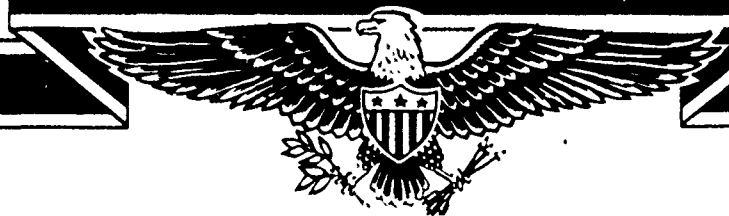


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Block 20. Abstract

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

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Detail Summary Sheet

Date: 29 Oct 90 Proj No: A-1-86 Status: Completed
 Title: Gravitational Effects on Hemodynamics in the Normotensive Primate and Effects of Pressure Suit Inflation

Start Date 26 Mar 86	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D. Robert Schwartz, MAJ, USAF MC Paul Celio, MAJ, USAF MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To describe the effects of the upright posture on waveform contour, regional PWV, Z_{in} and reflection along the aorta.

2) To determine the effect of pressure suit inflation in the upright posture on central systemic pressure, aortic and ventricular dimensions, and cardiac function.

Technical Approach: We evaluated the hemodynamic response to passive upright 70° tilt in 6 baboons to assess the effects of gravity on systemic compliance (C), characteristic aortic input impedance (Z_c) and peripheral resistance (R). High-fidelity catheters were used to record aortic root pressure and flow velocity which were digitized at 200 Hz. Thermodilution cardiac outputs were obtained. Data were fitted to a computer model (CM) of a 3-element Windkessel to determine Z_c , C, R. These were compared to conventional calculations (CC) of SVR, Fourier analysis for Z_c , and time constant of pressure decay for C.

Progress: The data showed that the CM fit of pressure and flow to determine Z_c , C, and R produced similar results to independent calculations. Gravitational stress to passive upright tilt had its most effect on C and little effect on Z_c and R.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-3-87 Status: Ongoing
 Title: Treatment of Chlorine Gas Inhalation Injury with Nebulized Sodium Bicarbonate Using a Sheep Model

Start Date 6 Jan 87	Est Comp Date:
Principal Investigator(vice Singletary) Carey Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Alan Morgan, CPT, MC
Key Words: Chlorine gas inhalation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 4005.92
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine the effect of treatment of chlorine gas inhalation injury with nebulized 5% sodium bicarbonate solution, using a sheep model.

Technical Approach: In Phase I, degree of injury induced by chlorine gas will be determined by exposing 10 subjects to chlorine gas, 500 ppm, for various periods of time. Subjects will be anesthetized, intubated and exposed to chlorine gas by insufflation technique as described under Phase II, with arterial blood gas determinations every 30 minutes following exposure for 2 hours. Following chlorine exposure, subjects will be observed for 24 hours, then sacrificed and necropsy performed.

In Phase II, subjects will be divided into 3 groups of eight sheep each. Group A will be exposed to chlorine gas, 500 ppm, for a period of time as determined in Phase I, followed by nebulized normal saline for 5 min. Group B will be exposed to chlorine gas, 500 ppm, for the same period as for Group A, followed by 5% sodium bicarbonate solution for 5 minutes. Group C will not be exposed to chlorine gas, but will be given nebulized 5% sodium bicarbonate solution for 5 minutes. Groups A and B will begin treatment 30 minutes post chlorine exposure.

Progress: Bench research has been completed. Final paper for publication in draft form with statistical gathering phase near completion.

Detail Summary Sheet

Date: 28 Aug 90 Proj No: A-12-87 Status: Completed
 Title: Hemodynamic Effects of Anesthetic Induction with Ketamine or Etomidate in Hypovolemic Swine

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator (vice Knight) Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Kevin Olson, CPT, MC John Ward, Ph.D.
Key Words: Hypovolemia	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1166.73
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): Phase I - To determine which anesthetic induction agent provides optimal hemodynamic stability in the presence of acute hypovolemia secondary to hemorrhage.

Phase II - To evaluate and compare the effects of Thiopental and Ketamine in a hypovolemic swine.

Technical Approach: Sixteen swine were instrumented with arterial and venous catheters, a Swan Ganz catheter, a Konigsburg ventricular micromanometer and a pair of sonomicrometer crystals in the left ventricular A-P axis for measurement of ventricular dimension changes during the cardiac cycle. Baseline cardiovascular data were collected after which the animals were splenectomized to minimize autotransfusion and the animals were hemorrhaged to a mean arterial pressure of 40 mm Hg. After a recovery period, measurements were repeated. The animals then received either Thiopental or Ketamine 6 mg/kg with subsequent measurements being performed at 1, 5, 15 and 30 minutes after injection.

Progress: Although both drugs depressed blood pressure and cardiac output initially, the mechanisms of these effects were different. Thiopental but not Ketamine appeared to exert its effects by depression of myocardial contractility. By the 30 minute measurement, both study groups had recovered to baseline levels.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-13-87 Status: Continue
 Title: A Comparison of the Effects of Resuscitation from Hemorrhagic Shock with Normal Saline, Hetastarch, Whole Blood, and Hypertonic Saline on Intracranial Pressure, Intracranial Compliance and Cerebral Metabolism

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator James M. Lamiell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery	Associate Investigators: David W. Mozingo, CPT, MC Danny Williams
Key Words: Shock, hemorrhagic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1532.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To establish a pig model of combined hemorrhagic shock and closed head injury, a combination common to both the battlefield and the emergency room.

2) To determine the effect on ICP and cerebral metabolism of using hemodynamic markers (BP, CVP, PAOP) as end points of fluid resuscitation in shock.

3) To compare the effects of fluid resuscitation with different solutions (whole blood, hetastarch, normal saline, and hypertonic saline) on ICP, intracranial compliance and cerebral metabolism in hemorrhagic shock with epidural mass.

Technical Approach: Following induction of adequate anesthesia, bilateral twist drill holes will be placed in the temporo-parietal regions of the skull. A Fogarty balloon catheter will be placed in the right parietal epidural space and an ICP monitor inserted through the left twist drill hole into the subarachnoid space. Baseline ICP and arterial pressure will be obtained. A pressure-volume curve will be generated utilizing the epidural balloon catheter (EBC). The inflection point (Pi) of this curve will be determined and recorded.

Progress: This study has been placed on hold temporarily. Experiments will resume in the near future.

Detail Summary Sheet

Date: 27 Sep 90 Proj No: A-1-88 Status: Completed
 Title: The Effect of Lysine on Substance P in Guinea Pigs

Start Date 2 Dec 88	Est Comp Date:
Principal Investigator Eleanor Ayala	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the in vivo effect of topical applications of L-lysine on substance P in guinea pigs.

Technical Approach: As outlined in the protocol. Male Hartley guinea pigs have been treated. Three days post treatment, tissue biopsies of inoculated sites and dorsal root ganglia (DRG) have been collected from each animal for immuno-histochemical detection of substance P (SP) with a Biotin-strep avidin tagged monoclonal antibody to SP.

The method of Tuchscherer and Seybold for the sectioning of tissue on the microtome was used. However, because it is difficult to recover 100% of the sectioned tissue and, because there appeared to be an uneven distribution of neurons in the kidney shaped DRG, an examination of every third tissue section was not an option.

Progress: Nine animals - 4 L-lysine treated, 2 SP treated, 1 CAP treated and 2 untreated - were studied. Although the sites did wheal and flare and dissipate within 30 minutes when the animals were given cutaneous injections of SP or CAP, the animals did not scratch, bite, or rub the injected sites. Approximately 100 sections were cut from each of the 56 DRGs and 10 tissue biopsies collected from each animal. For some DRGs, the numbers of SP stained cells per section varied as little as 100 cells; however, for others the numbers increased by as much as 300-500 as deeper sections were cut. Similar results were obtained from the DRGs of lysine treated and untreated animals. The DRGs of SP and CAP treated animals contained few SP stained cells. It was concluded that the techniques employed were inadequate to achieve statistical significance.

Detail Summary Sheet

Date: 20 Sep 90 Proj No: A-3-88 Status: Ongoing
 Title: Evaluation of Uncemented Canine Hip Prosthesis

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: William Ehler, D.V.M., Wilford Hall Arnold Penix, MAJ, USAF MC David L. Danley, MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): To develop and refine the techniques of uncemented hip arthroplasty in dogs and evaluate the remodelling of bone around the femoral stem of a titanium prosthesis.

Technical Approach: As outlined in the Company protocol.

Progress: Recommend continuation of study pending availability of appropriately sized subjects. Single subject study to date will be evaluated October 1990.

