the Training of Residents on Pigs"	
Principal Investigator: MAJ Gregory J. Kechejian, MC Associate Investigators: General Surgery Residents	
Department/Section: General Surgery/Vascular Surgery Service	
Key Words: Stapling	
Funding: FY 90: \$6,597	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To teach proper general surgical principles and exposure including suturing, stapling and retraction techniques to General Surgical residents. Materials to be used include the AUTO Suture Co. TA, GIA, EEA instrumentation on the intestines and stomach. End to end, side to side colon and small intestinal anastomoses will be performed using all instruments and suture materials at the discretion of the instructor. Anastomoses between portions of the small intestine and from small intestine to stomach and colon will be done. Anastomoses between the colon and rectum will be done. Resection of major abdominal organs, including, but not exclusive of the liver, spleen and kidneys will be performed. Vascular procedures including native and synthetic by-passes will be performed.

**TECHNICAL APPROACH:** Using an abdominal approach, portions of large bowel, small bowel and stomach and other abdominal viscera will be mobilized, enabling the surgeon to perform procedures indicated above. Closure of the animal will include fascia staples and skin staples.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A      Reporting Period: N/A

This is the third consecutive year this project has been on-going with excellent DIC and resident support. Well over 50 General Surgery residents have been trained with definite patient benefits seen in the operations at Tripler. Approximately 56 resident sessions have been held to date. This is a low cost/high yield clinical on-going training project with clear surgical resident and human patient benefits.

Detail Summary Sheet

Prot No: 42A89

Status: Terminated

TITLE: Experimental Techniques of Liver Surgery

Principal Investigator: CPT Thomas Knuth, MC

Associate Investigators: LTC Lawrence C. Runke, MC

Department/Section: Surgery/General Surgery Service

Key Words: Liver surgery; re-anastomose;

Funding: FY 90: \$5,081

FY 91:

Periodic Review Date: Jun 91

Gifts:

Decision: Terminate

OBJECTIVE: (1) To resect a portion of the liver and re-anastomose that portion in its same location or in another location and/or resect and re-implant the entire liver. (2) To maintain systemic and portal venous blood circulation via temporary catheterization while the liver is removed from the animal's circulation. (3) To re-implant the liver back into the animal resulting in a fully recovered live animal upon completion of the procedure. (4) To assess the liver damage in the post operation period by serial chemical analysis.

TECHNICAL APPROACH: We will develop techniques to rapidly mobilize and remove the entire liver from a pig. We will then establish vena caval and portal blood flow to the heart while the liver is out of the body cavity. Techniques will be developed to rapidly resect and/or repair damaged liver tissue and then reimplant the liver into the animal. Techniques will be used and developed to maintain the viability of the liver while out of the body cavity including, but not limited to, liver hypothermia and perfusion of the liver with nutrient solutions.

PROGRESS: Due to PCS of principal investigator, this project will be terminated. No associate investigators are available to continue the project. Project has been inactive for almost the last year.

Detail Summary Sheet

Prot No: 10H91	Status: Ongoing
TITLE: Normal Rate of Change for Serum Prostate-Specific Antigen (PSA)	
Principal Investigator: MAJ Jeffery D. Kroll, MC	
Associate Investigators: COL Martin L. Dresner, MC; CPT Allen F. Morey, MC	
Department/Section: Surgery/Urology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To determine what the change with time is for serial serum PSA Levels in men with no evidence of carcinoma of the prostate on prostate biopsy.

**TECHNICAL APPROACH:** Men who have undergone transurethral biopsy of the prostate without evidence of prostate cancer will be followed with serial serum PSA's every six months. The monthly rate of change of the serum PSA will be calculated.

**PROGRESS:** No. of Subjects Enrolled - To Date: 26      Reporting Period: 26

No progress to report.



Detail Summary Sheet

Prot No: 29H91	Status: Ongoing
TITLE: Carpal Tunnel Release With and Without Release of the Fascia of the Forearm: A Prospective Randomized Study	
Principal Investigator: COL William H. Milnor, Jr., MC	
Associate Investigators: LTC Elizabeth D.C. Quinlan, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: Does surgical release of the investing fascia of the distal one-third of the forearm (antebrachial), in conjunction with release of the transverse carpal ligament, improve the results of treatment of (chronic) carpal tunnel syndrome?

TECHNICAL APPROACH: Double-blind, two groups.

PROGRESS: No. of Subjects Enrolled - To Date: 10      Reporting Period: 10  
No progress to report.

Detail Summary Sheet

Prot No: 2H91	Status: Ongoing
TITLE: Rigid, Locked, Reamed Intramedullary Nailing of Fractures of the Humeral Shaft	
Principal Investigator: CPT R. Keith Moore, MC	
Associate Investigators: MAJ Kevin P. Christensen, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To evaluate the efficacy of intramedullary nailing of fractures of the humeral shaft for which operative treatment is indicated.

**TECHNICAL APPROACH:** Patients sustaining humeral fractures and needing operative intervention will be followed until clinical and radiographic union. Data will be compared to other treatment modalities in our attempts to evaluate efficacy of intramedullary nailing. There will be no randomization.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Only one patient has been included in this study from TAMC. Data from other Medical Centers have been retrospectively reviewed for comparison.

Detail Summary Sheet

Prot No: 21H90	Status: Completed
TITLE: DNA Ploidy of Hypoechoic Prostate Carcinomas: Correlation of Transrectal Ultrasonography and Flow Cytometry	
Principal Investigator: CPT Allen F. Morey, MC Associate Investigators:	
Department/Section: Surgery/Urology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

**OBJECTIVE:** 1) To determine if hypoechoic prostate carcinomas differ in DNA ploidy from tumors having hyperechoic, isoechoic, or mixed sonographic patterns.  
2) To correlate DNA ploidy with size, and Gleason tumor grading scores of prostate carcinomas  
3) To determine if prostate cancers detected on transrectal ultrasound (TRUS) correlate with the presence of a palpable nodule.

**TECHNICAL APPROACH:** Single extra ultrasound-directed biopsy cores will be obtained from areas of hypoechoic, mixed, and/or hyperechoic appearance; size of lesion and presence of capsular distortion will be noted. If no visible abnormalities are noted, a minimum of one extra biopsy will be obtained from each side of the isoechoic gland, thus comprising a control group.

The presence or absence of a palpable nodule will be noted with each specimen. The result will be a total of two extra samples per patient.

**PROGRESS:** No. of Subjects Enrolled - To Date: 50      Reporting Period: 0  
Fifty men have been enrolled in this study (6 of these 50 have cancer).



Detail Summary Sheet

Prot No: 14185	Status: Terminated
TITLE: Microvascular Lab-Psychomotor Skills	
Principal Investigator: LTC Elizabeth C. Quinlan, MC	
Associate Investigators: CPT James R. Ficke, MC; CPT Gregg A. Malmquist, MC; CPT Randolph E. Peterson, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: training; psychomotor skills;	
Funding: FY 90: \$4,596	FY 91:
Gifts: None	Periodic Review Date: Dec 90 Decision: Terminated

**OBJECTIVE:** To train residents in the repair of arteries and veins approximately 1 mm in diameter.

**TECHNICAL APPROACH:** Rats are anesthetized with sodium pentobarbital and one femoral artery and/or vein is transected and then reanastomosed. The wound is observed daily for any complications.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Due to personnel deployments to the Persian Gulf, no training has been conducted since Oct 90. Study is terminated pending re-write and resubmittal. We intend to start again after resubmitted protocol is approved; at that time COL William Milnor will be the principal investigator.

Detail Summary Sheet

Prot No: 15A87	Status: Terminated
TITLE: Menisci Energy-Absorbing Characteristics of Pig Hind Knee with Both Satic and Dynamic Loads	
Principal Investigator: CPT Kenneth Reesor, MC	
Associate Investigators: COL Kent Reinker, MC; MAJ John Uribe, MC Wayne Ichimura, Biomedical Engineer	
Department/Section: Surgery/Orthopedic Service	
Key Words: meniscal injuries;	
Funding: FY 89: \$4,212	FY 90:
Gifts: None	Periodic Review Date: Dec 90 Decision: Terminate

**OBJECTIVE:** To establish the energy-absorbing characteristics of the pig knee and to determine if these characteristics are dependent on the percentage of meniscal intact.

**TECHNICAL APPROACH:** Instrumentation to apply impact loading to isolated pig knees (slaughterhouse donation) will be developed and measurements made of 1) transmitted pressures 2) compression displacements and 3) circumferential elongation or expansion of exercise.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Project terminated pending rewrite and resubmittal.

Detail Summary Sheet

Prot No: 20H90 Status: Ongoing  
TITLE: Radiologic Evaluation of Cervical Spine Trauma; A Selective Approach  
Principal Investigator: CPT Bradley Roth, MC  
Associate Investigators:  
Department/Section: Surgery/General Surgery Service  
Key Words:  
Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

**OBJECTIVE:** To answer the following questions: (1) Can a selective approach to obtaining cervical spine radiographs be utilized for trauma patients without overlooking significant cervical spine injuries? (2) Can oblique radiographs of the cervical spine be eliminated from a "standard trauma cervical spine x-ray series" without sacrificing diagnostic accuracy?

**TECHNICAL APPROACH:** All patients that are seen in TAMC's ER for a decelerating type injury or trauma to the neck will be entered into the study. All patients will have a documented physical exam and five view cervical spine radiograph evaluation completed. If no injury was noted on their initial evaluation, they will be seen in thirty days to be evaluated for possible occult cervical injury.

**PROGRESS:** No. of Subjects Enrolled - To Date: 350    Reporting Period: 333

Study presently ongoing with good results.

Detail Summary Sheet

Prot No: 26A91	Status: Completed
TITLE: Endoloop Repair of Electrocautery Injury to Large and Small Bowel in the Pig Model	
Principal Investigator: CPT Bradley J. Roth, MC	
Associate Investigators: COL Peter J. Barcia, MC; MAJ Milo L Hibbert, MC; MAJ David P Halbach, MC	
Department/Section: Surgery/General Surgery Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

**OBJECTIVE:** To determine if an easy, reliable method to repair incidental electrocautery injuries of the large and small bowel can be performed with laparoscopic endoloops.

**TECHNICAL APPROACH:** Operation of two groups of pigs will occur. Group one will have an enterotomy made with electrocautery, then repair with an endoloop. The second group will not have the repair performed. The pigs will be allowed to recover and their postop courses will be compared. At the end of ten days, the pigs will be euthanized and compared.

**PROGRESS:** No. of Subjects Enrolled - To Date: 16      Reporting Period: 16

Study completed - results demonstrate that an endoloop does not cause bowel obstruction. Also, results demonstrate that the pig model is not adequate to study potential lethal injuries to the bowel in this type of experiment.

Study results were presented at the Gary Wratten Surgical Symposium in San Francisco, and will be presented at the Surgical Symposium in Korea.

Detail Summary Sheet

Prot No: 28H89	Status: Ongoing	
TITLE: Clinical Evaluation of a Percutaneous Pneumothorax Catheter Vs. Standard Tube Thoracostomy for the Treatment of Pneumothorax		
Principal Investigator: CPT Bradley J. Roth, MC Associate Investigators: LTC Greg A. Bowman, MC		
Department/Section: Surgery/Cardiothoracic Surgery Svc		
Key Words: pneumothorax catheter		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** Pneumothorax is a common disease that has routinely been treated with a tube thoracostomy. Recently many studies have shown that this disease may be treated with a much smaller pneumothorax catheter. This study will compare the two types of treatment for non-complicated pneumothorax in an attempt to support the hypothesis that the use of the pneumothorax catheter is less effective than tube thoracostomy.

**TECHNICAL APPROACH:** A chest tube on pneumothorax catheter is placed into the chest for the treatment of pneumothorax. The patient remains in the Protocol for 3 days. If the pneumothorax has not resolved than other treatment modalities are used.

**PROGRESS:** No. of Subjects Enrolled - To Date: 30 Reporting Period: 13

Thirty patients are enrolled to-date; study progressing well. Presently, data to be re-evaluated to compare results.

Detail Summary Sheet

Prot No: 14A90	Status: Terminated
TITLE: New Zealand White Rabbits as a Model for Induced Bipolaris Sinusitis	
Principal Investigator: CPT Christopher K. Sinha, MC	
Associate Investigators: MAJ L. Zieske, MC; CPT M. Sheridan, MC; MAJ R. Kopke, MC	
Department/Section: Department of Surgery/Otolaryngology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Terminate

**OBJECTIVE:** 1) To determine if the sinuses of the New Zealand White Rabbit will develop a fungal sinusitis with a Bipolaris species. 2) To determine the quantity of inoculant per area of sinus mucosa required for induction of fungal sinusitis.

**TECHNICAL APPROACH:** Animals will be separated into four groups. Group #1 will consist of control rabbits that receive no inoculant of Bipolaris hawaiiensis. This group, however, does undergo sham operation. Group # 2, #3, and #4 receive 0.5, 1.0, and 3.0 McFarland units of inoculant respectively. Control animals will be housed in a separate room. Immediately post inoculation, sinus x-rays are obtained for baseline study. On a weekly basis, sinus x-rays are obtained.

**PROGRESS:** No. of Subjects Enrolled - To Date: N/A Reporting Period: N/A

No progress to report; project is terminated.



Detail Summary Sheet

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Prot No: 45A89 Status: Terminated

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TITLE: Nonanatomic vs Anatomic Liver Resection in Pigs

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Principal Investigator: CPT Martin Tieva, MC  
Associate Investigators: COL Peter Barcia, MC

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Department/Section: Surgery/General Surgery Service

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Key Words: non-anatomic liver resection

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Funding: FY 90: NA FY 91: NA Periodic Review Date: Sep 91  
Gifts: Decision: Terminate

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OBJECTIVE: To demonstrate the speed, efficacy and safety of non-anatomic liver resection.

TECHNICAL APPROACH: Four pigs will have an anatomic resection and 4 pigs will have a non-anatomic resection. The outcome of the two groups will be compared as well as operative time and blood loss. At the end of the experiment, the animals will be euthanized and a cast made of their vasculature.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This protocol has been terminated without completion due to no time left to do research. Five non-anatomic liver resections were accomplished and only one anatomic liver resection was accomplished. The times and blood loss were similar. Because of the small numbers, no conclusion can be reached. There is no more time to finish this project.