Detail Summary Sheet

Date: 29 Nov 90 Proj No: A-4-88 Status: Ongoing
 Title: A Conscious Baboon (Papio anubis) Model to Study Ventricular Pressure-Volume Relations and Ventricular/Vascular Coupling in Altered Gravitational Environments.

Start Date 14 Apr 88	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: James R. Hickman, COL, USAF MC Bernard J. Rubal, Ph.D. Paul Celio, M.D. Curtis White John Ward, Ph.D.
Key Words:	
Accumulative MEDCASE Cost: \$75,000.00	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) Develop a conscious, tethered or lightly sedated, nonhuman primate model conducive to the study of ventricular/vascular hemodynamics using inductance telemetry in flight.

2) Describe ventricular pressure-volume relations and ventricular/vascular coupling supine (zero Gz, Igx) upright (1Gz, zero Gx), 1Gz environments and in microgravity or zero G environments.

2) Assess hemodynamic responses to a high flow, computer-driven pulsatile fluid filled anti-G suit with standard G-gated pulsations vs ECG-gated pulsations.

Technical Approach: Transducers will be applied via thoracotomy. Initial animals will use exteriorized cables. Animals will be trained to accept the tilt table. Pressure flow and crystal dimensions will be collected and converted real time.

Progress: Animal model has been developed and tilt studies have been performed. Centrifuge studies will begin soon. KC-135 flights schedules for January and May 1991.

Detail Summary Sheet

Date: 28 Aug 90 Proj No: A-5-88 Status: Completed
 Title: Use of a Swine Model for Evaluation and Training with the OHMEDA PAC Vaporizer (Draw-over Anesthesia Device)

Start Date 9 May 88	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Kevin Olson, CPT, MC Richard Peterson, CPT, MC Donald Fox, CPT, MC Emil J. Menk, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To gain experience with the use of this anesthesia delivery system in swine model and acquire physiological data that would be useful in anticipating its performance in human patients.

2) To provide on-going training and familiarization to military anesthesiologists and anesthetists with anesthesia equipment designed for the field environment.

Technical Approach: Fifteen swine were anesthetized with the three anesthetic agents in room air (21% oxygen) and with 1 L/m of supplemental oxygen added to the inspired mixture. Trials of ethrane, halothane, and isoflurane with controlled and spontaneous ventilation were performed. Both the agent specific and universal vaporizers were evaluated under these conditions.

Progress: Both the agent specific and universal vaporizers performed within specifications. Use of controlled ventilation enhanced oxygenation both with room air and supplemental oxygen because of the control of carbon dioxide levels. However, anesthetic delivery was enhanced with controlled ventilation such that a relative anesthetic overdose could occur if the operator was unaware of this information. Spontaneous ventilation with room air resulted in poor

A-5-88 (Continued)

oxygen levels in a significant number of animals. This deficit was easily corrected with the addition of oxygen or controlling ventilation or both.

A large degree of variability was detected in anesthetic concentrations between subjects when controlled ventilation was used. The devices were originally designed for use with spontaneous ventilation. It was found that a valve in the vaporizer outflow allowed a variable degree of backflow during controlled ventilation. Replacement of this mica valve with a more compliant teflon valve corrected this problem.

Also, we recommend use of a ventilator that generates a square wave rather than the sine wave that approximate spontaneous ventilation curves. This method proved the precision of vaporizer output for calibration.

Detail Summary Sheet

Date: 28 Aug 90 Proj No: A-6-88 Status: Terminated
 Title: Use of a Swine Model for Evaluation and Training with the PENLON Vaporizer (Draw-over Anesthesia Device)

Start Date 9 May 88	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Kevin Olson, CPT, MC Richard Peterson, CPT, MC Donald Fox, CPT, MC Emil J. Menk, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To gain experience with the use of this anesthesia delivery system in swine model and acquire physiological data that would be useful in anticipating its performance in human patients.

2) To provide on-going training and familiarization to military anesthesiologists and anesthesiologists with anesthesia equipment designed for the field environment.

Technical Approach: We will utilize the same approach as outlined in A-5-88.

Progress: The Penlon Oxford Miniature Vaporizer (OMV) has been well studied by other investigators and has seen widespread use throughout the world. Lessons learned from our experience with the PAC unit are equally applicable to the OMV as well. Consequently, further work and experience with the Penlon OMV was felt to be unnecessary and the protocol was terminated.

Detail Summary Sheet

Date: 28 Aug 90 Proj No: A-2-89 Status: Terminated
 Title: Comparison of Intravenous Antivenin vs Joint Irrigation in Treating
 Intra-articular Crotalus Atrox Venom Poisoning in a Rabbit Model

Start Date 6 Dec 88	Est Comp Date:
Principal Investigator Robert L. Norris, Jr., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: William Ehler, D.V.M. Carlin M. Okerberg, MAJ, VC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the degree of protection for articular cartilage and synovial membrane following intraarticular (IA) injection of C. atrox venom in a rabbit model using: (1) intravenously administered antivenin alone; (2) joint irrigation with normal saline alone; (3) intravneous antivenin combined with joint irrigation.

Technical Approach: As outlined in the study protocol.

Progress: This study was terminated due to REFRAID of the principal investigator.

Detail Summary Sheet

Date: 28 Aug 89 Proj No: A-3-89 Status: Terminated
 Title: Evaluation of Bone and Associated Soft Tissue Responses to a Resorbable Polymer Implant in Iatrogenic Proximal Tibial Fractures in Goats: A Pilot Study

Start Date 6 Dec 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Stephen J. Peoples, D.V.M. George D. Harrington, MAJ, MC R. Marvin Royster, MAJ, USAF MC John H. Cissik, COL, USAF BSC William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the fracture healing and general tissues responses to a resorbable polymer intramedullary implant in goats.

Technical Approach: The study will include an experimental group, composed of unilateral iatrogenic proximal tibial fractures with an intramedullary implant of the resorbable polymer, and a control group, composed of the same iatrogenic fracture but without the polymer implant. All fractures, experimental and control, will be stabilized by external casing. The responses of the bone and associated soft tissue and polymer degradation will be evaluated at three post-operative intervals.

Progress: This study was terminated by DuPuy/Dupont because of excessive delays in obtaining Air Force approval.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-7-89 Status: Completed
 Title: Histopathologic Features of Buried Vaginal Epithelium in the Rabbit

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To develop an animal model for buried vaginal epithelium and transcutaneous incorporation of nonabsorbable monofilament suture.

2) To objectively demonstrate the fate of buried vaginal epithelium and incorporated nonabsorbable monofilament suture.

Technical Approach: Nonabsorbable monofilament suture will be placed in a helical fashion through vaginal wall on both sides of the vagina. The ends of the suture will then be passed underneath the vaginal wall and anchored to the ipsilateral abdominal wall under mild tension. One suture will be placed on each side. A vaginal flap will be constructed on one side of the vagina and brought over the top of the helical vaginal suture already created. This buried vaginal epithelium and nonabsorbable monofilament suture knot will serve as the study specimen.

Progress: The results demonstrate that the buried vaginal flap maintains its vaginal epithelium without inclusion cyst development.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-8-89 Status: Ongoing
 Title: The Effect of Low Dose Dopamine on Renal Blood Flow Following Prolonged Renal Ischemia

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator (vice Ducey) James M. Lamiell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators: Glen E. Gueller, SFC Joseph P. Ducey, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the efficacy of low dose dopamine in enhancing renal blood flow (RBF) following unilateral renal artery occlusion in rabbits.

Technical Approach: RBF will be measured bilaterally throughout the study. Renal artery occlusion for 30 minutes will be achieved unilaterally using an hydraulic occluder. Animals will be divided into two groups. In Group A, dopamine will be infused at 2 micrograms/kg/min and RBF measured again, comparing the effect of dopamine on the normal and the post-ischemic kidney. Group B will receive D5W placebo. Cardiac output (CO) will be measured continuously using an aortic root probe so that RBF can be expressed as a percentage of CO as well as an absolute flow rate (ml/min). Hepatic artery flow also will be measured as a separate marker of DAS effect on splanchnic flow. Post-ischemic RBF will be compared between Groups A and B in terms of absolute flow and as a percent of CO. Left and right renal inulin clearance will be measured at baseline and after renal artery occlusion. Total clearance before and after occlusion will be compared as will relative clearance of the left and right kidneys.

Progress: Study temporarily on hold. Will begin investigation when staff available.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: A-9-89 Status: Ongoing
 Title: Cardiac Response to Semistarvation and Refeeding

Start Date 5 May 89	Est Comp Date:
Principal Investigator John A. Ward, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Eleanor A. Young, Ph.D., UTHSC-SA
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To participate in a comprehensive study of the effect of SS and RF on the gastrointestinal tract and the heart that will include measurement of cardiac Ca, K, P, Zn, Cu and Mg concentrations, histology of cardiac tissue, and detailed analysis of cardiac ultrastructure by electron microscopy.

2) To study semistarvation (SS) and subsequent refeeding (RF) in a systemic, controlled animal model, the rat.

3) To monitor cardiac function serially by screening electrocardiograms for arrhythmias.

Technical Approach: Obese rats, 480-540g, were divided into two groups: control 21-d (C21) and semistarvation 21-d (SS21). A nutritionally complete diet was received by C, while SS were pair-fed to C, receiving 20% of calories, but 100% of all essential nutrients. ECGs were recorded on day 1 and day 21. At sacrifice hearts were removed and weighed. RR, PR, QRS, and QT intervals were compared using ANOVA and Bonferroni corrected t-tests.

Progress: SS1 body weights decreased 17.7% ($p < 0.001$), while hearts weight 27.0% less than hearts of C21 ($p < 0.001$). RR intervals changed as shown in Table 1:

Table 1. RR Interval (msec)

Group	Day 1	Day 2	p
C21 (6)	157.2	153.2	NS
SS21 (5)	164.6	203.2	<0.01
P	NS	<0.01	

Obese rats exhibited a decreased heart mass and rate when on a semistarvation diet.

Detail Summary Sheet

Date: 27 Sep 90 Proj No: A-10-89 Status: Ongoing
 Title: Flow Cytometric Analysis of Guinea Pig Dorsal Root Ganglion Cells

Start Date 5 May 89	Est Comp Date:
Principal Investigator Eleanor Ayala, MT	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Janice Grassel, MT
Key Words:	David G. Burleson, LTC, MS
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2391.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To analyze guinea pig dorsal root ganglia cell populations on the basis of cell size, cytology, and peptide immunoreactivities by flow cytometric technique and to determine the distribution of substance P immunoreactive cells in the dorsal root ganglia of the guinea pig.

Technical Approach: The study will contain two parts. The first part will consist of experiments to characterize the DRG neuronal cell populations of the normal untreated GP by flow cytometric analysis and establish norms for that technique. The second set of experiments will characterize, by flow cytometric analysis, the DRG neuronal cell populations of the lysine treated GP for comparison with corresponding DRG C1-S1 of the controls. Characterization of the DRG neuronal cell population at the various segmental levels will include determination of the percent populations of large, intermediate, and small cells and the biochemical contents of the cells.

Progress: DRG cells from 16 guinea pigs have been collected, weighed, digested, fixed, stained for neuron specific enolase or for substance P and analyzed on a Coulter Epics Model 753 flow cytometer. Five thousand FALS gated FITC events were collected on each sample preparation analyzed. Histogram data was stored to disk for analysis and hard copies were made of histograms. An experiment employing double staining with FITC and PE for the two neuropeptides has been initiated for analysis on a BD FACS Star with LIS mode. Data are being analyzed by computer and results should establish the norms for analysis of DRG cells by flow cytometric technique.

Detail Summary Sheet

Date: 18 Jul 90 Proj No: A-11-89 Status: Completed
 Title: Physiologic, Anesthetic, and Mechanical Effects on Neurogenic Motor Evoked Potentials in a Porcine Model.

Start Date 12 Jun 89	Est Comp Date:
Principal Investigator Luke Short, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard E. Peterson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effects of individual physiologic factors (hypercarbia, hypocarbia, hypotension, and hypothermia) on the latency and amplitude of Neurogenic Motor Evoked Potentials (NMEP's).

Technical Approach: To study the effects of hypocarbia, hypercarbia, hypotension and hypothermia upon NMEP, eight pigs were subjected to changes in PCO₂ (10 mmHg increments, range 20 mm-70 mmHg), graded hypotension (MAP lowered in 10 mmHg increments, range 90 mm-30 mmHg), and hypothermia to 31 degrees centigrade. To study the effects of the commonly used inhaled anesthetic, 14 hogs were subjected to 1/4 MAC increments (up to 1/4 MAC) of Halothane, Isoflurane, and Enflurane as well N₂O (50% and 70%).

Progress: There was no significant effect of the wide range of PCO₂ alterations. Lowering MAP caused little change in latency but beginning at 60 mmHg a significant decrease in amplitude occurred and was 50% of baseline at 30 mmHg. Lowered temperature produced predictable increase in latency, but the effects on amplitude were variable. There was a predictable progressive decrease in amplitude with each of the potent inhaled agents with increasing 1/4 MAC multiples. At 1 MAC the response was obliterated for all agents except for 3 in the Enflurane group. There remained a small amplitude potential that was difficult to interpret in this subset of the Enflurane group. Both concentrations of N₂O (50% and 70%) cause substantial decreases in amplitude and little increases in latency.

A-11-89 (continued)

Conclusions: Significant effect of hypotension, hypothermia, and inhaled anesthetics on the latency and amplitude characteristics of the NMEP was shown. These results may have important ramifications on the interpretation of the NMEP response when there is a physiologic or anesthetic alteration either alone or in combination. These results in swine correlate with clinical experience in human subjects when inhalational agents are added to a narcotic based anesthetic.

Detail Summary Sheet

Date: 28 Aug 90 Proj No: A-12-89 Status: Ongoing
 Title: Bronchoalveolar Lavage as a Diagnostic Tool in Bacterial Pneumonia of Young Piglets

Start Date 10 Jul 89	Est Comp Date:
Principal Investigator Stephen Inscore, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$10,000.00 (AFSGO)
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine whether bronchoalveolar lavage (BAL) can reliably and accurately determine the etiology of acute bacterial pneumonia in young piglets when compared to lung biopsy as well as currently accepted modes of diagnosis.

Technical Approach: Twenty young piglets of either sex will be studied - 10 with and 10 without endotracheal intubation prior to BAL. Each animal will be infected blindly with one of two common bacteria causing acute pneumonia in children and serial chest x-rays taken until a pneumonic infiltrate develops. BAL will be performed using standard procedures in the uninfected, normal lung and then in the infected lung. Collected fluid will be processed in a standard manner and analyzed for total cell number, differential, gram stain and quantitative bacterial cultures.

Progress: No progress has been made due to lack of an adequate bronchoscope. The study will be started as soon as the bronchoscope is delivered.

Detail Summary Sheet

Date: 18 Jul 90 Proj No: A-13-89 Status: Completed
 Title: Effects of Ketamine, Isoflurane, Halothane, and Ethrane on Myocardial Contractility and Function in Hypovolemic Swine

Start Date 10 Jul 89	Est Comp Date:
Principal Investigator Sanford Silverman, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC John Ward, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): A comparison of hemodynamic, myocardial and biochemical effects of anesthetic levels of ketamine, halothane, ethrane, and isoflurane in normovolemic and hypovolemic swine.

Technical Approach: Sixteen acutely instrumented swine were mechanically ventilated with N₂O (70%) and O₂ (30%) and hemorrhaged to a mean arterial blood pressure of 40 mm Hg. After 15 minutes stabilization, ketamine (6 mg/kg) and thiopental (6 mg/kg) was administered as an intravenous bolus to stimulate the induction of anesthesia. Hemodynamic measurements from a pulmonary artery catheter were made at baseline and hemorrhagic states, and 1, 5, 15, and 30 minutes after drug administration. Cardiodynamics consisting of myocardial contractility (Ees) and left ventricular function were assessed from the end-diastolic pressure-dimension relationship (ESPDR) and pressure-dimension (PD) loops respectively. These cardiodynamics were generated from sonomicrometer crystals and a pressure transducer placed in the left ventricle.

Progress: Thiopental but not ketamine significantly depressed Ees ($P < 0.05$). Both anesthetics significantly increased end-diastolic dimension (Ded) and end-systolic dimension (Des). Thiopental increased mean pulmonary artery pressure (MPAP) and pulmonary vascular resistance (PVR). Ketamine increased PVR. Ketamine but not thiopental decreased cardiac index (CI) and increased systemic vascular resistance (SVR). Pulmonary capillary wedge pressure (PCWP) was significantly elevated by thiopental but not by ketamine. The PD loops obtained demonstrate similar pressure and dimension shifts for ketamine and thiopental, returning to their hemorrhaged state by 5 minutes.

A-13-89 (continued)

Conclusions: Both ketamine and thiopental depress cardiac function in hypovolemic swine, but thiopental has a greater myocardial depressant effect. Both anesthetics depress ventricular function with shifts of the PD relationship and increases in D_{ed} and D_{es} . Cardiac function returns to the hemorrhaged state by 5 minutes. Contractility is not the sole determinant of cardiac function and may not be adequate in assessing ventricular function in hypovolemic states. Assessment of the heart's interaction with vascular system utilizing the ESPDR and PD loops may be more useful in evaluating the effects of anesthetics in a hypovolemic model.