Detail Summary Sheet

Prot No: 26H90	Status: Ongoing
TITLE: Laparoscopic Appendectomy	
Principal Investigator: CPT Frederick T. Work, Jr, MC	
Associate Investigators: COL Peter J. Barcia, MC, LTC Milo L. Hibbert, MC	
Department/Section: Surgery/General Surgery	
Key Words: laparoscopic appendectomy	
Funding: FY 90: FY 91: \$108,000	Periodic Review Date: Sep 91
Gifts: MRDC grant	Decision: Continue

**OBJECTIVE:** To determine if laparoscopy is a tool which, in skilled hands, may be quickly, safely and effectively used to expedite early diagnosis of appendicitis and its surgical treatment.

**TECHNICAL APPROACH:** Patients over the age of 18 with abdominal pain suspected of having appendicitis will be offered laparoscopic appendectomy with the exception of those who have undergone previous abdominal surgeries in the lower quadrants. Procedures will be performed under general anesthesia using a standard technique for introduction of the instrument into the peritoneal cavity. All non-participants in the study will be used as the control group in this prospective study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 33      Reporting Period: 33

In March 91 the project was temporarily halted due to an increase in infectious complications. A review of these complications was performed which revealed a multifactoral etiology. Modifications in technique and strict guidelines for adherence to the protocol were instituted and the project was restarted. Since then, five laparoscopic appendectomies have been successfully performed without any complications.

**Presentations:** Gary Wratten Surg Symp; ACS (Hawaii Chapter); William Beaumont GI Symp; South Med Assoc; Univ of Minn; 38th Parallel Surgical Conf (Korea)

Detail Summary Sheet

Prot No: 15H91	Status: Terminated
TITLE: Base Sagittal V-Z Wedge Osteotomy for Metatarsus Primus Varus	
Principal Investigator: MAJ Barney Yanklowitz, MS	
Associate Investigators: COL William Milnor, MC	
Department/Section: Surgery/Orthopedic Service;Podiatry Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Aug 91
	Decision: Terminate

**OBJECTIVE:** To study the utility of the base sagittal V-Z wedge osteotomy (screw fixation) for the surgical treatment of metatarsus primus varus (adductus).

**TECHNICAL APPROACH:** A prospective clinical investigation including 36 patients ages 10-60 with a radiographically demonstrable intermetatarsal angle greater than 14 degrees in a rectus foot and greater than 12 degrees in an adductus foot will be conducted.

**PROGRESS:** No. of Subjects Enrolled - To Date:                      Reporting Period:

This project was terminated due to PCS of MAJ Yanklowitz.

Detail Summary Sheet

Prot No: 28H88	Status: Terminated
TITLE: Treatment Assessment of Multiple Plantar Warts with Acyclovir	
Principal Investigator: MAJ Barney A. Yanklowitz, MS; Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: plantar warts; acyclovir;	
Funding: FY 90:      FY 91:	Periodic Review Date: Aug 91
Gifts: None	Decision: Terminate

**OBJECTIVE:** To discover whether or not an occlusive foot dressing improves the reported results (25%, 38%, 39%) of topical 5% Acyclovir for the treatment of multiple plantar warts after 8 and then 12 weeks.

**TECHNICAL APPROACH:** A clinical investigation including 68 patients ages 2 to 70 (unless pregnant or nursing mother) with a clinical diagnosis of multiple plantar warts (6 or more) or a large surface area (greater than 2.54 cm. diameter) mosaic plantar warts will be treated.

**PROGRESS:** No. of Subjects Enrolled - To Date: 14      Reporting Period: 0

This project was terminated due to the PCS of MAJ Yanklowitz.

Detail Summary Sheet

Prot No: 37H88	Status: Terminated
TITLE: Sonography of Morton's Neuromas	
Principal Investigator: MAJ Barney A. Yanklowitz, MS	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: Morton's neuromas;	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Aug 91
	Decision: Terminate

**OBJECTIVE:** To evaluate the size of the third webspace plantar nerve on sonography as a positive predictive indicator of biopsy confirmed Morton's neuromas.

**TECHNICAL APPROACH:** Aggressive conservative therapy for Morton's neuroma includes: examination of duty and recreational footwear; limitation or cessation of hyperextension (of MTPJ) causing activities for six weeks; the use of pedal orthoses (insoles, metatarsal pads) for six weeks; NSAID for 12 weeks; plantar intermetatarsal nerve blocks (local anesthetic and corticosteroid). After failure of aggressive conservative therapy or in the presence of a palpable mass, elective sonography of the affected webspace will be requested by a member of the Orthopedic Service. This routine sonography will be scheduled by appointment and completed by personnel assigned to the Ultrasound Section, Department of Radiology. The resultant hard copy images will be used by the attending Orthopedic staff for operative planning and patient education. Photographs of sonographs and neuromas (in situ or biopsied specimens) will be completed for no more than 48 patients. Neuromas will be confirmed by standard biopsy techniques.

**PROGRESS:** No. of Subjects Enrolled - To Date: 12 Reporting Period: 0

This project was terminated due to the PCS of MAJ Yanklowitz.

Detail Summary Sheet

Prot No: 22A89

Status: Ongoing

TITLE: Altered Consciousness Induced by Overdrainage of Cerebrospinal Fluid

Principal Investigator: COL Donald W. S. Yim, MC

Associate Investigators: COL Bernard Robinson, MC, USAR;

John R. Claybaugh, Ph.D.; MAJ Jon Graham, MC;

MAJ Kevin Foley, MC; MAJ James R. Doty, MC

Dr. Robert Jones, MD (Kaiser Medical Center)

Department/Section: Surgery/Otolaryngology Service

Key Words: cerebrospinal fluid;

Funding: FY 90:

FY 91:

Periodic Review Date: Sep 91

Gifts: None

Decision: Continue

OBJECTIVE: To characterize altered consciousness induced by overdrainage of cerebrospinal fluid.

TECHNICAL APPROACH: To create an animal model in which coma can be induced by overdrainage of cerebrospinal fluid. Additionally, we hope to be able to demonstrate complete reversal of coma by replacing the volume of CSF removed. Various parameters of vital functions are to be monitored during the investigation. These include evoked responses (auditory, somatosensory, brainstem), blood pressure, electrocardiogram, and pulse rate. Intracranial pressure will also be measured. Cerebral blood flow monitoring is ultimately desired but will not be pursued until a suitable experimental model is confirmed. We hope to characterize any changes in these parameters induced by the test maneuver (CSF Drainage). The test animal will require a craniectomy and insertion of a reservoir to be used for the actual access to the intrathecal compartment chosen for removal of CSF.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

No animals have been done in the past year due to lack of available time.

Detail Summary Sheet

Prot No: 24A90	Status: Terminated
TITLE: D-Lactate as a Serum Marker for Intestinal Ischemia in a Rat Model	
Principal Investigator: CPT Vik Zadoo, MC	
Associate Investigators: CPT David Watts, MC; COL Peter Barcia, MC CPT Carol Eisenhauer, VC	
Department/Section: Department of Surgery/General Surgery Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Feb 91 Decision: Terminate

OBJECTIVE: To identify a serum marker of intestinal ischemia before the onset of frank infarction.

TECHNICAL APPROACH: Two groups of rats will be used in the study. Group 1, the control group will be subjected to sham laparotomy, handling of the bowel and closure of the abdomen. Group 2 rats will all undergo laparotomy with ligation of the superior mesenteric artery at its origin. The experiment will also include an additional 8 rats for a pilot study to investigate the potential problems in experimental procedures (ie, timing, difficulty in obtaining blood, and response of d-lactate).

PROGRESS: No. of Subjects Enrolled - To Date: N/A      Reporting Period: N/A

Protocol was terminated in Mar 91 (reference 32P91).



Detail Summary Sheet

Prot No: 32P91	Status: Completed
TITLE: Modification of the D-Lactate Ischemia Bowel Model	
Principal Investigator: CPT Vik Zadoo, MC	
Associate Investigators: CPT Bradley Roth, MC; COL Peter J. Barcia, MC; CPT Steve Adams, MC	
Department/Section: Surgery/General Surgery	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Mar 91
Gifts:	Decision: Completed

OBJECTIVE: To identify a serum marker of intestinal ischemia.

TECHNICAL APPROACH: Ligation of ileocolic artery with measurement of D-lactate after 48 hours.

PROGRESS: No. of Subjects Enrolled - To Date: N/A          Reporting Period: N/A

- (1) 100 rats run.
- (2) 40 rats run with refined technique
- (3) Results:
  - D-lactate (48 hr)
  - Control -  $.01 \pm .01$
  - Ischemic -  $.046 \pm .04$
  - Need to determine p-values
- (4) Will attempt to document d-lactate in 24-hour groups

[Reference 34A91]

Detail Summary Sheet

Prot No: 33H90	Status: Ongoing	
TITLE: D-lactate as a Serum Marker for Intestinal Ischemia in a Human Model		
Principal Investigator: CPT Vik Zadoo, MC		
Associate Investigators: COL Peter Barcia, MC; COL Robert Hill, MC		
Department/Section: Surgery/General Surgery		
Key Words: D-lactate; intestinal ischemia		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** To identify a serum marker of intestinal ischemia before the onset of frank infarction.

**TECHNICAL APPROACH:** Patients admitted to the TAMC General Surgery Service for an acute surgical abdomen will be enrolled in this study. They will have a serum and urine D-lactate level performed. Other data (e.g. admitting diagnosis, white blood cell count, blood pressure upon admission) will be correlated with the admitting d-lactate level.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Project on hold until technician can be hired to support this study.

Detail Summary Sheet

Prot No: 34A91	Status: Ongoing
TITLE: D-Lactate as a Serum Marker for Intestinal Ischemia in a Rat Model	
Principal Investigator: CPT Vik Zadoo, MC	
Associate Investigators: CPT Bradley Roth, MC	
Department/Section: Surgery/General Surgery	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: To identify a serum and/or urine marker of intestinal ischemia.

TECHNICAL APPROACH: Ligation of ileocolic order to measurement of D-lactate after 48 hours.

PROGRESS: No. of Subjects Enrolled - To Date: N/A      Reporting Period: N/A

- (1) 100 rats run
- (2) 40 rats run with refined technique
- (3) Results:
  - D-lactate (48 hr)
  - Control -  $.01 \pm .01$
  - Ischemic -  $.046 \pm .04$
  - Need to determine p-values
- (4) Will attempt to document d-lactate in 24-hour groups

[Reference 32P91]

Detail Summary Sheet

Prot No: 7H88	Status: Ongoing
TITLE: Urine Detectability in Patients and Physicians of Intranasal 4% Topical Cocaine During Clinical Utilization	
Principal Investigator: MAJ Larry A. Zieske, MC	
Associate Investigators: LTC Charles V. Watson, MS; CPT Eileen M. Mahoney, MC; MAJ Mark F. Sheridan, MC; CPT Christopher Sinha, MC; CPT Philip Wiley, MC; CPT Sharon M. Tomaski, MC; CPT Christopher Himmelheber, MC	
Department/Section: Surgery/Otolaryngology Service	
Key Words: topical cocaine;	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine the detectability of intranasally applied 4% topical cocaine in patients and physicians, applying this in their routine clinical practice. A dose versus time post-exposure graph is to be sought. To determine the protectability of surgical gloves to the applying physician. To determine cutaneous absorption of cocaine by urine drug screening.

**TECHNICAL APPROACH:** To obtain base lines on each physician and patient. To sample patients urine post controlled and documented exposure to cocaine by ENT physicians. The sampling will be: First 6-8 hours post-op and then on a daily basis for 3 days (beyond the normally expected point of negative detection) after any cocaine exposure. Quantification of urine metabolite level will be done as much as possible. Physician samples will also be obtained after use of cocaine with and without latex glove use to check for glove protection and cutaneous absorption. Approximately 24 exposures will be monitored (24 patient and 24 surgeons). The analysis will be by IRA and mass spectrometry. Documenting of all medications will be done (over the counter and prescribed). Chain of custody will be maintained.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No subjects have been enrolled in the past year. Project has not been conducted due to lack of available time.

Detail Summary Sheet

Prot No: POG 8158(83)	Status: Ongoing	
TITLE: NWTS Long Term Follow-up Study		
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:		
Department/Section: Pediatrics/Hematology-Oncology Section		
Key Words: Wilms' tumor;		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** To examine the late consequences of successful treatment given for Wilms' tumor.

**TECHNICAL APPROACH:** Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor will be eligible. Treatment will be as outlined in the study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been entered into this protocol as yet. This is a non therapeutic study designed to gather epidemiologic and late effects data on long term (>5yrs) survivors of Wilms' tumor. No Tripler patients have been registered to date. Nationally 1037 patient registrants have been accrued. No detailed results are available yet and the study remains open.

Publications: Abstract-AACR 27:204, 1986  
J Natl Cancer Inst 80:592-595, 1988  
Cancer 1990 (accepted)

Detail Summary Sheet

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Prot No: POG 8398(91) Status: Completed

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TITLE: Up-Front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Childhood

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Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators: MAJ Shirley E. Reddoch, MC

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Department/Section: Pediatrics/Hematology-Oncology Section

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Mar 91  
Gifts:    Decision: Completed

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OBJECTIVE: 1) To determine the toxicity and complications, short and long term, of alternating intensive chemotherapy pairs in children with acute lymphocytic leukemia of poor prognosis. Intensive chemotherapy pairs are:  
6-MP/MTX  
VM-26/Ara-C  
Daunomycin/Ara-C  
2) To obtain very preliminary data about disease-free survival and sites of relapse (if any); 3) Feasibility of using this as one of three arms in POG's ALinC #14 front-line study; 4) To assess the feasibility and toxicity of this regimen in infants (<12 months of age).

TECHNICAL APPROACH: Groupwise treatment of newly diagnosed Acute Lymphocytic Leukemia (ALL), non-T, non-B cell type or B-cell ALL with L<sub>1</sub> or L<sub>2</sub> morphology, who are <365 days of age.

PROGRESS: No. of Subjects Enrolled - To Date: 0                      Reporting Period: 0

Study is closed to new patient registrations.

Publication: Abstract - ASCO 7:179, 1988

Detail Summary Sheet

Prot No: POG 8451(86)	Status: Completed
TITLE: Intergroup Rhabdomyosarcoma - Study III	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology Section	
Key Words: rhabdomyosarcoma;	
Funding: FY 90:                      FY 91:	Periodic Review Date: Sep 91
Gifts: Drugs	Decision: Completed

**OBJECTIVE:** This protocol is the new Intergroup Rhabdomyosarcoma III study designed to provide definitive care to all new cases of rhabdomyosarcoma less than 21 years of age.

**TECHNICAL APPROACH:** Multiagent chemotherapy and radiotherapy tailored to: site of disease, histologic subtype and stage of disease. Results will be compared to IRS I & II (historical controls).

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Six years into the study there have been 1,122 patients registered and 1006 are evaluable. A total of 280 patients have completed therapy. There have been deaths (126 tumor related, 8 toxicity related and 25 related to infections). The Pediatric Oncology Group statistical office is now analyzing the data.

Abstracts: ASCO 1989, 1990, 1991

Detail Summary Sheet

Prot No: POG 8600/01/02(86) Status: Completed  
TITLE: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALinC 14C)  
Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators:  
Department/Section: Pediatrics/Hematology-Oncology Section  
Key Words: Leukemia;  
Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Completed

**OBJECTIVE:** To thoroughly classify by laboratory methods the type of leukemia in children newly diagnosed with ALL, to see if better characterization of newly diagnosed leukemia can better define different prognostic groups. To provide comprehensive care of children newly diagnosed with ALL.

**TECHNICAL APPROACH:** Multiagent chemotherapy of ALL. Results of therapy will be compared to previous POG protocols for therapy of ALL which serve as historical controls. Data will be used to construct new treatment regimens based on prognostic groups and previous therapeutic studies.

**PROGRESS:** No. of Subjects Enrolled - To Date: 7 Reporting Period: 0

Seven TAMC Pediatric patients enrolled at this time. Fourteen hundred fifty patients have been entered into the treatment portion of the study (8602) nationally. It appears that chromosome Ploidy, is an important prognostic factor. Event free survival for all patients at 18 months follow-up is about 80%.

Publication: Blood 75: 1170-1177, 1990  
Blood 76: 117-122, 1990  
Blood 76: 489-494, 1990  
Cancer 66: 1183-1189, 1990  
J Clin Oncol 8: 1389-1398, 1990

POG 8600 has enrolled 2,065 patients nationally the following factors have been found to be prognostic: (1) Within non-T, non-B: White count, age, ploidy, MYIO. (2) Within T: No significant factors. (3) Pre-B is not a significant factor at this time. 8602 Summary: Total accrual at time of completion 1951. (1) Overall remission induction rate is 97%. (2) Pre-B has not been a significant adverse prognostic factor, no significant difference in event free survival between Arm D and the other arms. (3) CNS relapses are rare; no isolated testicular relapses have yet occurred and marrow relapses are low. (4) Three year event free survival is 80%. (5) Duke MYIO and St. Jude Ploidy are significant prognostic factors for early event free survival. (6) Toxicity concerns have been infections, allergic reactions, transaminase elevations and hematologic suppression. The Pediatric Oncology Group Stat Office is conducting ongoing analysis.

Detail Summary Sheet

Prot No: POG 8615(90)	Status: Ongoing
TITLE: A Phase III Study of Large Cell Lymphomas in Children and Adolescents--A Comparison of Two Treatment Regimens--ACOP+ Versus APO	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:                      FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Continue

OBJECTIVE: (1) To determine the influence of cytoxan therapy in advanced stage large cell lymphomas in children and adolescents, by comparing in a randomized prospective study the efficacy and toxicity of a modified ACOP+ versus a modified APO regimen.

(2) To reduce the adverse effects of treatments by eliminating involved field and cranial radiotherapy.

(3) To evaluate the adequacy of one year of total therapy.

TECHNICAL APPROACH:

A (adriamycin) 75 mg/m <sup>2</sup>	vs.	A (adria) 75 mg/M <sup>2</sup>
C (cytoxan) 800 mg/M <sup>2</sup>		P (prednisone) 40 mg/M <sup>2</sup>
O (vincristine) 1.5 mg/M <sup>2</sup>		O (vincristine) 1.5mg/M <sup>2</sup>
P (prednisone) 40 mg/M <sup>2</sup>		

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients are enrolled to date. POG Stat Office providing ongoing statistical analysis.



Detail Summary Sheet

Prot No: POG 8625/26(90)	Status: Ongoing
TITLE: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA, Hodgkin's Disease in Pediatric Patients	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: Hodgkin's disease	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** (1) To compare the effectiveness of 3 cycles of MOPP/ABVD vs 2 cycles of MOPP/ABVD plus low-dose radiation therapy in terms of duration of remission and eventual survival in children with early stage Hodgkin's disease; (2) To compare the incidence and severity of acute/long-term toxicity of MOPP/ABVD vs MOPP/ABVD plus involved field, low-dose radiation therapy; (3) To evaluate the incidence of CR after 2 cycles of MOPP/ABVD; (4) To search for prognostic factors that may correlate with duration of survival; (5) To determine the salvage rate of patients who fail to respond to 2 cycles of MOPP/ABVD or who fail to achieve a CR after completion of prescribed therapy.

**TECHNICAL APPROACH:** Pediatric patients under the age of 21 with new diagnoses of early stages of Hodgkin's disease will be eligible. Treatment will be as outlined in the study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients registered to date. There are 163 patients registered nationally. POG Stat Office is providing ongoing analysis.

Detail Summary Sheet

Prot No: POG 8631(87)	Status: Completed
TITLE: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs. Standard Dose Irradiation	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: medulloblastoma; radiation;	
Funding: FY 90:            FY 91:	Periodic Review Date: Jan 91
Gifts: None	Decision: Completed

**OBJECTIVE:** To see if reduced irradiation to the spinal contents and supratentorial area of the brain can achieve an equal rate of disease-free survival and a lesser degree of psychomotor retardation as compared to standard dose irradiation.

**TECHNICAL APPROACH:** All registered children will be randomized into one of two treatment arms (a) Arm 1--3600 rads to whole brain and spinal contents plus an additional 1800 rads to posterior fossa, and (b) Arm 2--2340 rads to whole brain and spinal contents plus an additional 3060 rads to posterior fossa.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No Tripler patients have been enrolled in this study. Nationally a total of 59 patients have been registered. Toxicity has been mild. Too early in the study to determine statistical differences. Of note there is a 17% ineligible rate due to poor compliance. The Pediatric Oncology Group Stat office is evaluating the data from this study.

Detail Summary Sheet

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Prot No: POG 8633/34(89) Status: Completed

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TITLE: The Treatment of Children Less Than Three Years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation

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Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators:

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Department/Section: Pediatrics/Hematology-Oncology Service

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Key Words: postoperative chemotherapy;

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Apr 91  
Gifts: None    Decision: Completed

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**OBJECTIVE:** To determine if the use of postoperative chemotherapy in children less than 36 months of age with malignant brain tumors will allow for the delay of cranial irradiation for 12 months in children 2-3 years at diagnosis and 24 months for those less than two years old. To estimate the response (CR or PR) to two cycles of cyclophosphamide and vincristine in children with measurable tumor at the initiation of chemotherapy. To estimate the objective response rate (CR, PR, SD) and disease control interval with this multi-agent chemotherapy regimens. To estimate the disease control interval, recurrent-free survival, and survival for children following chemotherapy and radiation therapy in each disease category. To establish the acute and chronic toxicities of this approach, including neurological, neuro-psychological, endocrine, and somatic effects.

**TECHNICAL APPROACH:** Children will be randomized to one of two treatment programs based on age at diagnosis. Chemotherapy will consist of vincristine (.065 mg/kg) and cytoxan (65 mg/kg) alternated with cisplatinum (4 mg/kg) and VP-16 (6.5 mg/kg) as per the attached treatment schema. Upon completion of chemotherapy, children with a complete response will receive radiotherapy. Children with stable disease or a partial response may have a second surgical procedure followed by radiotherapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1                      Reporting Period: 0

One TAMC patient enrolled during this evaluation period demonstrated persistent disease following treatment on 8633. He has just completed radiation therapy per POG 8634. POG November 1989 report indicates 206 patients enrolled as of November 1988; 137 in 0-23 month age group, 69 in 24-36 month age group. Seventy five patients went off study for progressive disease but only 42 were registered on 8634. Overall survival at 2 years are essentially the same for each age group. See attached survival figures to include evaluation by histologic types. It is too early for analysis of response on 8634. The Pediatric Oncology Group is providing ongoing analysis.

Publication: Brain Dev 11:36-367, 1989

Detail Summary Sheet

Prot No: POG 8650(89)	Status: Ongoing
TITLE: National Wilms' Tumor Study 4	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: Wilms' tumor;	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To compare the relapse-free and overall survival rates of  
1) stages I and II FH patients and stage I anaplastic patients treated with conventional CT vs pulse-intensive CT with vincristine and actinomycin D; 2) patients with stage III and IV FH Wilms' and stage I-IV CCSK who are treated with conventional CT vs pulse-intensive CT with vincristine, actinomycin D, and Adriamycin + XRT; 3) patients with stage II-IV anaplastic Wilms' who are treated with vincristine, actinomycin D, and Adriamycin vs those three drugs in combination with cyclophosphamide and XRT; 4) patients with stage II-IV FH and stage I-IV CCSK who are treated for 6 mos vs approximately 15 mos post-nephrectomy.

**TECHNICAL APPROACH:** Patients with stage I-IV favorable histology (FH) or stage I-IV anaplastic Wilms' tumor, or stage I-IV clear cell sarcoma of the kidney (CCSK). Must have undergone nephrectomy, but no prior CT or XRT. Must be <16 yrs of age. **Followed:** Must have stage I-IV anaplastic Wilms' tumor, stage I-IV CCSK, or stage I-IV malignant rhabdoid tumor of the kidney. Must have a medical or social reason precluding randomization (see Sec. 4.122), including age >16 yrs. **Registered:** 1) Patients with histologically confirmed mesoblastic nephroma or diagnosis other than Wilms', anaplastic, clear cell, or rhabdoid tumor (to include those patients who have been previously treated or who have died post-op); OR 2) patients who have received prior therapy

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 1

Nationally 487 patients have been registered. No statistical analysis available at this time. The intergroup (NWTs) office is providing ongoing data analysis.

Detail Summary Sheet

Prot No: POG 8651(86)	Status: Ongoing	
TITLE: Osteosarcoma Study #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Nonmetastatic Osteosarcoma, Phase III		
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:		
Department/Section: Pediatric/Hematology-Oncology Section		
Key Words: osteosarcoma, chemotherapy;		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: Methotrexate		Decision: Continue

**OBJECTIVE:** To compare delayed surgery group to their immediate surgery controls to see if (1) those patients considered ineligible for limb salvage can be converted to candidates for limb salvage, and (2) preoperative chemotherapy improves disease-free survival.

**TECHNICAL APPROACH:** Multiagent chemotherapy utilizing methotrexate, adriamycin, cis-platinum, Bleomycin, Actinomycin-D and Cytosan over 42 weeks. One half of patients are randomized to immediate therapy. The remainder receive 10 weeks of adjuvant chemotherapy prior to definitive surgery.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3      Reporting Period: 0

Three TAMC patients have been enrolled in this study. Toxicity has been primarily hematopoietic. Bleomycin induced (transient) pulmonary toxicity was noted in one patient. Two patients are alive and well with no evidence of active disease. One TAMC patient has died of recurrent disease.

As of POG April 90 report, 76 patients have been registered; 38 to pre-surgery chemotherapy, 38 to post-operative chemotherapy. Most common toxicities are neutropenia, thrombocytopenia, stomatitis/mucositis and elevated transaminases. Treatment specific response remains masked but overall disease-free survival curve and life table analysis has been provided. The Pediatric Oncology Group is providing ongoing statistical analysis.

Detail Summary Sheet

Prot No: POG 8653/54(90)	Status: Ongoing
TITLE: A Study of Childhood Soft Tissue Sarcomas (STS) Other than Rhabdomyosarcoma and its Variants	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** A) To determine whether adjuvant chemotherapy with vincristine, Adriamycin, cyclophosphamide, and actinomycin D (VACA) increase the relapse-free survival (RFS) of patients with localized soft tissue sarcoma (STS) who are in complete response (CR) status after surgery with or without post-operative radiation (Protocol 8653).

B) To compare VACA with VACA plus STIC (VACAD) therapy in regard to CR and RFS rates in patients with (1) metastatic STS at diagnosis or (2) previously "untreated" recurrent STS (patients on the no chemotherapy control arm of "adjuvant" study 8653 or (3) localized persistent gross residual STS after surgery and radiation therapy (Protocol 8654).

**TECHNICAL APPROACH:** Patients on 8653 undergo surgery ± XRT and then are randomized to observation only or multiagent chemotherapy (Vincristine, Adriamycin, Cytoxan - alternated with Vincristine, Adriamycin-D, Cytoxan) for 52 weeks. Clinical Group III and IV (8654) are randomized to two different chemotherapy regimens lasting 78 weeks. Each arm receives XRT.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Detail Summary Sheet

Prot No: POG 8704(89)	Status: Ongoing
TITLE: T-Cell #3 Protocol	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: lymphoblastic lymphoma;	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To determine efficacy of multiagent chemotherapy targeted for patients with T-cell malignancies (leukemia and advanced T-cell lymphoblastic lymphoma). 2) To determine value of high dose L-asparaginase in the first phase of maintenance chemotherapy. 3) To study the biology of malignant T-cell disease.

TECHNICAL APPROACH: Common 14 week induction therapy of Vincristine, Prednisone, Cytoxan, Adriamycin, VM-26, Ara-C, Asparaginase and CNS Prophylaxis or treatment followed by randomization to one of two treatment arms: Trt I - 10 nine-week cycles of alternating Cytoxin/Ara-C, Vincristine/Pred/Adriamycin/6-MP, and VM-26/Ara-C Trt II along with L-asparaginase weekly x 20 weeks starting at beginning of maintenance.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

One TAMC patient enrolled to date, subsequently transferred to another POG institution (WRAMC) for continued therapy on protocol.