Detail Summary Sheet

Date: 25 Sep 90 Proj No: A-14-89 Status: Ongoing
 Title: Study of Feral Domestic Cats (Felis domestica) for Lyme Spirochetes at Fort Sam Houston and Camp Bullis, Texas

Start Date 10 Jul 89	Est Comp Date:
Principal Investigator	Facility
Nelson R. Powers, MAJ, MS	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Preventive Medicine Service	Erik Torring, CPT, VC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To evaluate the current and potential threat of Lyme disease in relation to feral domestic cats and fleas at FSH and Camp Bullis, TX.

Technical Approach: Serum samples will be submitted for serological testing for antibody response to Lyme borreliosis. Blood was drawn and fleas were collected from the stray feral cats which were held for the required three days. Collected specimens were submitted to the Bureau of Laboratories, Texas Department of Health, Austin, TX. Fleas and arthropods will be examined by direct microscopic examination and culture techniques. Collection of samples must be scheduled so that time requirements for mailing are taken into account so that they will be immediately processed upon arrival at the Texas Department of Health.

Progress: To date sampling for Lyme spirochetes from ectoparasites and analysis of serum for titers of lyme antibodies are still being conducted. This sampling program is to be completed within the next few months.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-1-90 Status: Ongoing
 Title: Evaluation of Cricothyrotomy Devices in Swine

Start Date 17 Nov 89	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare three commercially available cricothyroidotomy devices for ease of use, successful placement and damage to tracheal, laryngeal and esophageal structures.

Technical Approach: Swine utilized for other animal protocols will be randomized to receive one of three commercially available cricothyroidotomy devices prior to euthanasia. The person placing the device will complete an evaluation of the device and the proximal trachea, larynx and esophagus will be resected en-bloc for gross and histopathologic examination. The success rate, the time for placement, and a subjective evaluation of each device will be gathered and analyzed.

Progress: This study has been completed but remains open for completion of final report.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-2-90 Status: Ongoing
 Title: The Development of Adenocarcinoma of the Colon with a Two-Stage Vesico-Colonic Anastomosis

Start Date 17 Nov 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if there exists a similar risk of adenocarcinoma of the colon developing with a uretero-colo-colonic bowel anastomosis as with ureterosigmoidostomy.

Technical Approach: Animals will be randomized into treatment arms. One arm (USO) will undergo bladder patch uterosigmoidostomy. A second arm (two-stage) will undergo a similar procedure with interposition of a colonic segment. The incidence of dysplasia and adenocarcinoma of the colon will be compared between the two groups.

Progress: To date, histologic evaluation of animals undergoing one and two-stage vesicocolonic anastomoses has revealed no cases of adenocarcinoma. One animal underwent transrectal endoscopic biopsy but suffered a bowel perforation and expired. For this reason, biopsies will not be performed in future animals.

Detail Summary Sheet

Date: 29 Aug 90 Proj No: A-3-90 Status: Terminated
 Title: Gastrointestinal Dialysis: Does the Type of Charcoal Used Make a Difference?

Start Date 7 Feb 90	Est Comp Date:
Principal Investigator Calvin Bell, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Danny Williams
Key Words:	SSG Rene Cardona
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1301.60
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine if a charcoal with a high affinity (Norit A) is better than a charcoal with a high binding capacity (Actidose Aqua) in performing gastrointestinal dialysis in a blinded crossover animal study.

Technical Approach: Phase 1, the control phase, will consist of administration of aminophylline in a single intravenous bolus. Prior to administration of aminophylline each animal will be placed on a cardiac monitor. Phase 2 will consist of anesthetization, intubation and administration of aminophylline in the same dose as in phase 1; however, one hour prior to administration of the drug a 1g/kg dose of either Actidose Aqua or Norit A shall be administered through an orogastric tube. The personnel conducting the study will be blinded as to which type of charcoal is being administered. Phase 3 will consist of administration of the other type of charcoal in exactly the same setting.

Progress: This study was terminated due to failure of principal investigator to keep scheduled commitments for conducting his research.

Detail Summary Sheet

Date: 18 Sep 90	Proj No: A-4-90	Status: Ongoing
Title: Botulinum Toxin Detection by Mouse Bioassay		

Start Date 7 Feb 90	Est Comp Date:
Principal Investigator Michael Gray	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology and ALS	Associate Investigators: David Culak
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To establish and maintain a standing procedure for the mouse bioassay as a means for detecting Clostridium botulinum toxin in cultures, food products, serum and fecal specimens.

Technical Approach: Pairs of mice are selected and anesthetized with 2 ml of halothane in an enclosed glass container. The test suspension is injected IP into each of two mice using a 21 gauge, 1.25 inch needle. The mice recover from anesthesia within 1-2 minutes and are monitored on a daily basis up to 3 days.

Progress: Three clinical specimens were submitted to rule out Clostridium botulinum toxin requiring the use of 60 mice.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-5-90 Status: Ongoing
 Title: Production of Mouse Positive and Negative Control Slides for Use in Rabies FRA Test.

Start Date 7 Feb 90	Est Comp Date:
Principal Investigator David Culak	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology and ALS	Associate Investigators: Michael R. Gray
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To produce negative and positive control slides for use in the Rabies Fluorescent Antibody Test (FRA).

Technical Approach: Twenty-five, 3-5 week old mice are anesthetized with halothane and are injected intracranially (IC) with .03ml of CVS-11 rabies virus suspension utilizing a 1/4 inch, 27 gauge needle and tuberculin syringe. As mice exhibit symptoms of rabies and become moribund, they are euthanized by CO₂ asphyxiation. Brain and brain stem are collected, impression smears are prepared and held for future use.

Progress: A total of 45 mice were utilized this fiscal year for the described procedure. The prepared slides were acceptable for use in the FRA test for Rabies. This is a continuous requirement so future requests will be forwarded.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: A-6-90 Status: Completed
 Title: Experimental Evaluation of Various Suture Types and Sizes Used in
 Orchiopexy on Testicular Histology

Start Date 7 Mar 90	Est Comp Date:
Principal Investigator	Facility
Timothy Dixon, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Urology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To determine if there exist a correlation between suture type and size used in orchiopexies with the degree of intratesticular inflammation and abscess formation and effects on spermatogenesis.

Technical Approach: The incidence of poor outcome using suture sizes proportional to those used in human infants undergoing orchiopexy for undescended testis will be investigated. Sprague Dawley rats will be used to study the effects of rapidly absorbable, slowly absorbable and non-absorbable sutures of several sizes on testicular histopathology, intratesticular inflammation, abscess formation and effects on spermatogenesis.

Progress: Significant inflammatory response was observed in all suture types and sizes. Granulomatous orchitis was noted with extensive tubular destruction and reduction in spermatogenesis as compared to controls.

No suture size or type could clearly be recommended for use as a fixation suture but 5-0 chromic and 5-0 prodene resulted in the lowest inflammatory response. These histologic changes may be reflected in the diminished fertility associated with cryptorchidism and testicular torsion. From this data, we recommend adequate mobilization of the testis and placement of the testis within a dartos pouch without suture fixation when performing orchiopexy for the undescended testis.

Detail Summary Sheet

Date: 20 Sep 90 Proj No: A-7-90 Status: Ongoing
 Title: Clinical Investigation on the Biodegradation of Lactide-Based Polymers in Rabbits

Start Date 7 Mar 90	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators J. Tamai, CPT, MC Danny Williams SSG Rene Cardona
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the mechanical and biological behavior of biodegradable polymer rods synthesized at Smith and Nephew-Richards Medical Company after implantation in the dorsal muscle of rabbits.

Technical Approach: Thirty male rabbits will be used for the experiments. Four cylindrical rod samples will be implanted paraspinally in the dorsal musculature of each rabbit. Four thin circular discs will also be implanted by the side of the cylindrical implants for histological examination. The implantation site may be changed after mutual agreement but all animals will be treated identically.

Progress: Fifteen implants completed without problem. Lack of pathology support capability has been demonstrated. Study will continue until July 1991.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-8-90 Status: Terminated
 Title: A Comparison of Two Methods of Cardiac Output by Thermodilution:
 Baird/Driscoll Mechanical Injector vs. Manual Bolus Injection in the Swine Model

Start Date 7 May 90	Est Comp Date:
Principal Investigator Dennis M. Driscoll, CPT AN	Facility Brooke Army Medical Center
Dept/Svc Nursing Service Branch, ISR	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if cardiac output determination with the Baird/Driscoll mechanical injector will lower the degree of variability of measurements obtained using the manual bolus injection technique in normovolemic swine.