POG April 1990 report reveals 256 T-cell ALL and 146 lymphoblastic lymphoma patients registered as of Nov 89. Post induction CR is 97% for T-ALL, 96% for T-NHL. Disease free survival at two years (8691/8704 combined) appears superior to LSA<sub>2</sub>L<sub>2</sub> + XRT.

Comparison between arms remains masked. Two-year disease free survival figure is provided. The POG Stat Office is providing ongoing statistical analysis.

Detail Summary Sheet

Prot No: POG 8710(90)	Status: Completed	
TITLE: Simal #5: Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia		
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators: MAJ Shirley E. Reddoch, MC		
Department/Section: Pediatrics/Hematology-Oncology Section		
Key Words: acute lymphoblastic leukemia		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Completed

OBJECTIVE: The major objective is to increase the cure rate in children with acute lymphoblastic leukemia in first bone marrow or bone marrow and extramedullary relapse. Primary objectives: (1) to compare disease-free survival of a regimen including MTX/VM-26 with a control regimen; (2) To compare disease-free survival of a regimen including IFN with a control regimen. Secondary objectives: (1) To estimate and compare remission duration and toxicity in patients receiving either MTX/VM-26 or IFN as continuation therapy components; (2) To determine the prognostic value of clinical and biologic features at relapse including various clinical features, cytogenetics and immunophenotype in all patients and number of Type I Interferon receptors in those receiving IFN; (3) To estimate the frequency of multidrug resistance in leukemia cells at relapse; (4) To characterize oncogene expression in human leukemic cells at relapse.

TECHNICAL APPROACH: Treatment of any patient under 21 years of age at the time of diagnosis with non-T, non-B, acute lymphoblastic leukemia or undifferentiated leukemia on initial classification or non-lymphoblastic non-Hodgkin's lymphoma with first relapse at any time in marrow (>25% blasts) or extramedullary site, excluding isolated CNS disease with prednisone, vincristine, daunomycin, and L-asparaginase over 28 days to achieve marrow remission. All patients will receive VM-26 and Ara-C and some patients will be randomized to receive either VM-26 and methotrexate or interferon to consolidate remission. If remission is achieved, 96 weeks of continuation therapy with 2 or 3 drug combinations will be given. The purpose of this study is to achieve remission and compare ability of different combination or drug combinations plus interferon to prolong remission.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No Tripler patients registered on this study. POG Stat Office analyzing data.

Detail Summary Sheet

Prot No: POG 8719(91)	Status: Ongoing
TITLE: Trial of Shortened Therapy without Maintenance for the Treatment of Localized Non-Hodgkin's Lymphoma	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 91:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To determine if 24 weeks of maintenance chemotherapy with daily oral 6-MP and weekly methotrexate contributes to relapse-free survival and survival for patients with localized non-Hodgkin's lymphoma when added to a 9 week induction and consolidation regimen as administered in POG 8314; 2) To maintain a high cure rate with minimum toxicity for children with localized non-Hodgkin's lymphoma in favorable sites; 3) Clinical features and outcome of patients on this study will be available for correlation with data from the Laboratory Subclassification of NHL Study (POG #8315).

TECHNICAL APPROACH: Patients are randomized to one of two treatment arms. Arm A receives therapy through week 64. Arm B receives maintenance therapy from week 64-232 with 6-MP plus weekly MTX with periodic intra-thecal therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients registered to date; 158 patients registered nationally. The POG Stat Office is providing ongoing statistical analysis.



Detail Summary Sheet

Prot No: POG 8731(91)	Status: Ongoing
TITLE: Phase II Study of Low-Dose "Continuous" Oral Methotrexate in the Treatment of Children with Progressive or Recurrent Brain Tumors	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 91:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: A) To determine the effectiveness of low-dose "continuous" oral methotrexate in the treatment of children with progressive or recurrent brain tumors; B) to evaluate the toxicity associated with the use of this agent given in this manner.

TECHNICAL APPROACH: Phase II study (national protocol). Pediatrics patients with measurable progressive or recurrent brain tumor are administered weekly low dose methotrexate (7.5mg/M<sup>2</sup>/dose) by mouth every six hours for eight doses. Treatment continues as long as there is no evidence of progressive disease or critical toxicity.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

As of Nov 90, POG data indicates 77 patients registered group wide. POG analysis continues. Responses masked for all strata except for medulloblastoma which has been closed to patient entry due to clear lack of disease response. No abstracts/publications.

Detail Summary Sheet

Prot No: POG 8739(88)	Status: Completed
TITLE: Evaluation of Alpha Interferon in the Treatment of Recurrent Brain Tumors in Children - a Phase II Study	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: Alpha-Interferon	Decision: Completed

OBJECTIVE: To determine the efficacy of alpha<sub>2</sub>-interferon (α-IFN) in children with recurrent brain tumors resistant to standard therapy in regard to response rate of different histologic subtypes to α-IFN, and to further assess the toxicity of α-IFN in children.

TECHNICAL APPROACH: Treatment of recurrent brain tumors in children

PROGRESS: No. of Subjects Enrolled - To Date: 0    Reporting Period: 0

With regard to the master protocol, strata 1, 2, 4, 5 and 6 closed May 91 as a result of insufficient patient accrual; however, strata 3 remained open (i.e., the patients with medulloblastomas). Protocol closed to Group (POG) as of May 91. POG data analysis in progress. No publications or abstracts.

Detail Summary Sheet

Prot No: POG 8741/42(87)	Status: Ongoing
TITLE: Treatment of Stage D and Stage C Neuroblastoma in Children Greater Than or Equal to 365 Days at Diagnosis	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: neuroblastoma;	
Funding: FY 90:                      FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** This study is designed to look specifically at children in the worst prognostic groups of neuroblastoma. This study will employ four phase two agents in addition to standard chemotherapy.

**TECHNICAL APPROACH:** Children will be randomized to receive one of 4 phase two agents as initial drug therapy. After two courses they will then be randomized to one of two standard treatment arms for completion of therapy. Results will be compared to historical group controls.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

8741 is temporarily closed Jun 90 as ifosfamide, CBDCA and CHIP arms completed initial and secondary samples and epirubicin completed initial sample with response rate which did not meet requirements for secondary sample.

POG 8742 remains open with 232 patients accrued as of Apr 91 POG data. Treatment specific response and survival results are masked although combined data across both treatment arms are available. POG analysis continues.

**ABSTRACTS:** ASCO #857, 1987; SIOP, 1990.

Detail Summary Sheet

Prot No: POG 8743(88)	Status: Completed
TITLE: Treatment in "Better Risk" Neuroblastoma: POG Stage B (All Ages), and POG Stage C, D, and DS (IVS) <365 Days	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Uncology Section	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Dec 90 Decision: Completed
Gifts:	

**OBJECTIVE:** a) To prospectively identify, by flow cytometric DNA index, patients <365 days of age at diagnosis who will fail to achieve complete remission (CR) with cyclophosphamide (CYC) and Adriamycin (ADR) and delayed surgery; then to alter therapy in these patients and evaluate the CR and survival rates with alternate therapy, using cis-platinum (CDDP) and VM-26.  
b) To evaluate the disease-free survival (DFS) and survival in a larger group of patients currently considered to be "better risk" patients with neuroblastoma.  
c) To evaluate DFS and survival in a larger group of infants with DS disease (Stage IV-S) observed without therapy versus those treated with CYC-ADR.  
d) To evaluate the prognostic value of LDH at diagnosis, N-myc gene amplification in tumor at diagnosis, GD<sub>2</sub> level in tumor and serum at diagnosis, and serum neuron-specific enolase (NSE) and serum ferritin at diagnosis.

**TECHNICAL APPROACH:** The therapy of all children less than 21 years of age with neuroblastoma and children less than 365 days of age with Stage C, D, and IVS disease.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Group study completed Oct 90. Local registrant remains disease free following completion of therapy. POG analyses of early data indicates therapy effective for hyperdiploid infants with stage B, C, or D, infants with stage D and >365 day old patients with stage B disease. More detailed POG analysis available, as well as ongoing data review. No abstracts/publications.

Detail Summary Sheet

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Prot No: POG 8759(88) Status: Completed

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TITLE: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Osteosarcoma

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Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators:

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Department/Section: Pediatrics/Hematology-Oncology Section

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Key Words:

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Completed

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**OBJECTIVE:** a) To estimate the response rate to Ifosfamide in patients presenting with metastatic osteosarcoma or unresectable primary osteosarcoma prior to treatment of those patients with other chemotherapeutic reagents.  
b) To estimate the response rate to Ifosfamide in previously treated patients with osteosarcoma.  
c) To explore the feasibility and toxicity of the addition of Ifosfamide to a multi-agent combination chemotherapy regimen which includes drugs known to be active in the treatment of osteosarcoma. If the regimen can be given without excessive toxicity and if the regimen is effective, it will be explored further as frontline treatment for patients presenting without metastases.  
d) To study the DNA content of primary and metastatic tumors.

**TECHNICAL APPROACH:** Treatment of previously untreated patients with metastatic osteosarcoma or unresectable primary osteosarcoma or patients with previously chemotherapy-treated osteosarcoma now recurrent.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0                      Reporting Period: 0

POG study completed Oct 90 with 72 patients across all categories accrued to study. Limited response data available as of Apr 91; POG data collection/analysis ongoing.

Abstracts: Proc ASCO, 1991

Detail Summary Sheet

Prot No: POG 8763(90)	Status: Completed
TITLE: Evaluation of Response and Toxicity of Ifosfamide and VP-16-213 in Children with Resistant Malignant Tumors	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

**OBJECTIVE:** To determine the antitumor activity and toxicity of ifosfamide plus VP-16 against malignant solid tumors resistant to conventional chemotherapy.

**TECHNICAL APPROACH:** VP-16 100 mg/M<sup>2</sup>/d x 3 day  
Ifosfamide 2.0 gm/M<sup>2</sup>/d x 3 days + (Mesna/uroprotection)  
Repeat every 14 - 21 days as peripheral counts permit. Total therapy time is 18 months or until there is evidence of progressive disease.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients enrolled. POG study was completed with 307 patients accrued to study. Response rates ranged from 19-29% (varying with tumor type). Bacterial infection, neutropenia and thrombocytopenia were most common and severe toxicities. More detailed POG data should become available. Manuscript is in progress.

Abstract: ASCO, May 89; ASCO 91

Detail Summary Sheet

Prot No: POG 8764(88)	Status: Completed
TITLE: Chemotherapy Regimen for Early and Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: Lymphoblastic leukemia	
Funding: FY 90:            FY 91:	Periodic Review Date: Jun 91
Gifts: None	Decision: Completed

OBJECTIVE: To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regimen of VM-26 and continuous infusion cytosine arabinoside (Ara-C); to estimate the one-year disease-free survival for early and initial induction failures in childhood ALL, based on a new regimen; to try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

TECHNICAL APPROACH: Remission induction with standard dose continuous ARA-C, high dose VM-26 and TIT. Continuation therapy with MTX, ARA-C, VM-26, Daunomycin and 6-MP.

PROGRESS: No. of Subjects Enrolled - To Date: 1            Reporting Period: 0

POG study completed Jun 91 with sufficient patient accrual. Response and survival data masked as of Apr 91 report. POG data analysis in progress.

Detail Summary Sheet

Prot No: POG 8820(90)	Status: Ongoing
TITLE: VP-16, AMSA ± 5-Azacytidine in Refractory ANLL (A POG Randomized Phase II/III Study)	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Continue

OBJECTIVE: (1) To compare, in a randomized study, the remission rate of VP-16/AMSA vs. VP-16/AMSA/5-AZA in children with recurrent or refractory acute non lymphocytic leukemia.  
(2) To determine the duration of remission, using pulses of the induction regimen as continuation therapy.  
(3) To study the relative toxicities of these two therapies.

TECHNICAL APPROACH: (A) AMSA 100mg/M<sup>2</sup>/d x 5 days + VP-16 200mg/M<sup>2</sup>/d x 2 days  
(B) Treatment A above plus 5-AZA 250mg/M<sup>2</sup> on day 4 & 5.

One or two courses for remission induction followed by 10 courses of maintenance.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients enrolled at this time. Ninety patients registered group wide as of April 91. Responses seen in both disease strata with both treatment arms. Treatment specific data not yet released. Most common complication reported is infection.

Detail Summary Sheet

Prot No: POG 8821(88)	Status: Ongoing
TITLE: AML#3: Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant Early in First CR for Children with Acute Myelocytic Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: acute myelocytic leukemia;	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** a) To determine the disease-free survival (DFS) and event-free survival (EFS) in childhood acute myelocytic Leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses. b) To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/Cytosan preparative regimen and 4-Hydroperoxycyclophosphamide (4-HC) purged marrow is effective therapy. c) To compare, in a randomized study, the results of the above two regimens. d) To correlate the treatment outcome with clinical and laboratory features.

**TECHNICAL APPROACH:** Patients to be equally randomized (after remission induction with 6-TG, ARA-C and Daunomycin to standard chemotherapy for maintenance or autologous bone marrow with 4-HC purging and no further therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3            Reporting Period: 2

POG Apr 91 recorded 140 patients accrued in study over the preceding year with a total of 319 patients registered to that date. Actual randomization has been lower than expected, however at 50% (with provisions for these exceptions in the protocol). Treatment specific response/survival data remains masked at this time; POG data analysis continues.

Detail Summary Sheet

Prot No: POG 8823/24(90)	Status: Ongoing
TITLE: Recombinant Alpha-Interferon in Childhood Chronic Myelogenous Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** (1) To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed "adult" CML in chronic phase, and for "juvenile" CML occurring within the first two decades.

(2) To obtain prospective clinical, laboratory and genetic data on cases of adult and juvenile CML treated with v-alpha interferon.

**TECHNICAL APPROACH:** After diagnostic materials are collected, patients are treated with 24 million u/M<sup>2</sup> r-alpha interferon x 14 days then Q O D x 90 days. Patients are then evaluated for further maintenance or off therapy. Transplant may be performed at any time.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

Twenty-seven patients accrued to this POG protocol as of Apr 91. Response and survival data remain masked; POG data analysis continues.