Technical Approach: Ten Yorkshire swine will be weighed, anesthetized with halothane, intubated and mechanically ventilated. An arterial catheter will be placed via cutdown for pressure monitoring and blood sampling. A Swan Ganz pulmonary artery catheter will be placed in the wedge position during continuous pressure monitoring. The balloon will be deflated and the pulmonary artery pressure wave form observed and validated. Baseline hemodynamic and pulmonary artery pressures, plus core temperature will be recorded. Each cardiac output determination will use 5 ml of room temperature 5% dextrose in water solution. The fluid will be injected through a CO set closed system. Three successive measurements will be obtained with each method of injection. An American Edwards Laboratory Cardiac Output computer will be used to gather digital data. To provide variety, the series will be done in alternate sequence first by Baird/Driscoll injector, then by manual bolus technique.

Progress: The preliminary findings show a statistical difference between the two methods. Further development and refinement of the mechanical injector is in progress. Following the refinement and production of a new prototype, evaluation will then be considered.

Detail Summary Sheet

Date: 25 Sep 90 Proj No: A-9-90 Status: Ongoing
 Title: Biosynthesis of Polyclonal Anti-peptide Antibodies in Rabbits

Start Date 1 Jun 90	Est Comp Date:
Principal Investigator Gerald Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To develop antibodies to specific conformational regions of the model protein believed to be important in enzyme function and stability to aid in analysis of this procedure for studying protein structure.

Technical Approach: To aid in the analysis of the conformation of the model protein through use of an indirect CELIA, polyclonal antibodies will be directed in rabbits. Approximately 5 ml of pre-immune sera will be obtained from an ear vein of each rabbit to use as a negative control to which to compare the subsequently obtained post-immunization sera for the production of anti-peptide antibodies. The procedure would require that the peptides be conjugated to a carrier to make them immunogenic and then addition of adjuvants to make an oil in water immunogen. This immunogen system would be injected intraperitoneally and intravenously on multiple occasions for a minimum of three immunizations.

Progress: Two rabbits were immunized with synthesized peptides conjugated to poly-l-lysine. The peptides were sequences corresponding to the 17 N-terminal amino acids of rhodanese and the interdomain sequence (15 amino acids) of rhodanese. These regions are conformationally important areas to which no monoclonal antibodies had been produced under protocol C-13-88. Site directed polyclonal antibodies are a useful alternative to MABs and can be used as conformational probes.

The rabbit immunized with the tether peptide has demonstrated a titer against both rhodanese and the immobilized tether peptide (but not the amino peptide) in excess of 1:1000. This rabbit is being boosted to achieve high titer antisera prior to exsanguination. The rabbit immunized with the amino peptide has only a marginal titer of antibody that detects either rhodanese or immobilized peptide. This rabbit and two additional rabbits are presently being immunized with increased doses of the immunogen in an attempt to initiate a specific immune response to the peptide.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: A-10-90 Status: Ongoing
 Title: An Evaluation of Neurogenic Motor Evoked Potentials (NMEP) and Spinal Cord Protection in the Swine Model

Start Date 1 Jun 90	Est Comp Date:
Principal Investigator Paul D. Mongan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Danny Williams SSG Rene Cardona
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,848.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the use of neurogenic motor evoke potentials (NMEPs) as a noninvasive intraoperative monitor of spinal cord protection during thoracic aorta surgery.

Technical Approach: This study will be conducted on 45 swine divided into three equal groups. Group one will serve as a control. Group two will have cerebrospinal fluid drainage in an attempt to improve spinal cord blood flow (SCBF). Group three will have CSFD combined with intrathecal papaverine to improve spinal cord protection. After a left thoracotomy the descending thoracic aorta will be clamped distal to the left subclavian artery and NMEPs will be monitored. After loss of the NMEPs the distal aorta will be reperfused at varying intervals. NMEPs will be monitored for return and correlation with immediate postoperative neurologic function.

Progress: Twenty-four swine have been studied. No reportable data are available at this time.

Detail Summary Sheet

Date: 29 Aug 90 Proj No: A-11-90 Status: Ongoing
 Title: Evaluation of Anti-Tumor Activity of Cimetidine in the Murine Transitional Cell Carcinoma Model

Start Date 30 Aug 90	Est Comp Date:
Principal Investigator William S. Boykin, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the response of an established murine transitional cell carcinoma line (MBT-2) to immunotherapy with an H2 receptor antagonist.

Technical Approach: One hundred twenty female C3H/HE mice will be randomized into four groups. Group 1 (controls) will be inoculated with 1×10^4 viable MBT-2 cells into the right hind limb. This group will receive no other therapy. Three days prior to inoculation group 2 will receive cimetidine added to drinking water for continuous consumption. Following inoculation with tumor line, as in controls, group 3 will be administered cis-platinum intraperitoneally on a weekly basis beginning on day 7 following inoculation. Three days prior to inoculation, group 4 will receive cimetidine continuously as in group 2. Following tumor inoculation, cis-platinum will be administered on a weekly basis as in group 3.

Progress: Cells were obtained from the University of Texas Health Science Center. Appropriate cell counts were evaluated and confirmed prior to injection. However, the viability of the injected cells was poor because tumor implantation and growth was much less than the near 100% rates. Corrective measures were taken to improve tumor implantation and growth by assessing cell viability with Trypan blue exclusion method and injecting the animals with 1×10^4 viable cells.

Detail Summary Sheet

Date: 25 Sep 90 Proj No: A-12-90 Status: Ongoing
 Title: Evaluation of Coumarin and 7-OH Coumarin in the Treatment of
 Transitional Cell Carcinoma.

Start Date 5 Jul 90	Est Comp Date:
Principal Investigator Timothy K. Dixon, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC M. Ernest Marshall, M.D. Michael Sarosdy, M.D. Scott Optenberg, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the response of transitional cell carcinoma to coumarin and 7-OH coumarin and evaluate if an immune response is present with this therapy.

Technical Approach: Part 1 requires 90 male syngeneic C3H mice which will be randomized into three groups. Group 2 will consist of 30 mice which will be inoculated in the right hind limb with 1×10^4 transitional cell carcinoma cells of the MBT-2 transitional cell carcinoma line. Group 2 will be similarly inoculated with 1×10^4 MBT-w cells and treated with daily intraperitoneal injections of 80 mg/kg coumarin until death from the tumor. Group 3 will be treated with daily intraperitoneal injections of 80 mg/kg 7-OH coumarin until death from the tumor. Part 2 attempts to establish the presence of immune modulation in therapy with coumarin.

Progress: Part 1 - Coumarin has resulted in 58.9% reduction in mean tumor volume compared to controls ($p = 0.000067$). 7-OH coumarin has not resulted in a significant change in tumor volume. Neither coumarin or 7-OH coumarin has resulted in a change in survival.

Part 2 - Surgical mortality in the mice resulted in group sizes that are too small to evaluate. Analysis of macrophages and NK cell activity in excised tumors are pending in Dr. Marshall's Biologic Response Modifiers Laboratory at the University of Cincinnati.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: A-13-90 Status: Ongoing
 Title: Effects of Propofol and Ketamine on Myocardial Contractility and Function in Normovolemic Swine

Start Date 5 Jul 90	Est Comp Date:
Principal Investigator Jeffrey J. Bauerle, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators: Danny Williams
Key Words:	SSG Rene Cardona Charles P. Kingsley, MAJ, MC John Ward, Ph.D.
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the hemodynamic and myocardial effects of anesthetic levels of propofol and ketamine in normovolemic swine.

Technical Approach: Pressure/diameter loops will be constructed from sonomicrometer data and ventricular pressure recordings. Alterations in contractility as evidenced by changes in end-systolic elastance in response to thes anesthetic agents will be described. Normovolemic animals will be studied in an effort to further evaluate the effects of propofol on the myocardium.

Progress: Approximately 10 normovolemic swine have been studied. Results so far show a decrease in end-systolic elastance in response to propofol. At this time we plan to study propofol in approximately 20 more normovolemic swine.

Detail Summary Sheet

Date: 18 Sep 90 Proj No: A-14-90 Status: Ongoing
 Title: Papilloma of Vaginal Cyst

Start Date 5 Jul 90	Est Comp Date:
Principal Investigator Michael H. Enghardt, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): Presentation of a previously unreported phenomenon with evaluation of pathology and histogenesis.

Technical Approach: The original tissue to be studied was fixed in buffered formalin and embedded in paraffin. The same processing will be undertaken with primary and secondary controls. Secondary controls consist of sections from two human sources provided by Dr. Valente including tissue from the mesosalpinx acquired during a tubal ligation and a human embryo. Fifteen day old rat embryos will be used as the primary control to determine whether or not the antibodies function in our system of staining (avidin-biotin conjugate procedure).

Progress: Still awaiting rat embryos. Completing ancillary studies (EM and routine light microscopic).

Detail Summary Sheet

Date: 24 Oct 90 Proj No: A-15-90 Status: Ongoing
 Title: Hemodynamic Effects of Dobutamine in a Porcine Hemorrhagic Shock Model

Start Date 30 Aug 90	Est Comp Date:
Principal Investigator R. Bernard Rochon, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators: James M. Lamiell, LTC, MC David W. Mozingo, CPT, MC Glen E. Gueller, SFC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the effect of dobutamine with small resuscitation fluid volume on resuscitation from hemorrhagic shock, a condition common on the battlefield.

2) To establish a dose response of the microcirculation to different dobutamine infusion rates as reflected by regional blood flow.

3) To establish that dobutamine plus small resuscitation fluid volume in hemorrhagic shock will resuscitate swine to physiologic endpoints.

Technical Approach: Piglets will be anesthetized, placed on an Airshields respirator and maintained on 100% oxygen. The pCO₂ will be kept in the normal range by periodic blood gas monitoring. Doppler flow probes will be placed on the aorta, renal artery, superior mesenteric artery, and hepatic artery to monitor regional blood flow. Four groups of six pigs will be studied. Medication for sedation will be ketamine 10 mg/kg IM. Additional anesthesia will be maintained with ketamine at 5 mg/kg.

Progress: This is a new study.

Detail Summary Sheet

Date: 24 Oct 90 Proj No: A-16-90 Status: Ongoing
 Title: Maintenance of Mouse Bladder Tumor Cell Line and Assessment of Karyotype of MBT-2 Cells versus Time.

Start Date 12 Sept 90	Est Comp Date:
Principal Investigator Timothy K. Dixon, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: William Boykin, MAJ, MC Ian M. Thompson, MAJ, MC Eric S. Zeidman, MAJ, MC Paul Desmond, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To maintain MBT-2 cell line in tissue culture and in vivo in syngeneic C3H mice as a resource for current and future urologic investigations.

Technical Approach: The MBT-2 cell line will be maintained in tissue culture and in vivo using C3H mice. Also karyotype analysis will be obtained on the cells in culture every three months to assess chromosomal changes versus growth time in culture.

Progress: This is a new study.

Detail Summary Sheet

Date: 24 Oct 90 Proj No: A-17-90 Status: Ongoing
 Title: Evaluation of Antitumor Activity of Cimetidine When Used in Conjunction with BCG Immunotherapy of Bladder Cancer in a Murine Model.

Start Date 12 Sep 90	Est Comp Date:
Principal Investigator Steven C. Lynch, CPT, USAF, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC Steven M. Dresner, MAJ, USAF, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To investigate possible synergy between the immunotherapeutic effects of cimetidine and BCG.

Technical Approach: One hundred twenty female C3H/He mice will be provided tap water and chow ad libitum. The mice will be randomized into four groups.

Group 1 (controls) receive 1×10^4 viable MBT-2 cells into the hind limb. This group will receive no further therapy.

Group 2 to receive continuous cimetidine (100 mg/kg/day) added to drinking water beginning three days before tumor inoculation.

Group 3 to receive BCG (1×10^8 CFU) intraperitoneally on a weekly basis for two weeks. This begins the day following tumor inoculation.

Group 4 to receive cimetidine three days before tumor inoculation, as in Group 2. Following tumor inoculation they receive BCG as in Group 3.

Progress: This is a new study.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-2-85 Status: Ongoing
 Title: Utilization of Goats for Training Special Forces Aidman

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator (vice Rubla) Cjarles J. Mihelic, CPT, VC	Facility Special Forces School, Fort Bragg, NC
Dept/Svc	Associate Investigators:
Department of	
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 18 Apr 90	Results Continue

Objective(s): To conduct training of the special forces aidman in the care of high velocity ballistic wounds.

Technical Approach: Training is conducted as outlined in the study protocol. Approximately 200 animals are used per class with approximately two thousand goats used annually.

Progress: Training continues as outlined in the protocol dated 20 February 1990.

Detail Summary Sheet

Date: 27 Sep 90 Proj No: T-7-86 Status: Terminated
 Title: Mouse Inoculation Test (MI) - Rabies Diagnosis

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Daniel Guerrero	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To establish and maintain a standing procedure for the MI test as a means of diagnosis for rabies vitus and as a confirmation of the more rapid fluorescent rabies antibody (FRA) test.

Technical Approach: As outlined in the training protocol.

Progress: Because of changes in study design, this protocol was terminated. A new study is now in progress under #A-5-90.

Detail Summary Sheet

Date: 27 Sep 90 Proj No: T-8-86 Status: Terminated
 Title: Production of Positive and Negative Controls for Rabies FA Test

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Daniel R. Guerrero	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 2 Oct 89 Results Continue	

Objective(s): To provide provide positive and negative control slides for use in the fluorescent rabies antibody (FRA) test and to provide a means of confirming that the procedure of directly tagging rabies virus in a brain impression is specific and the fluorescent intensity is optimized.

Technical Approach: As outlined in the training protocol.

Progress: This study has been replaced by protocol #A-4-90.

Detail Summary Sheet

Date: 2 Oct 90	Proj No: T-9-86	Status: Ongoing
Title: Orthopaedic Microsurgery - A Training Protocol		

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 66.30
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 27 Sep 89	Results Continue
Objective(s): To train Orthopaedic Resi; and maintain Orthopaedic Staff expertise at BAMC in the techniques used microsurgery.	

Technical Approach: The protocol is broken up into four phases. In the first phase, the trainee will learn basic suturing techniques using the operating microscope. The second phase will teach the techniques of microvascular anastomoses of arteries and veins, and vein grafts. The third phase will teach the technique of microneurorrhaphy, and the four phase will teach the technique of free tissue transfer using microvascular anastomoses.

Progress: Improvemer in surgical techniques have been realized, and improvement in patient care has been noted. This skill (microsurgery) is a mission-essential training for orthopaedic surgeons.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-10-86 Status: Ongoing
 Title: Supervised Basic Abdominal and Vascular Surgical Experience

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator(vice Rosenthal)	Facility
Michael J. Walters, COL, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/General Surgery	Robert Solenberger, MAJ, MC
Key Words:	

Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost: 910.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 3 Oct 90	Results Continue

- Objective(s): 1) To provide basic proficiency to junior housestaff in the handling of the GI and vascular systems before actually operating on humans.
- 2) To increase the proficiency of more senior surgeons in the performance of seldom performed procedures, so as not to lose their skills.
- 3) To learn new techniques and operations on animals before starting to use them on humans.

Technical Approach: Training is conducted as outlined in the protocol.

Progress: Training of 6 residents was continued on a bi-monthly basis.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-11-86 Status: Ongoing
 Title: Microsurgery Training Protocol for Plastic Surgery Staff, Residents and Rotators.

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Robert N. Young, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Plastic Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 347.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To familiarize plastic surgeons of microsurgical procedures with the use and care of microscope and microsurgical instruments, and techniques of microsurgery.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: Training continues on a regularly scheduled basis.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-13-86 Status: Ongoing
 Title: Swine Model for Technical Procedure Training of Emergency Medicine Residents

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator	Facility
William Dice, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Emergency Medicine	Katherine T. Lovello, MAJ, MC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost: 2,450.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 3 Oct 89 Results Continue	

Objective(s): To develop familiarity and competency in performing life saving technical skills applicable to the Emergency Room environment.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: Training of residents in frequently used emergency procedures continues on a monthly basis.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-1-87 Status: Ongoing
 Title: Military Working Dogs utilization in teaching first aid, bandaging, gastric tube passage and subcutaneous injections of medications to kennel masters

Start Date 19 Nov 86	Est Comp Date:
Principal Investigator George E. Moore, CPT, VC	Facility Academy of Health Sciences
Dept/Svc Department of Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 3 Oct 89	Results Continue

Objective(s): To familiarize kennel supervisors on treating medical emergencies on military working dogs in the event a veterinarian and/or animal care specialist is not available.

Technical Approach: Training is conducted as outlined in the training protocol.

Progress: Training was conducted on a regularly scheduled basis of eight dogs per month.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-2-87 Status: Ongoing
 Title: Anesthesiology for ANC Officers Course (6F-66F)

Start Date 6 Feb 87	Est Comp Date:
Principal Investigator Gary Zarr, LTC, AN	Facility Academy of Health Sciences
Dept/Svc Department of Nursing	Associate Investigators: Jeff Serogham, LTC, AN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 7 Mar 90 Results Continue	

Objective(s): To augment/enhance the formal platform instruction students receive in their medical pharmacology and physiology courses.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: 36 students were trained during FY 90.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-3-87 Status: Ongoing
 Title: Abdominal Surgical Experience - Gynecology Service

Start Date 19 Feb 87	Est Comp Date:
Principal Investigator Clifford Hayslip, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 420.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 3 Oct 89	Results Continue

Objective(s): To provide hands-on surgical experience (for obstetrics and gynecology residents) in emergent surgical techniques.