Detail Summary Sheet

Prot No: POG 8828(90)	Status: Ongoing
TITLE: Late Effects of Treatment of Hodgkin's Disease	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words: Hodgkin's disease	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** Primary: (1) To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG #8625/26 and POG #8725; (2) To compare the two treatment arms of POG #8625/26 and the two treatment arms of POG #8725 for the incidence of the above late effects. Secondary: (1) To attempt to identify disease and treatment-related factors and post-treatment factors which contribute to specific late effects; (2) To attempt to identify pre-treatment factors, on-treatment and/or post-treatment factors which predict high risk of specific late effects.

**TECHNICAL APPROACH:** Patients will participate either in POG #8625 ("early stage" Hodgkin's disease) or POG #8725 ("late stage" Hodgkin's disease) therapeutic studies. Data will be obtained to help identify patients long-term follow-up needs, particularly earlier recognition and management of high-incidence treatment toxicities. Should treatment arms of the therapeutic Hodgkin's protocols (8625/26 and 8725) produce equivalent disease responses, this long-term toxicity data will be critical in the determination of the "better" treatment arm.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

This is a long term/lab effects study - no interpretable data available yet.

Detail Summary Sheet

Prot No: POG 8829(91)	Status: Ongoing
TITLE: Protocol for a Case-Control Study of Hodgkin's Disease in Childhood	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: 1) To conduct the first interview case-control study of childhood Hodgkin's disease to learn more about the epidemiology of the disease in children; 2) To evaluate whether, on epidemiologic grounds, childhood Hodgkin's disease is distinct from the young adult and old adult diseases; 3) To evaluate the hypothesis that children with Hodgkin's disease have different patterns of infectious disease than do matched controls; 4) To assess day-care of children (with its attendant increased risk of infectious diseases acquired at early ages) as a risk factor for childhood Hodgkin's disease; 5) To evaluate the association between breast-feeding and risk of childhood Hodgkin's disease; 6) To evaluate association between indicators of socioeconomic status and childhood Hodgkin's disease; 7) To evaluate parental occupational exposure as risk factors for Hodgkin's disease in children; 8) To evaluate environmental exposures to wood and chemicals as possible risk factors in children; 9) To evaluate familial aggregation of Hodgkin's disease (and possibly increased risk of other malignancies or multiple sclerosis); 10) To evaluate risk factors of childhood - Hodgkin's disease separately for each histologic subtype of the disease, and by disease stage and age at diagnosis.

TECHNICAL APPROACH: Questionnaire administered by telephone interview of parents of patients <15 years of age with newly diagnosed Hodgkins (intergroup study involving POG and CCSG).

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Data collection in progress.

Detail Summary Sheet

Prot No: POG 8832(90)	Status: Completed
TITLE: Pre-Irradiation Chemotherapy in Supratentorial Malignant Tumors	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Completed

**OBJECTIVE:** (1) To determine, acute, subacute and combined-treatment toxicities of chemotherapy with cisplatin and ARA-C followed by cranial irradiation in children.  
(2) To estimate the efficacy of a 15 week period of chemotherapy with cisplatin and ARA-C in children with malignant supratentorial (primary CNS) tumors.  
(3) To estimate the feasibility and completeness of second surgical resection in children with incompletely resected supratentorial tumors after treatment with initial chemotherapy.

**TECHNICAL APPROACH:** All patients must have diagnostic biopsy. Chemotherapy every three weeks for five courses. Patients will then proceed to a second resection and/or standard radiation therapy. Full evaluation will occur at week 70 or earlier as clinically indicated.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Sixty-five patients accrued to study as of Apr 91. POG study completed Aug 91. No unexpected toxicities observed; chemotherapy in general well-tolerated. POG analysis of response/survival by stratum (disease stratified by histology) in progress.

Detail Summary Sheet

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Prot No: POG 8850(89) Status: Ongoing

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TITLE: Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly-Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone: A Phase III Intergroup Study

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Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators:

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Department/Section: Pediatrics/Hematology-Oncology Section

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Key Words: Ewing's sarcoma;

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Continue

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**OBJECTIVE:** Primarily: To determine and compare the EFS of patients treated with VP-16 and Ifosfamide in addition to standard therapy vs treatment with standard therapy alone. Secondarily: a) Evaluate toxicities and adverse orthopedic outcomes associated with disease and therapies; b) Assess significance of tumor site, size, histology and EM pattern in determining outcome; c) Correlate imaging characteristics with response, prognosis, RT adequacy, and survival; d) Assess prognostic value of cellular DNA content and chromosome changes.

**TECHNICAL APPROACH:** Patients with newly diagnosed Ewing's sarcoma or PNET of bone will be evenly randomized to one of two treatment arms: Reg A-52 week course of chemo including Vincristine, Adriamycin, Cytosan, Actinomycin D with surgery and/or XRT as needed (standard therapy). Reg B-52 week including Ifosfamide and Etoposide as well as therapy employed in Regimen A.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0                      Reporting Period: 0

POG Apr 91 report reveals 98 patients entered on study to date. Response masked by statistical office; no unexpected toxicities.

Detail Summary Sheet

Prot No: POG 9000(91)	Status: Ongoing
TITLE: ALinC #15 Laboratory Classification (C) Protocol	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** 1) To continue to characterize the biologic findings of the acute lymphoblastic and undifferentiated leukemias (immunologic markers, ploidy (DNA index), karyotyping, morphology) and their relationship, as prognostic factors for attaining and maintaining remission; 2) To apply to therapy selection, the determination that ploidy and certain structural chromosomal abnormalities predict poor prognosis; 3) To learn whether outcome is related to patient differences in methotrexate availability as measured by sequential determination of red blood cell (RBC) methotrexate (MTX) and folate levels; 4) To determine the frequency of myeloperoxidase (MPO) gene expression in the blast cell population of all newly diagnosed cases of infant leukemia, in an effort to improve detection of early stages of myeloid lineage; 5) To determine by in vitro testing if there is inadvertent stimulation of infants' lymphoblasts by hematopoietic growth factors (HGF); 6) To evaluate the usefulness of PCR technique in detecting minimal residual disease in patients with disease demonstrating t(9;22) or t(1;19) chromosomal abnormalities.

**TECHNICAL APPROACH:** Submission of blood and bone marrow aspirate samples of newly diagnosed ALL patients to designated reference labs for disease/type verification and additional biologic information for disease response prognostication.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

New POG protocol; too early for data analysis.

Detail Summary Sheet

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Prot No: POG 9005(91) Status: Ongoing

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TITLE: ALinC #15: Dose Intensification of Methotrexate and 6-Mercaptopurine for ALL in Childhood - A Pediatric Oncology Group Randomized Phase III Study

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Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators: MAJ Shirley E. Reddoch, MC

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Department/Section: Pediatrics/Hematology-Oncology Section

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Key Words:

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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**OBJECTIVE:** To determine, in a randomized trial, whether intensification with intermediate-dose methotrexate (ID MTX), and intravenous 6-mercaptopurine (IV 6-MP) is superior or inferior to repeated low-dose, oral methotrexate (LD MTX) and IV 6-MP for prevention of relapse in children with ALL in first remission and at lower risk for relapse.

**TECHNICAL APPROACH:** Treatment of newly diagnosed in remission non-T, non-B ALL patients >12 months and ≤21 years of age with "better risk" disease on a two arm randomized study of intensification with intermediate dose MTX and IV-6MP vs repeated low-dose, oral MTX and IV-6MP followed by a common maintenance therapy of weekly IM MTX and daily p.o. 6-MP.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1            Reporting Period: 1

Local registrant achieved induction remission. Transferred to WRAMC for continuing treatment. New POG protocol; no data yet available.

Detail Summary Sheet

Prot No: POG 9006(91)	Status: Ongoing
TITLE: ALinC #15: Up-front 6-MP/Methotrexate vs. Up-front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Childhood - A Pediatric Oncology Group Randomized Phase III Study	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To compare, in a randomized trial of children with ALL at higher risk for relapse, the efficacy and toxicity of a) 12 early intensive courses of IV methotrexate (MTX) plus IV 6-mercaptopurine (6-MP) vs b) 12 early intensive courses of alternating intensive chemotherapy combinations (6-MP/MTX, VM-26/Ara-C, vincristine/prednisone/PEG-L-asparaginase/daunomycin/Ara-C.

**TECHNICAL APPROACH:** Treatment of newly diagnosed non-T, non-B ALL patients, 1-21 years of age with poor prognostic features but with successful remission induction, on a two arm randomized study of intensification therapy with IV MTX/6-MP vs three alternating chemotherapy pairs (MTX/6MP, VM-26/Ara-C, daunomycin/Ara-C) to be followed by a common maintenance therapy of weekly IM MTX and by mouth daily 6-MP.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

New POG protocol; too early for data analysis.

Detail Summary Sheet

Prot No: POG 9047(90)	Status: Ongoing
TITLE: Neuroblastoma Biology Protocol	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: To characterize the biological nature of neuroblastoma.

TECHNICAL APPROACH: Referral of fresh unfixed tumor material plus serum and plasma to POG reference laboratories.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

POG data as of Apr 91 indicates 30 patients on study. Too early for additional data reports.

Detail Summary Sheet

Prot No: POG 9060(90)	Status: Ongoing
TITLE: Intensive QOD Ifosfamide for the Treatment of Children With Recurrent or Progressive CNS Tumors	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** A) To determine the activity of ifosphamide delivered every other day x3 (i.e. Monday, Wednesday, Friday) in the treatment of children with recurrent or progressive brain tumors.

B) To quantitate the ototoxicity associated with treatment as per a. above

C) To determine the incidence of neurotoxicity associated with the proposed qod schedule of administration in patients who have had: 1) no prior treatment with cisplatin; 2) prior cisplatin therapy with total doses of  $\leq 300$  mg/M<sup>2</sup>; and 3) prior cisplatin therapy with total doses  $> 300$  mg/M<sup>2</sup>.

**TECHNICAL APPROACH:** Treatment of children  $\leq 21$  years of age with recurrent or progressive CNS tumors with Ifosphamide, IV 3gm /M<sup>2</sup>/day QOD x 3 doses every 21 days as long as stable or resolving disease evident.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

As of POG Apr 91 report, 23 patients registered on study. Response masked to date; no grade III/IV neurotoxicity reported; one patient with grade 4 renal toxicity; no unanticipated hematologic toxicity.

Detail Summary Sheet

Prot No: POG 9061(90)	Status: Ongoing
TITLE: The Treatment of Isolated Central Nervous System Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/ Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:**

- A. To determine the efficacy and toxicity of intensified systemic treatment with delayed craniospinal irradiation for children with acute lymphoblastic leukemia (ALL) and isolated central nervous system disease.
- B. To describe the pharmacokinetics and cytotoxic effect within the cerebrospinal fluid (CSF) of intravenous 6-mercaptopurine (6-MP) given as a single agent in an "up-front" window and to determine the level at which 100% of the blasts are cleared from the CSF.
- C. To measure parameters of CNS tissue injury (free fatty acids and phospholipids within the CSF) and and associate these with the effects of CNS leukemia and treatments.

**TECHNICAL APPROACH:** Treatment of patients >1 yr of age in first bone marrow remission with isolated CNS relapse looking at utilizing escalating doses of IV 6-MP in an upfront 2 week therapeutic window followed by systemic induction, consolidation and intensification chemotherapy and intrathecal chemotherapy then C/S irradiation followed by additional chemotherapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

POG report as of Apr 91 indicates 13 patients registered. Clearing of blasts during during IV 6-MP therapeutic window not yet demonstrated so this dose escalation continues. Otherwise remission achieved with no recurrence to date. No unexpected toxicities.



Detail Summary Sheet

Prot No: POG 9107(91)	Status: Ongoing
TITLE: Infant Leukemia Protocol	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** 1) To determine the toxicity associated with one year of intensive post-induction chemotherapy consisting of rotating courses of high-dose Ara-C/DNR, IV 6-MP/MTX, VP-16/Ara-C, vincristine/prednisone/Cytoxan/Ara-C given to patients <12 months of age with acute lymphocytic leukemia in remission; 2) to determine the incidence, severity, and duration of neutropenia, thrombocytopenia, and anemia associated with each of the above courses; 3) to determine other systemic toxicities (infections, nutritional, etc) associated with this intensive one-year post-induction chemotherapy; 4) to determine the feasibility of using this regimen in a groupwide phase III protocol for patients <12 months of age with acute lymphocytic leukemia.

**TECHNICAL APPROACH:** Treatment of all infants <12 months of age with previously untreated non T-cell and non B-cell ALL, (following induction with Vincristine, Prednisone, Cyclophosphamide and Ara-C) with intensive chemotherapy consisting of rotating courses of four different chemotherapy combinations.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Too early to report; POG analyses when data sufficient.

Detail Summary Sheet

Prot No: POG 9110(91)	Status: Ongoing	
TITLE: SIMAL #6 - Rotational Drug Therapy After First Marrow Relapse Of ALL Group-Wide Pilot		
Principal Investigator: LTC Bruce A. Cook, MC		
Associate Investigators: MAJ Shirley E. Reddoch, MC		
Department/Section: Pediatrics/Hematology-Oncology Section		
Key Words:		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Continue

**OBJECTIVE:** Using the "Investigational Window" technique, the efficacy and toxicity of doxorubicin given by continuous infusion will be assessed, as will feasibility and acceptability of a rotating weekly parenteral drug regimen for continuation therapy. In this initial pilot program, the major question to be addressed is toxicity. If toxicity is shown to be acceptable, a groupwide randomized protocol, comparing continuous infusion with bolus doxorubicin in an investigational window will be instituted.

**TECHNICAL APPROACH:** As above.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: POG 9139(91)	Status: Ongoing
TITLE: A Dose-Escalating Study of Cisplatin, Used Concomitantly with Hyperfractionated Irradiation in the Treatment of Children with Newly-Diagnosed Brain Stem Gliomas. A Phase I Study.	
Principal Investigator: LTC Bruce A. Cook, MC Associate Investigators: MAJ Shirley E. Reddoch, MC	
Department/Section: Pediatrics/Hematology-Oncology Section	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine the acute and subacute toxicities associated with the administration of cisplatin by continuous infusion, to be used as a radiosensitizer given simultaneously with a previously-tested hyperfractionated irradiation regimen in children with newly-diagnosed brain stem glioma (BSG), and also to establish the dose level of infusional cisplatin that results in maximum tolerated toxicity when combined with hyperfractionated radiotherapy to the brain stem.

**TECHNICAL APPROACH:** XRT to be administered as 117 cGy/fraction BID; 5 days/week for 6 weeks to a total of 7020 cGY. Cisplatin to be administered as continuous infusion over the 120 hours of each 5 day radiation period.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

New POG protocol; no data as yet available.

Detail Summary Sheet

Prot No: CRCH 8900(90)	Status: Ongoing
TITLE: Efficacy and Safety Trial of Toremifene vs Tamoxifen in Postmenopausal Patients with Metastatic Breast Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Toremifene; Tamoxifen; breast cancer	
Funding: FY 90:      FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

OBJECTIVE: To compare the efficacy and side effects of tamoxifen and toremifene (at 2 different dose levels) in postmenopausal patients with metastatic breast cancer.

TECHNICAL APPROACH: Patients will be randomized to (1) tamoxifen 10mg twice a day p.o.; (2) toremifene 60mg once a day p.o.; or (3) toremifene 200mg once a day p.o.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There is no data available yet.



Detail Summary Sheet

Prot No: CRCH 8903(89)	Status: Ongoing
TITLE: A Multicenter Phase II Trial of Intravenous PEG-Interleukin-2 (Modified Recombinant Human) (PEG IL-2) in Patients with Advanced Renal Cell Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Interleukin-2;	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine the response rate to PEG IL-2 in patients with advanced renal cell carcinoma.

**TECHNICAL APPROACH:** Patient agreeing to participate will receive PEG IL-2 over 15 minutes IV weekly for 8 weeks and then be reassessed for further treatment depending on their response. The patients will be hospitalized for 24 hours after the first dose to monitor for toxicity.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0    Reporting Period: 0

There is no available data yet.



Detail Summary Sheet

Prot No: CRCH 8905(90)	Status: Ongoing
TITLE: Daily Treatment of Myelodysplastic Syndrome (MDS) with Oral Idarubicin	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: To determine if treatment with oral Idarubicin can result in improvement in hematologic parameters in patients with poor prognosis myelodysplastic syndrome.

TECHNICAL APPROACH: Patients agreeing to participate will receive p.o. Idarubicin daily for 21 days out of each 28 days. Treatment for 6 months total is planned.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

There are no data available.

Detail Summary Sheet

Prot No: NSABP B17(86)	Status: Terminated
TITLE: A Clinical Trial to Evaluate Natural History and Treatment of Patients with Noninvasive Intraductal Adenocarcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas; LTC Aida P. Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: adenocarcinoma, noninvasive intraductal;	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Terminate

**OBJECTIVE:** To determine whether lumpectomy is an effective operation for the treatment of noninvasive breast cancer and if radiation treatments add to that effectiveness.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will be randomized after lumpectomy to receive or not receive radiation therapy to the involved breast.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

There are no national data available yet about this study except that the study reached its patient accrual goal and was terminated. Results will be published after about two more years of follow-up.

Detail Summary Sheet

Prot No: NSABP B18(89)	Status: Ongoing	
TITLE: A Unified Trial to Compare Short Intensive Preoperative Systemic Adriamycin Cyclophosphamide Therapy with Similar Therapy Administered in Conventional Postoperative Fashion		
Principal Investigator: COL Jeffrey L. Berenberg, MC Associate Investigators: LTC William J. Uphouse, MC		
Department/Section: Medicine/Hematology-Oncology Service		
Key Words: adriamycin;cyclophosphamide;		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** To determine whether 4 courses of preoperative chemotherapy will more effectively prolong disease-free survival and survival than the same 4 courses of chemotherapy given postoperatively in patients with operable breast cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive 4 cycles of adriamycin and cytoxan (day 1 IV every 3 weeks) preoperatively or to receive the same 4 cycles of chemotherapy post-operatively. Tamoxifen will be given twice a day after surgery to all patients age 50 years or more (regardless of which chemotherapy group they are assigned).

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 0

This study is still accruing patients and no results are available except that nationally there have been no toxic deaths and toxicity is primarily nausea and vomiting on the day of treatment in 45% of the patients.



Detail Summary Sheet

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Prot No: NSABP B22(89) Status: Terminated

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TITLE: A Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy on the Disease-Free Survival and Survival of Patients with Primary Breast Cancer and Positive Axillary Nodes

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS;  
LTC Yeu-Tsu Margaret Lee, MC;  
MAJ Marianne M. Young, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: adriamycin-cyclophosphamide (AC);

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Terminate

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**OBJECTIVE:** To determine whether giving larger doses of CTX is the first 2 or 4 cycles of adjuvant CTX and ADRIA chemotherapy will improve the survival of breast cancer patients over patients given standard doses of those 2 drugs for 4 cycles. To determine if larger doses of CTX in all 4 cycles is superior to 4 cycles at standard doses.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive 1 of 3 dose schedules of CTX and ADRIA IV day one every 3 weeks for 4 cycles (i.e., 12 weeks). Patients age 50 and over will also receive Tamoxifen 10 mg p.o. twice daily for 5 years.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5 Reporting Period: 0

This protocol was terminated in May 91 as it reached its accrual goal and no national data is available. The TAMC patients have completed their treatment, but increased nausea and vomiting requiring potent anti-emetics were noted with the higher dose cyclophosphamide arms.

Detail Summary Sheet

Prot No: NSABP B23(9T)	Status: Ongoing
TITLE: A Clinical Trial Comparing Short, Intensive AC ± Tamoxifen With Conventional CMF ± Tamoxifen in Node-negative Breast Cancer Patients With ER-Negative Tumors	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine in resected breast cancer patients with negative nodes whether 4 cycles of adriamycin plus cyclophosphamide (AC) is superior to six cycles of cyclophosphamide, methotrexate, 5-FU (CMF) and to determine if adding tamoxifen to either of the above 2 programs is more efficacious than each program by itself.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive either 1) adriamycin IV day 1 and cyclophosphamide IV day 1 with these drugs repeated every three weeks for four cycles or 2) cyclophosphamide p.o. day 1-14 plus methotrexate IV day 1 & 8 plus 5FU IV day 1 & 8 repeated monthly for six cycles. All patients will also be randomized to receive or not receive tamoxifen twice a day for five years.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: NSABP B24(91)	Status: Ongoing
TITLE: A Clinical Trial to Evaluate the Worth of Tamoxifen in conjunction with Lumpectomy and breast Irradiation for the Treatment of Noninvasive Intraductal Carcinoma (DCIS) of the Breast	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine if tamoxifen does or does not add to lumpectomy plus postoperative breast irradiation for noninvasive intraductal cancer (DCIS) in terms of preventing subsequent invasive breast cancers.

**TECHNICAL APPROACH:** Patients will be randomized after lumpectomy to receive either tamoxifen for at least 5 years plus radiation or to receive placebo for at least 5 years plus radiation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0  
New start.

Detail Summary Sheet

Prot No: SWOG 7804(84)	Status: Ongoing
TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin C (FAM) versus Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; COL Peter J. Barcia, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: gastric adenocarcinoma	
Funding: FY 90:      FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine whether or not chemotherapy (FAM) given to patients with advanced but resected gastric carcinoma will prevent relapses and prolong life.

**TECHNICAL APPROACH:** Patients will be randomized to either (1) receive chemotherapy with FAM twice a month for 1 year or (2) receive no treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

National accrual continues and completion of this study will hopefully be in the near future. Toxicity has been tolerable with some nausea and vomiting (reversible) and some hematologic toxicity (reversible). Of the 212 patients on the study there were 2 deaths possibly related to chemotherapy. One was due to congestive heart failure but the patient appeared to actually have had a myocardial infarction. The other was due to hemolytic-uremia syndrome, an unusual complication of mitomycin-c.

Detail Summary Sheet

Prot No: SWOG 8312(85)	Status: Completed	
TITLE: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Metastatic Breast Cancer, Phase III		
Principal Investigator: COL Jeffrey Berenberg, MC		
Associate Investigators: MAJ William Uphouse, MC; LTC Joseph Woods, MC		
Department/Section: Medicine/Hematology-Oncology Service		
Key Words: breast cancer, metastatic		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Completed

**OBJECTIVE:** To determine if combined hormone therapies are superior to single hormone therapy in sequence for metastatic breast cancer.

**TECHNICAL APPROACH:** All patients agreeing to this study will be randomized to one of three treatments: (1) megestrol acetate, (2) aminoglutethimide plus hydrocortisone, or (3) megestrol acetate plus aminoglutethimide plus hydrocortisone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

There are no TAMC patients on this study. Nationally, 288 patients were registered on the study. The study has been completed and results have shown that the response rates were similar for all three arms (11-15%) and the median survivals were identical (25 months). The conclusion was that megestrol acetate is the preferred treatment dose to less side effects (6%) versus the other two (14-28% with side effects).

Detail Summary Sheet

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Prot No: SWOG 8326/27(85) Status: Ongoing

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TITLE: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blast Crisis, Phase III

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William Uphouse, MC; MAJ Luke M. Stapleton, MC;  
MAJ Lawrence Sakas, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: leukemia, adult acute; leukemia, chronic granulocytic

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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**OBJECTIVE:** To determine the response and response duration of a high-dose program of Ara-C in patients with relapsed acute leukemia.

**TECHNICAL APPROACH:** Patients agreeing to the study will be randomized to receive (1) six days of high dose Ara-C, (2) the same Ara-C plus three days of m-AMSA, or (3) the same Ara-C plus three days of Mitoxantrone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2 Reporting Period: 0

Accrual has been slow nationally to date but continues. High dose Ara-C continues to be the most promising drug in relapsed leukemia. One TAMC patient registered on this study achieved a complete remission of her leukemia and did well for 9 months but then relapsed and died. A second TAMC patient did not achieve a complete remission and died. Nationally, Arm 2 with m-AMSA was terminated previously due to 9 deaths among 39 patients. So far, 176 patients have been entered into the other induction arms. Fatal toxicities have been seen in 7 of 89 patients on arm (1) and 12 of 87 on Arm 3. No response or survival data is available yet.

Detail Summary Sheet

Prot No: SWOG 8393(84)	Status: Ongoing	
TITLE: National Intergroup Protocol for Intermediate Thickness Melanoma		
Principal Investigator: COL Jeffrey Berenberg, MC		
Associate Investigators: LTC William Uphouse, MC; COL Peter J. Barcia, MC		
Department/Section: Medicine/Hematology-Oncology Service		
Key Words: melanoma		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts: None		Decision: Continue

**OBJECTIVE:** (1) To determine the optimal surgical margins (2 versus 4 cm) around the intermediate thickness melanomas (1-4 mm) that are being resected for cure. (2) To evaluate the value of elective regional lymph node dissection in these same melanomas.

**TECHNICAL APPROACH:** Patients with primary melanomas of the head or neck or distal extremities will be randomized to receive or not receive elective node dissection, but all patients in this group will have 2 cm surgical margins. Patients with melanomas of the trunk or proximal extremities will undergo two randomizations, (1) to receive or not to receive elective node dissection, and (2) to have either a 2 or 4 cm surgical margin.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2 Reporting Period: 0

Two Tripler patients have been registered on this protocol. It is too early to assess efficacy of this protocol approach. Nationally, 93 patients have been registered. No other data is available.

Detail Summary Sheet

Prot No: SWOG 8417/19(85)	Status: Ongoing
TITLE: Evaluation of the Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: leukemia, lymphoblastic	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** To compare two consolidation chemotherapy programs in terms of remission, duration, and survival.

**TECHNICAL APPROACH:** All patients agreeing to participate will be randomized to receive either the L-10M consolidation or the new (shorter) consolidation program.

**PROGRESS:** No. of Subjects Enrolled - To Date: 6    Reporting Period: 0

This study is the frontline study for patients with newly diagnosed acute lymphoblastic lymphoma and remains open. Of the 6 TAMC patients entered on this study, all 6 entered complete remission. Nationally, only toxicity data is available. Of 383 patients available for induction toxicity, 29 (7%) had treatment-related deaths. This is not unexpected in leukemia induction chemotherapy.

Detail Summary Sheet

Prot No: SWOG 8516(86)	Status: Terminated
TITLE: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBOM vs MACOP-B in Patients with Intermediate and High-Grade Non-Hodgkin's Lymphoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Lymphoma, non-Hodgkin's	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Terminate

OBJECTIVE: To determine which of the four leading chemotherapy programs for aggressive lymphomas is best in terms of response, survival, and toxicity.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive one of the four treatment programs listed above.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 0

We have been slow to accrue non-Hodgkin's cases because these cases have been relatively uncommon hospital-wide. Of the 3 patients entered on this study 2 went into complete remission, one has relapsed and another patient is being followed at another institution (on the mainland). Only toxicity data is available nationally. The major toxicity has been leucopenia and, given the intensity of these programs, fatal toxicities have ranged from 2-3% with CHOP and ProMACE-CytaBOM to 6% with m-BACOD and MACOP-B. Response and survival data will be published in the near future nationally.



Detail Summary Sheet

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Prot No: SWOG 8600(87) Status: Ongoing

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TITLE: A Randomized Investigation of High Dose Versus Standard Dose Cytosine Arabinoside With Daunorubicin In Patients With Acute Non-Lymphocytic Leukemia

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC;  
CPT Scott Martin, MS; LTC Lawrence Sakas, MC;

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: cytosine arabinoside and daunorubicin

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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**OBJECTIVE:** To compare, among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose cytosine arabinoside and daunorubicin or high dose cytosine arabinoside and daunorubicin. Also to compare these 2 programs when used in the consolidation phase.

**TECHNICAL APPROACH:** Patients are randomized to receive standard or high dose cytosine arabinoside initially. If remission is achieved then patients are randomized again to receive standard or high dose cytosine arabinoside for consolidation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 6 Reporting Period: 0

Of the 6 TAMC patients enrolled on this study in 1988-89, 4 achieved a complete remission. Nationally there are no data yet on response but of 607 patients evaluable for induction toxicity, 48 died as a result of therapy. Due to the toxic nature of leukemia treatment in general, this figure is probably not high.