Technical Approach: Training conducted as outlined in the training protocol.

Progress: Training of 2 residents has been conducted on a regularly scheduled basis. Training has been rescheduled on a available time basis.

Detail Summary Sheet

Date: 3 Oct 90 Proj No: T-4-87 Status: Ongoing
 Title: Canine Utilization for Rigid Endoscopic Training

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Moss) Kweon Stambaugh, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
at of Periodic Review _____	Results _____

Objective(s): 1) To provide hands-on experience to residents in Otolaryngology and Thoracic Surgery, (and possibly general surgery) in the art of rigid endoscopy.

2) To ultimately increase the quality of care to our endoscopy patients by decreasing their surgical risks through laboratory training.

3) To simulate the scenario of an esophageal or tracheobronchial foreign body, in a live, anesthetized animal, for the purpose of developing endoscopic foreign body removal skills.

Technical Approach: Training conducted as outlined in the protocol.

Progress: This course continues to be a truly successful endeavor. This course is critical to the teaching program and allows us an effective laboratory to teach residents the proper, safe method of passing an esophagoscope and bronchoscope and the use of CO₂ laser in the larynx. The course has immeasurable benefits in that proper training in endoscopy surgery prevents the dreaded possible complication of a ruptured esophagus or bronchus and CO₂ laser complication.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-6-87 Status: Ongoing
 Title: Utilization of Goats for the Training of Physicians and Physician Assistants in the Advanced Trauma Life Support Instructor Course and Warrant Officer Candidates in the Military Physician Assistant (PA) Course

Start Date 13 May 87	Est Comp Date:
Principal Investigator David A. Roberts, COL	Facility Academy Health Sciences
Dept/Svc Medicine and Surgery Division	Associa Investigators: Richard L. Lowney, CW4
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To improve trauma management skills of non emergency personnel.

Technical Approach: Training is conducted as outlined in the protocol.

Progress: Approximately 68 PA students and ATLS instructors were trained during FY 90.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-7-87 Status: Ongoing
 Title: Utilization of Goats for Training of 91B Medical NCO for the Medical NCO Course

Start Date 13 May 87	Est Comp Date:
Principal Investigator Gretchen Mayes, MAJ, AN	Facility Academy of Health Sciences
Dept/Svc Combat Medical Specialist Division	Associate Investigators: Claude Kucinskis, CPT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review 7 Mar 90	Results Continue

Objective(s): To improve trauma management skills of 91B Medical NCO.

Technical Approach: Training conducted as outlined in the protocol.

Progress: Wounding of the animal has been deleted from this protocol and superficial laceration repair added.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-1-88 Status: Ongoing
 Title: Oculoplastic Seminar and Laboratory and Wound Closure

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Robert A. Mazzoli, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Calvin E. Mein, LTC, MC Donald A. Hollsten, LTC, MC Arthur T. Glover, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 3 Oct 89 Results Continue	

Objective(s): Provide advanced proficiency to members of the Brooke Army Medical Center House Staff in primary repair of oculoplastic wounds, learn new techniques and operations on animals before starting to use them on humans, and apply the principles of oculoplastic closure and management of ocular and oculoplastic trauma.

Technical Approach: Procedures performed include various types and depths of skin surface incisions and wounds, with subsequent closure utilizing flaps, grafts, and Z-plasties.

Progress: Training of ophthalmology residents continues to be conducted on an annual basis.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-1-89 Status: Ongoing
 Title: Utilization of Goats for Training of DOD Medical Department Officers
 for the Combat Casualty Care Course (C4B)

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator (vice Hobbs)	Facility
Roy J. Hobbs, CPT, USAF VC	Academy of Health Sciences
Dept/Svc	Associate Investigators:
Training Division, JMRTC	Mark E. Wolken, MAJ, VC
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 7 Mar 90	Results Continue

Objective(s): To provide training for gynecologists and urologists in abdominal surgical procedures.

Technical Approach: This course encompasses a formal 3 day curriculum including the Amercian College of Surgeons' Approved Advanced Trauma Life Support course as well as war surgery specific lectures and abdominal surgical procedures. Surgical procedures performed during this training course will not include wound debridement as the goats will not be rounded.

Progress: 2989 students were trained during FY 90.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-2-89 Status: Ongoing
 Title: Utilization of Goats for Training Veterinary Corps Officers, Veterinary Service Warrant Officers and Veterinary Service Enlisted Personnel in the Veterinary Service in the Theater of Operations Course (VESTO) (6G-F2)

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator Robert G. Hicks, LTC, VC	Facility Academy of Health Sciences
Dept/Svc Veterinary Science Division	Associate Investigators: Albert E. Randall SFC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 7 Mar 90	Results Continue

Objective(s): To train individuals in proper procurement of animals, humane care of animals for laboratory use, and humane euthanasia with proper disposal of euthanized animals following completion of the training class.

Technical Approach: Classes in the above mentioned objectives will be conducted as outlined in the study protocol.

Progress: Training was continued as proposed in the protocol.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-3-89 Status: Ongoing
 Title: Pediatric Intubation Training Utilizing the Feline Model

Start Date 15 Sep 89	Est Comp Date:
Principal Investigator Stephen C. Inscore, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 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: The laboratory exercises will concentrate on developing the health professional's confidence in establishing an airway. Each individual will be required to intubate a cat employing a laryngoscope and endotracheal tube three times for physicians and one time for nurses or other personnel who are not required to intubate on the job. Two groups of students will be arranged: the first group will attend a didactic in-service on proper use of airway adjuvant and airway control while the second will attend the Cat Intubation Laboratory. At least one instructor will teach the in-service and at least two instructors will teach the Cat Intubation laboratory. Anesthesia will be maintained throughout the procedure.

Progress: Training has been conducted as outlined in the protocol.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-1-90 Status: Ongoing
 Title: Utilization of Goats for Training Enlisted Personnel in the Special Operations Medical Sergeant Course (011-18D30)

Start Date 14 Mar 90	Est Comp Date:
Principal Investigator Bruestle, Larry W., LTC VC	Facility Academy of Health Sciences
Dept/Svc Veterinary Science Division	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To teach antemortem inspection, postmortem inspection, field-slaughter procedures and tissue pathology recognition.

Technical Approach: Training is conducted as outlined in the protocol.

Progress: Training has been conducted as on a regularly scheduled basis.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-2-90 Status: Ongoing
 Title: Urologic Microsurgery - A Training Protocol

Start Date 14 Mar 90	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To train Urology Residents at BAMC the techniques used in micro-surgery.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: Training has been conducted on a regularly scheduled basis.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-3-90 Status: Ongoing
 Title: Utilization of Goats for The Special Forces Sergeants Advanced Non-Commissioned Officers Course, USAJFKSWCS, Special Forces Medical Training Detachment, D Co, 1st Bn, 1st SWTG, Fort Bragg, NC

Start Date 8 Aug 90	Est Comp Date:
Principal Investigator Charles J. Mihelic, CPT, MC	Facility USAJFKSWCS, Fort Bragg, NC
Key Words:	Associate Investigators:
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To refresh and refine the Special Forces Medical Sergeant's medical skills as well as to update knowledge on new techniques and procedures.

Technical Approach: Laboratory training is conducted over days 2 through 5 of the 25 day course. Three courses are offered per year with a maximum student load of 30 students per class.

Progress: Training is progressing as outlined in the study protocol.

Detail Summary Sheet

Date: 2 Oct 90 Proj No: T-4-90 Status: Ongoing
 Title: Cardiology Training Protocol

Start Date 8 Aug 90	Est Comp Date:
Principal Investigator J. Mark Moody, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To provide junior cardiology fellows practical experience in various resuscitation techniques prior to initial human clinical experience.

Technical Approach: As outlined in the training protocol.

Progress: Training is conducted on an annual basis.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 7804 Status: Ongoing
 Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date FY 78	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TMM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucous and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: There are 206 patients in this Phase III study, which is now twelve years old. The study will be closed as soon as the new gastric adjuvant protocol is available. This study will be not quite appropriate to analyze as soon as it is closed since it is very mature.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 7808 Status: Ongoing
 Title: Combined Modality Treatment for Stages III and IV. Hodgkin's Disease
 MOPP # 6.

Start Date FY 1979	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Hodgkin's Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP.

2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Therapy will follow the schema outlined

Progress: This study is closed to new patient accrual. However, it will remain open for followup purposes.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 7827 Status: Ongoing
 Title: Combined Modality Therapy for Breast Carcinoma, Phase III.