Detail Summary Sheet

Prot No: SWOG 8614(90)	Status: Completed
TITLE: Chemotherapy of gastric cancer with VM-26, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Completed

**OBJECTIVE:** To determine the response rate and response duration in patients with advanced gastric cancer treated with VM-26.

**TECHNICAL APPROACH:** Patients agreeing to participate will all receive VM-26 IV over 45 minutes daily for 5 consecutive days every 3 weeks (until tumor progression).

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study accrued 23 patients and there was only one partial remission. The drug is not clinically active in gastric cancer and will not be studied further in the malignancy.

Detail Summary Sheet

Prot No: SWOG 8616(87)	Status: Ongoing
TITLE: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With or Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: ifosfamide; mesna	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine if adding ifosfamide and mesna to the usually employed drugs of doxorubicin and dacarbazine will improve the response rate, response duration and survival in metastatic soft tissue and bone sarcoma.

**TECHNICAL APPROACH:** Patients agreeing to participate will have a central line (port-a-cath) placed and receive 4 days of doxorubicin and dacarbazine continuously through this line. These patients will also be randomized to receive or not receive 4 days of therapy with ifosfamide and mesna. These latter drugs are given together through a peripheral IV (in patients randomized to receive them). This whole chemotherapy regimen is repeated every 3 weeks until disease progression is noted.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

The one TAMC patient entered had stabilization of his disease with the 4 drug arm for 8 months but then progressed. Nationally 438 patients have been treated. So far, response rates (about 15%) and median survivals (12 months) appear to be the same in both arms. Nationally the original ifosfamide dose had to be decreased due to 6 deaths in 163 patients given the original dose. Deaths were due to infections. Other toxicities were primary transient nausea or vomiting in many patients.

Detail Summary Sheet

Prot No: SWOG 8691(89)	Status: Ongoing
TITLE: A Randomized Comparison of Deoxycoformycin vs. Alpha Interferon in Previously Untreated Patients with Hairy Cell Leukemia	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: deoxycoformycin; alpha interferon	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To compare the rates of partial and complete remission and the durations of survival in patients treated with the alpha interferon or deoxycoformycin.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive 1) alpha interferon subcutaneously three times a week for 6 months and then be reassessed for a second 6 months of treatment or 2) deoxycoformycin IV every 2 weeks until the leukemia is gone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Nationally, there are no response data available (although we know from other studies the responses will be very high). Of the 356 patients on the study to date, only one died of what might be called drug related toxicity (i.e., infection in this case). Toxicity has otherwise been primarily fevers or nausea or vomiting in a minority of patients.

Detail Summary Sheet

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Prot No: SWOG 8692(87) Status: Ongoing

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TITLE: Therapy in Premenopausal Women with Advanced, ER-positive or PgR Positive Breast Cancer: Surgical Oophorectomy versus the LH-RH Analog, Zoladex, Phase III Intergroup

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC;  
CPT Scott Martin, MC; LTC Lawrence Sakas, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words:

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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**OBJECTIVE:** To determine the response rate and response duration and survival associated with either medical or surgical castration in advanced breast cancer in premenopausal patients.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive an oophorectomy or receive a monthly SQ injection of zoladex until disease progression. At the time of disease progression patients will be offered the other arm of treatment (for example, zoladex patients will be offered oophorectomy).

**PROGRESS:** No. of Subjects Enrolled - To Date: 0    Reporting Period: 0

This study remains open; although, we have no patients enrolled to-date.

Detail Summary Sheet

Prot No: SWOG 8695(90)	Status: Terminated
TITLE: A Randomized Comparison of Hydroxyurea versus 5-FU Infusion and Bolus Cisplatin as an Adjuvant to Radiation Therapy in Patients with Stages II-B, III and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Terminate

**OBJECTIVE:** To determine whether hydroxyurea or the combination of 5-Fluorouracil and cisplatin is superior as a potentiator of radiation therapy in advanced cervical carcinoma

**TECHNICAL APPROACH:** Patients are randomized to receive hydroxyurea by mouth twice a week during radiation or to receive cisplatin bolus plus a 5FU infusion during radiation therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

A total of 387 patients have been entered on this study, so it was terminated having reached its accrual goal. Results have not yet been reported.

Detail Summary Sheet

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Prot No: SWOG 8710(89) Status: Ongoing

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TITLE: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC plus Cystectomy in Patients with Locally Advanced Bladder Cancer

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; COL Martin Dresner, MC;  
CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: cystectomy;

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Continue

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OBJECTIVE: To compare the survival of patients with locally advanced bladder cancer treated with either cystectomy alone or cystectomy plus chemotherapy with M-VAC (Methotrexate, Vinblastine, Adriamycin and Cisplatin).

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive 1) cystectomy alone or 2) 3 cycles of M-VAC chemotherapy and then cystectomy.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

The one TAMC patient enrolled was randomized to the chemotherapy arm and had a good response to chemotherapy. He has had his surgery and is doing well on a recent followup visit. Nationally 130 patients have been entered. The only information available is that toxicity has been very tolerable with the only serious toxicity being transient leucopenia.

Detail Summary Sheet

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Prot No: SWOG 8711(89) Status: Ongoing

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TITLE: A Study of Reproductive Function in Patients with Testicular Cancer

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Principal Investigator: COL Jeffrey L. Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; COL Martin L. Dresner, MC;  
MAJ Marianne Young, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: testicular cancer;

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts: None    Decision: Continue

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**OBJECTIVE:** To evaluate the natural history of seminal fluid and hormone parameters in patients with testicular cancer after orchiectomy and after other treatments such as retroperitoneal node dissection, chemotherapy, and radiation therapy.

**TECHNICAL APPROACH:** Patients agreeing to participate will have semen analysis beginning after orchiectomy and these will occur every 3 months for 3 years then every 6 months out to 5 years. Testosterone and FSH blood levels will also be done but only half as often as the semen analysis.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3      Reporting Period: 0

There are no data available yet on this natural history study.

Detail Summary Sheet

Prot No: SWOG 8736(88)	Status: Ongoing
TITLE: Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Non-Hodgkin's Lymphoma;	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: To compare the survival rates and toxicity of two curative approaches in patients with localized (stage I & II), intermediate or high grade non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive either 1) 8 cycles of chemotherapy (CHOP) or 2) 3 cycles of CHOP and then 4000 rads of radiation to the involved area.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently after some administrative delays. So far 200 patients have been entered nationally on this study. There are no results yet but there have been no deaths due to toxicity.

Detail Summary Sheet

Prot No: SWOG 8789(89)	Status: Terminated
TITLE: A Randomized Study of Etoposide + Cisplatin and Etoposide + Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: etoposide; cisplatin; carboplatin (CBDCA);	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Terminate

**OBJECTIVE:** To determine the differences in response rate, time to relapse and survival between two active chemotherapy regimens, VP-16 plus Cisplatin and VP-16 plus Carboplatin for good risk patients with germ cell tumors.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive either 1) VP-16 plus Cisplatin IV every 3 weeks for 4 cycles or 2) VP-16 plus Carboplatin IV every 4 weeks for 4 cycles.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

The one Tripler patient was randomized to cisplatin and VP-16 and has gone into a complete remission and has finished treatment. Nationally, 106 patients have been entered; the study has been terminated. Results should be available soon.

Detail Summary Sheet

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Prot No: SWOG 8791(89) Status: Terminated

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TITLE: Adjuvant Trial of Soft Tissue Sarcoma, Phase III

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
LTC Y-T Margaret Lee, MC; MAJ Luke M. Stapleton, MC;  
MAJ Marianne M. Young, MC; CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: adriamycin; ifosfamide; mesna

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts:    Decision: Terminate

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**OBJECTIVE:** Patients who have a high grade (Grade III) soft tissue sarcoma completely removed surgically have about a 25% 5-year survival. This study seeks to improve this statistic.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive either 1) chemotherapy with Adriamycin, DTIC, Ifosfamide and Mesna given continuously IV over 4 days in the hospital every 3 weeks for 6 cycles or 2) no treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Only two patients were entered on this study nationally, apparently due to lack of interest in the study. Due to prior accrual, the study was terminated.

Detail Summary Sheet

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Prot No: SWOG 8793(88) Status: Ongoing

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TITLE: Randomized Phase III Evaluation of Hormonal Therapy vs. Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy

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Principal Investigator: COL Jeffrey L. Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: hormonal therapy; pelvic lymphadenectomy; radical prostatectomy

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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**OBJECTIVE:** To compare the time to progression and the survival time for patients with resected stage D1 (positive lymph nodes) prostate cancer when they receive immediate hormone therapy vs. hormone therapy when the disease progresses.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will be assigned to receive hormone therapy or observation. If they are assigned to the hormone therapy arm, the patient may choose either orchiectomy or zoladex (a hormone which given qmon SQ produces castrate testosterone levels and has no serious side effects).

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study is ongoing. No data is available yet, except that 42 patients have been entered so far.



Detail Summary Sheet

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Prot No: SWOG 8795(89) Status: Ongoing

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TITLE: Randomized Prospective Comparison of Bacillus Calmette-Guerin (BCG) and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder with DNA Flow Cytometric Analysis, Phase III

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Principal Investigator: COL Jeffrey L. Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; COL Martin L. Dresner, MC;  
CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: bacillus calmette-guerin (BCG); mitomycin-C;

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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**OBJECTIVE:** To compare the efficacy of Bacillus Calmette-Guerin (BCG) in preventing recurrence of superficial transitional cell carcinoma of the bladder with that of mitomycin-C.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive BCG intravesically weekly for 6 weeks then, beginning on week 8, monthly for 11 more treatments, or to receive mitomycin-C intravesically on the same schedule.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study is ongoing and there is no data available yet, except that 275 patients have been entered to date.

Detail Summary Sheet

Prot No: SWOG 8805(88)	Status: Ongoing
TITLE: Neoadjuvant Cisplatin and VP-16 Plus Concurrent Chest and Brain Irradiation for Patients with Stage III Non-Small Cell Lung Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; MAJ Marianne M. Young, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Cisplatin; VP-16;	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

OBJECTIVE: To assess the response rate, resectability rate and, ultimately, survival in patients with locally advanced non-small cell lung cancer treated with simultaneous chemotherapy and radiation prior to assessment for possible surgery. The benefit of prophylactic cranial radiation will also be examined.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 2 cycles of Cisplatin and VP-16 plus simultaneous chest and cranial radiation therapy. If they are then considered resectable, they will then have a thoracotomy with resection.

PROGRESS: No. of Subjects Enrolled - To Date: 1    Reporting Period: 0

The one TAMC patient entered on this study so far has done extremely well with all of his tumor (except one microscopic focus) disappearing after chemotherapy and radiation. He is doing well off all treatment. Nationally, there are no data available yet, except that 98 patients have been entered and there has been one death due to toxicity (infection).

Detail Summary Sheet

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Prot No: SWOG 8809(89) Status: Ongoing

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TITLE: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas

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Principal Investigator: COL Jeffrey L. Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; MAJ Marianne M. Young, MC; CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: ProMACE-MOPP;

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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**OBJECTIVE:** To determine the response rate and survival of low grade lymphoma patients treated with ProMACE-MOPP. Also to compare the disease-free survival in these patients who receive alpha interferon after chemotherapy compared to those who receive only the chemotherapy.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive 6 cycles of ProMACE-MOPP (followed by limited field radiation if complete remission is not achieved with the ProMACE-MOPP) and then be randomized to receive or not receive low dose alpha interferon 3 times a week subcutaneously for 2 years.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2 Reporting Period: 0

The one Tripler patient did very well with the chemotherapy and is now in a complete remission. He was just randomized to receive the interferon. The other patient is too early to assess. Nationally, 219 patients have been entered; there have been four toxic deaths (infection).

Detail Summary Sheet

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Prot No: SWOG 8810(88) Status: Ongoing

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TITLE: Six Courses of 5-FU and Cis-platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinomas of the Head and Neck, Phase II

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: squamous cell carcinomas;

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Funding: FY 90:                      FY 91:                      Periodic Review Date: Sep 91  
Gifts: None    Decision: Continue

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OBJECTIVE: To determine if 6 cycles of Cis-platinum plus 5-FU will result in more complete remissions of locally advanced head and neck cancer than 3 cycles.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 3 cycles of Cis-platinum plus 5-FU. Patient who then achieve at least a partial remission (50% or more tumor shrinkage) will get 3 additional cycles. With less than partial, come off study.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has opened recently. There is no data available yet, except that 63 patients have been entered.

Detail Summary Sheet

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Prot No: SWOG 8812(89) Status: Ongoing

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TITLE: Treatment of Limited Small Cell Lung Cancer with Concurrent  
Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent  
Randomization to Maintenance Interferon or No Maintenance

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS;  
LTC Lawrence Sakas, MC; MAJ Marianne M. Young, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: GM-CSF

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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**OBJECTIVE:** To determine if alpha interferon given after induction chemotherapy and radiation prolongs survival in patients with limited small cell lung cancer. Also this study seeks to determine if GM-CSF will ameliorate the myelosuppression that occurs during induction therapy.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to either receive or not receive maintenance interferon 3 times a week SQ for 2 years after 6 cycles of chemotherapy with radiation with or without GM-CSF.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and there are no data available yet, except that 186 patients have been entered and there was one toxic death due to infection.

Detail Summary Sheet

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Prot No: SWOG 8857(89) Status: Terminated

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TITLE: Alternating Cisplatin/VP-16 with Continuous CAV and Consolidation  
Chemotherapy for Extensive Small Cell Lung Cancer with PCI for Complete  
Responders

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse,MC; MAJ Luke M. Stapleton,MC;  
CPT Scott Martin, MC; LTC Lawrence Sakas, MC;  
MAJ Marianne Young, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words:

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Funding: FY 90:           FY 91:           Periodic Review Date: Sep 91  
Gifts:                    Decision: Terminate

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OBJECTIVE: To determine the response rate and survival in patients with small cell lung cancer given a new chemotherapy regimen which uses standard drugs but at higher doses.

TECHNICAL APPROACH: Patients agreeing to participate in the study will all receive cytoxan, adriamycin and vincristine alternating with cisplatin/VP-16 at 4 week intervals. After 16 weeks (i.e., 4 cycles) the patients will be restaged. Patients with no tumor then will receive one more cycle of each regimen (i.e., 6 cycles total) and get prophylactic brain radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 0   Reporting Period: 0

This study was terminated as it reached its accrual goal (45 patients). No results have been released yet.

Detail Summary Sheet

Prot No: SWOG 8892(89)	Status: Ongoing
TITLE: A Study of Radiotherapy with and without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: nasopharyngeal cancer;	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts: None	Decision: Continue

**OBJECTIVE:** To compare the complete response rate and survival of patients with Stage III of IV Nasopharyngeal cancer treated with definitive radiation versus those treated with definitive radiation plus Cisplatin.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive either 1) radiation (7,000 rads over 7 weeks) or 2) the same radiation plus 3 doses of concurrent Cisplatin (at 3 week intervals).

**PROGRESS:** No. of Subjects Enrolled - To Date: 1    Reporting Period: 1

The TAMC patient entered on the study has had a complete remission of his tumor and is doing well. Nationally, 18 patients have been entered to date and there have been no toxic deaths.

Detail Summary Sheet

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Prot No: SWOG 8894(89) Status: Ongoing

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TITLE: A Comparison of Bilateral Orchiectomy With or Without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D2 Prostate Cancer

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators:

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words:

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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OBJECTIVE: To compare the survival of patients with metastatic (ie, D2) prostate cancer who undergo 1) a bilateral orchiectomy plus take a placebo or 2) a bilateral orchiectomy plus flutamide (an anti-androgen).

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to undergo 1) a bilateral orchiectomy and take placebo or 2) a bilateral orchiectomy and take flutamide.

PROGRESS: No. of Subjects Enrolled - To Date: 2    Reporting Period: 1

This study opened recently and there are no data available, except that 403 patients were entered. One Tripler patient has had disappearance of all his bone pain, and the other patient has had pain relief.

Detail Summary Sheet

Prot No: SWOG 8896(90)	Status: Terminated
TITLE: Protocol for Surgical Adjuvant Therapy of Rectal Carcinoma: A Controlled Evaluation of a) Protracted Infusion 5-FU as a Radiation Enhancer and b) 5-FU Plus Methyl-CCNU Chemotherapy	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: rectal carcinoma	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Terminate

**OBJECTIVE:** To compare the recurrence rates and survival in patients having potentially curative resections of Astler-Coller Stage B2 and C rectal cancer treated with sequential chemotherapy and radiation therapy using 5-FU as a radiation enhancer given either by simple IV bolus or by protracted venous infusion concomitant with radiation therapy.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized post-op to receive either 1) 2 5-day cycles of 5-FU 5 weeks apart and then radiation therapy to the pelvis beginning on day 64. Three days of 5-FU will also be given on the first and 5th week of radiation. Finally, 5-FU will be given again for 2 5-day cycles beginning 28 days after radiation is completed or 2) the same treatment as #1 but with constant IV infusion 5-FU during all of radiation therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0    Reporting Period: 0

This study has been terminated after accruing 165 patients. Results should be available soon.

Detail Summary Sheet

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Prot No: SWOG 8899(88) Status: Ongoing

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TITLE: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Observation Following Curative Resection in Selected Patients with Duke's B2 or C Colon Cancer

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: leucovorin;

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Funding: FY 90: FY 91: Periodic Review Date: Sep 91  
Gifts: None Decision: Continue

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OBJECTIVE: To determine if surgery plus either 5-FU and low dose Leucovorin or 5-FU and high dose Leucovorin will result in improved survival over surgery alone in resected Duke's B2 and C colon cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized post-operatively to receive 1) 5-FU plus low dose Leucovorin IV push Day 1-5 q4-5 weeks x 6 cycles, or 2) 5-FU plus high dose Leucovorin IV over 2 hours weekly for 6 of each 8 weeks for 24 doses, or 3) no chemotherapy.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 2

This study is still open but has been just changed with deletion of the "no chemotherapy" arm and addition of two other arms (one with 5-FU plus levamisole and another with 5-FU plus levamisole plus leucovorin). These changes occurred out of the results of a large intergroup study showing better survival in these patients given 5-FU plus levamisole or leucovorin versus patients given no treatment.

Detail Summary Sheet

Prot No: SWOG 8900(89)	Status: Ongoing
TITLE: Randomization Trial of VAD and VAD/Verapamil for Refractory Multiple Myeloma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS. LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: vincristine, adriamycin, dexamethasone, verapamil	
Funding: FY 90:	FY 91:
Gifts: None	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine the response rate and response duration to chemotherapy alone (VAD) and to chemotherapy (VAD) plus Verapamil in multiple myeloma patients who have failed previous chemotherapy.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive VAD given as a 4 day IV infusion or to receive the same VAD plus p.o. Verapamil.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

There is no data available yet.

Detail Summary Sheet

Prot No: SWOG 8905(89)	Status: Ongoing
TITLE: Phase II/III Study of Fluorouracil (5-FU) and Its Modulation in Advanced Colorectal Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

OBJECTIVE: To determine and compare the response rates of 5-fluorouracil given by different schedules and/or with biochemical modulators to patients with advanced colorectal cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 5-FU by one of seven schedules. Those schedules involve infusional or IV push 5-FU with or without leucovorin or PALA.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There is no data available yet.

Detail Summary Sheet

Prot No: SWOG 8906(90)	Status: Ongoing
TITLE: Evaluation of Merbarone in Hepatoma, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: hepatoma	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To evaluate the response rate and response duration of advanced hepatomas treated with merbarone.

**TECHNICAL APPROACH:** Patients agreeing to participate will all receive merbarone by continuous IV infusion for 5 days with these cycles repeated every 3 weeks until the patient shows tumor progression. A central line (Hickman or Port-a-cath) is placed for these infusions.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Sixteen patients have been entered on this study to date, but information about response rate has been released.

Detail Summary Sheet

Prot No: SWOG 8910(90)	Status: Ongoing
TITLE: Evaluation of Low Dose Continuous 5-Fluorouracil (5-FU) and weekly Cisplatin (CDDP) in Advanced Adenocarcinoma of the Stomach, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: To determine the response rate and toxicity of low dose continuous 5-FU and weekly cis-platinum in patients with advanced adenocarcinoma of the stomach.

TECHNICAL APPROACH: Patients on this study receive continuous low dose 5FU from a constant infusion pump through a central line (Hickman catheter). They also receive low doses of cisplatin weekly until they evidence tumor progression.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

The only information available is that 24 patients have been entered to date.

Detail Summary Sheet

Prot No: SWOG 8912(89)	Status: Completed
TITLE: Evaluation of Fazarabine in Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:            FY 91:	Periodic Review Date: Sep 91
Gifts:	Decision: Completed

**OBJECTIVE:** To determine the efficacy of Fazarabine in the treatment of recurrent head and neck cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive fazarabine IV over 45 minutes for 5 days every 4 weeks.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1    Reporting Period: 0

This study has been completed and no partial or complete responses were seen in the 18 patients entered nationally. The one TAMC patient had only a short-lived minor response. It is concluded that this drug is not active in head and neck cancer.

## Detail Summary Sheet

Prot No: SWOG 8917(90)	Status: Ongoing
TITLE: 5-Fluorouracil, Leucovorin and Roferon-A in Advanced Colorectal Cancer, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine the response rate of advanced colorectal cancer to a combination of 5-fluorouracil, leucovorin and Roferon-A (interferon).

**TECHNICAL APPROACH:** Patients agreeing to participate will all receive 5-fluorouracil plus leucovorin IV push daily for 5 days every 4 weeks for 2 cycles then every 5 weeks thereafter. Simultaneously they will receive interferon (Roferon-A) subcutaneously three times each week.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study just opened and there are no data available yet, except that 32 patients have been entered nationally to date.

Detail Summary Sheet

Prot No: SWOG 8936(91)	Status: Ongoing
TITLE: Evaluation of Piroxantrone in Gastric Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To assess the response rate and duration of response of advanced gastric carcinoma to piroxantrone.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive piroxantrone IV over 1 hour every 3 weeks until their tumor shows signs of increase in size.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

The patient on this study did not respond to piroxantrone but tolerated it well.

Detail Summary Sheet

Prot No: SWOG 8939(90)	Status: Ongoing
TITLE: Evaluation of Merbarone in Colorectal Cancer, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: colorectal cancer	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To evaluate the response rate and response duration in patients with metastatic colorectal carcinoma treated with merbarone.

**TECHNICAL APPROACH:** Patients agreeing to participate will all receive merbarone by continuous IV infusion for 5 days with these cycles repeated every 3 weeks until the patient shows progression of the tumor. A central line (i.e., Hickman or Port-a-cath) is placed for these infusions.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start; there is no data available. No patients have been enrolled in this study.

Detail Summary Sheet

Prot No: SWOG 8940(90)	Status: Ongoing
TITLE: A Phase I Study of the Combination of Recombinant Human Interleukin 1-Beta, Etoposide and Carboplatin in Patients with Metastatic Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To determine the maximum tolerated dose of recombinant human interleukin 1-beta in cancer patients receiving the combination of carboplatin and etoposide and to determine the tumor response to this 3 drug combination.

**TECHNICAL APPROACH:** Patients agreeing to participate will all receive monthly cycles of carboplatin (day 1) IV and etoposide (day 1, 2, 3) IV plus recombinant human interleukin 1-beta (given IV for 5 days starting on either the first or fifth day of chemotherapy). The first chemotherapy cycle, however, will not include the interleukin.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2 Reporting Period: 1

Of the two TAMC patients entered on this study, neither one had a partial or complete response, but both tolerated the therapy very well. No other data is available.

Detail Summary Sheet

Prot No: SWOG 8952(90)	Status: Ongoing
TITLE: Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

OBJECTIVE: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, survival and toxicities.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) MOPP/ABV every 28 days for 8 cycles or 2) ABVD every 28 days for 8 cycles.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 1

The two TAMC patients achieved complete remissions on treatment. The only other data available are that 47 patients have been entered nationally, to-date.

Detail Summary Sheet

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Prot No: SWOG 8957(90) Status: Ongoing

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TITLE: Feasibility Trial of Post-Operative Radiotherapy + Cisplatin Followed by Three Courses of 5-FU + Cisplatin in Patients with Resected Head and Neck Cancer, Phase II

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators:

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words:

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Funding: FY 90:            FY 91:            Periodic Review Date: Sep 91  
Gifts:                            Decision: Continue

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OBJECTIVE: To evaluate the feasibility of administering 3 courses of chemotherapy to resected head and neck cancer patients who have received cisplatin and radiation post-operatively.

TECHNICAL APPROACH: Patients agreeing to participate will all receive cisplatin once every 3 weeks for 3 doses during post-operative radiation therapy and then receive cisplatin plus 5-FU every 3 weeks for 3 doses after radiation therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1    Reporting Period: 1

The only national data available is that 11 patients have been entered, to-date. The TAMC patient has been doing well with no relapse so far.

Detail Summary Sheet

Prot No: SWOG 8997(89)	Status: Ongoing
TITLE: Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words:	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91
	Decision: Continue

**OBJECTIVE:** To determine the response and duration of remission with cisplatin, etoposide and bleomycin versus cisplatin, etoposide and ifosfamide.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized one of the above 2 programs and receive 4 cycles of that program every 3 weeks.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study just opened recently and there is no data available yet, except that 39 patients have been entered nationally.

Detail Summary Sheet

Prot No: SWOG 9013(90)	Status: Ongoing
TITLE: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Local Regional Disease, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: esophagus; squamous carcinoma	
Funding: FY 90:	FY 91:
Gifts:	Periodic Review Date: Sep 91 Decision: Continue

**OBJECTIVE:** To compare the relapse rate and survival in patients with local regional esophageal cancer treated with surgery alone versus pre-op and post-op chemotherapy plus surgery.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive surgery alone or to receive 3 cycles of Cisplatin plus 5-FU then surgery, then 2 further cycles of Cisplatin plus 5-FU.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There have been no patients enrolled in this study.

Detail Summary Sheet

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Prot No: SWOG 9028(91) Status: Ongoing

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TITLE: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of 1) VAD to BAD/Verapamil/Quinine for induction; 2) Alpha-2b Interferon or Alpha-2b Interferon Plus Periodic VMCP for Remission Maintenance

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators:

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words:

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Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Continue

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**OBJECTIVE:** To compare the VAD Chemotherapy regimen to VAD plus chemosensitizers (verapamil/quinine). Also this study compares two maintenance regimens; interferon versus interferon plus chemotherapy (VMCP).

**TECHNICAL APPROACH:** In this study, patients receive a 4 day infusion of adriamycin and vincristine IV plus dexamethasone, and this is repeated every three weeks. They are randomized to receive or not to receive the chemosensitizers verapamil and quinine along with the IV chemotherapy. After achieving remission, they are randomized to receive interferon or interferon plus VMCP.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No data available yet.



Detail Summary Sheet

Prot No: SWOG 9040(90)	Status: Ongoing	
TITLE: Intergroup Rectal Adjuvant Protocol, A Phase III Study		
Principal Investigator: COL Jeffrey Berenberg, MC		
Associate Investigators:		
Department/Section: Medicine/Hematology-Oncology Service		
Key Words:		
Funding: FY 90:	FY 91:	Periodic Review Date: Sep 91
Gifts:		Decision: Continue

**OBJECTIVE:** To determine the relative efficacy of 1) 5-FU, 2) 5-FU and Leucovorin, 3) 5-FU and levamisole, and 4) 5-FU, leucovorin, and levamisole when combined with pelvic radiation in Dukes stage B2 and C rectal cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be randomized to one of four treatment arms. In arm one the patient will receive 5FU daily for one week, repeated monthly for six cycles plus receive pelvic radiation for six weeks (5,000 rads). In arm two, the patient will receive the same 5FU and radiation as in arm one, but get IV leucovorin with each 5FU dose. In arm three, the patients get the same 5FU and radiation as arm one but also receives levamisole p.o. with the first two and last two 5FU cycles. In arm four, the patient receives 5FU, radiation, leucovorin, and levamisole as in the above schedules.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

No data available nationally yet, but one TAMC patient took therapy for several months but then failed to return and was lost to follow-up.

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Commander US Army Health Care Studies and Clinical Investigation Activity ATTN: HSHN-I Fort Sam Houston, TX 78234-6060	2
Each US Army Medical Center Department of Clinical Investigation	1