Start Date FY 80	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 61	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1. To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

2. To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.

3. To compare the disease-free interval and recurrent rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

4. To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

5. To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Therapy will follow the schema outlined in the study protocol.

Progress: All the components of this study are now closed. The ER-negative portion comparing one versus two years of CMFVP now has adequate follow-up to draft an initial manuscript. The postmenopausal ER-positive portion of the study was recently closed and the results will be presented at ASCO. It shows no advantage for combining one year of CMFVP to one year of tamoxifen. The premenopausal portion of the study comparing CMFVP $\pm$ ovariectomy was also recently closed as the necessary accrual has been reached. It will be analyzed for its first public report this Fall. This study is closed to new patient accrual. However, it will remain open for followup purposes.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8216/38 Status: Ongoing
 Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	3
Date of Periodic Review	16 Oct 89 Results Continue

Objective(s): 1) To compare the effectiveness of intravesical BCG immunotherapy with intravesical adriamycin chemotherapy with respect to disease-free interval and two-year recurrence rate.

2) To compare the toxicity of topical immunotherapy and chemotherapy.

3) To obtain experience regarding disease-free interval and the recurrence rate in patients who develop tumor recurrence and are then crossed over to the alternative treatment arm.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8229 Status: Ongoing
 Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for
 Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body
 Radiotherapy + Vincristine-Prednisone for Maintenance or Solidation.
 Evaluation Phase II

Start Date FY 1983	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	18
Date of Periodic Review 16 Oct	Results Continue

Objective(s): 1) To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

2) For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.

3) For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy with Vincristine

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8294 Status: Ongoing
 Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer.

Start Date FY 1983	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast Node Negative	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 33	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm.

2) To assess the impact of surgical procedures, ER status, menopausal status and tumor size.

3) To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

4) To assess the value to CEA in predicting recurrence and survival rates.

5) To assess the natural history of a subgroup with N-, ER+ small tumors.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8300 Status: Ongoing
 Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Radiation plus Chemotherapy (FOMi/CAP), Phase III.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	10
Date of Periodic Review	16 Oct 89 Results Continue

Objective(s): 1) To compare combination chemotherapy plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration.

2) To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC.

3) To evaluate the responsiveness of small tumor burdens to FOMi/CAP (i.e., less than metastatic disease).

4) To determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMi/CAP.

5) To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity or survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8309 Status: Ongoing
 Title: Autologous Marrow Transplantation for the Treatment of Non-Hodgkin's Lymphoma, Phase II.

Start Date FY 1988	Est Comp Date:
Principal Investigator:	Facility:
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center
Dept/Svc:	Associate Investigators:
Department of Medicine/Oncology	
Key Words:	
Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): To determine the therapeutic potential of high-dose cyclophosphamide and total body irradiation followed by autologous marrow transplantation (AMT) in patients with an otherwise poor prognosis for cure in the specific lymphoma disease categories.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8312 Status: Ongoing
 Title: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine whether combination hormonal therapy with Aminoglutethimide and Hydrocortisone (AH) plus Megestrol Acetate (M), agents thought to have different mechanisms of action, offers an improved response rate with prolonged response duration and increased patient survival over the sequential use of each agent in Estrogen Receptor (ER) positive patients who have progressed after responding to primary hormonal treatment with tamoxifen.

2) To assess the relative toxicities of Megestrol Acetate and medical adrenalectomy.

3) To assess the value of progesterone receptor (PgR) in predicting subsequent responses to a variety of hormonal therapies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8313 Status: Ongoing
 Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare through a randomized prospective recurrence rates and disease-free intervals (DFI) for postope. node positive estrogen receptor negative (ER-) breast cancer p adjuvant therapy with either short term intense chemotherapy (t year standard chemotherapy (CMFVP).

2) To compare the effect of these two adjuvant therapies on survival.

3) To compare the relative toxicity of the two therapies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This trial has reached its necessary accrual of 616 patients and will be closed. There continues to be only two fatalities related to drug toxicity. One patient died from sepsis. the other died from acute respiratory distress syndrome thought to be drug related. There have been several Grade 4 toxicities on each treatment arm.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8326/27 Status: Ongoing
 Title: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, adult acute Leukemia, chronic granulocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the effectiveness of three different drug combinations using high dose Ara-C alone or high dose Ara-C in combination with m-AMSA or Mitoxantrone for remission induction in relapsed adult leukemias including both acute non-lymphocytic leukemia, chronic granulocytic during accelerated or blastic phase, as well as untreated secondary acute leukemias.

2) To monitor the side effects of the above combination chemotherapy schedules.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study remains open and it is anticipated that another nine months of accrual will be needed for the AML arm of the study. This study will continue to be opened for CML patients in blast crisis until the replacement study being written by Dr. List is completed.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8393 Status: Ongoing
 Title: MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine the safest excision margins around the primary melanoma.

2) To evaluate the management of the regional lymph nodes (immediate vs delayed lymphadenectomy).

3) To evaluate the relative prognostic value of various histopathological parameters of melanoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The Southwest Oncology Group has contributed 82 patients or 12% of the total to this intergroup study. Randomization has achieved good balance in both pathologic and demographic factors. This study will remain open for another year with a strong effort to recruit patients with head and neck primaries as well as those with melanomas of the distal extremity.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8406 Status: Ongoing
 Title: Evaluation of Esorubicin (4' Deoxydoxorubicin) in Malignant Lymphoma, Phase II.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine the response rate and response duration of malignant lymphoma treated with Esorubicin.

2) To define the qualitative and quantitative toxicities of Esorubicin administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8417 Status: Ongoing
 Title: Evaluation of two Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adult acute lymphoblastic leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	5
Date of Periodic Review	16 Oct 89 Results Continue

Objective(s): 1) To compare the effects on remission duration and survival of two consolidation regimens: the L10-M consolidation used in SWOG 8001 versus a regimen employing Daunomycin, Cytosine Arabinoside, 6-Thioguanine and escalating Methotrexate/L-Asparaginase in patients with adult acute lymphoblastic leukemia.

2) To compare the toxicities of the two consolidation regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study remains open but is nearing its accrual goals. We anticipate finishing this study by the end of the year.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8500 Status: Completed
 Title: Second-Line Treatment of Advanced Measurable Ovarian Cancer with
 CHIP, Phase II

Start Date FY 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) to evaluate the antitumor response to CHIP in patients with metastatic or recurrent epithelial carcinoma of the ovary who have failed first-line cisplatin or carboplatin-containing therapy.

2) To further characterize the toxicity of the cisplatin analogue CHIP.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8501 Status: Ongoing
 Title: Intraperitoneal Cis-Platinum/Intravenous Cyclophosphamide in Patients with Non-Measurable (Optimal) Disease Stage III Ovarian Cancer, Phase III Intergroup.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	16 Oct 89 Results Continue

Objective(s): 1) To carry out a Phase III₂ randomized trial of intermediate dose intraperitoneal cis-platinum (100 mg/M²) plus intravenous cyclophosphamide versus intermediate dose intravenous cis-platinum (100mg/M²) plus intravenous cyclophosphamide for optimal Stage III ovarian cancer.

2) To evaluate the toxicities and complications of the two combination drug regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: SWOG-8501 (INT 0051) has accrued 370 patients as of May 1990. Forty patients have been declared ineligible mainly due to ineligible pathology (16), disease not documented as stage III (10), and no data submitted(7). Toxicity information is available on 257 eligible patients. There have been no fatal toxicities reported. Grade 4 granulocytopenia has been reported in 18 patients on the IV cisplatin arm and in 14 patients on the IP cisplatin arm. Nine on the IV arm and 10 on the IP arm had Grade 4 leukopenia. Three patients on the IV arm and two on the IP arm had Grade 4 thrombocytopenia. The study will remain open until 450 fully eligible patients have been registered.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8507 Status: Ongoing
 Title: Maintenance versus no Maintenance Bcg Immunotherapy of Superficial Bladder Cancer, Phase III

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Bladder cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	12
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare the effectiveness of intravesical and percutaneous BCG immunotherapy given on a maintenance versus a no maintenance schedule with respect to disease free interval and rate of tumor recurrence in patients with transitional cell carcinoma of the bladder.

2) To assess the toxicity of maintenance and no maintenance BCG immunotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8509 Status: Ongoing
 Title: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To assess the antitumor activity of menogaril in patients with advanced adenocarcinoma of the prostate.

2) To define the qualitative and quantitative toxicities of menogaril administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual. However, it will remain open for followup purposes.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8515 Status: Ongoing
 Title: Evaluation of Menogaril in Non-Hodgkins Lymphoma, Phase II.

Start Date 13 May 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Non-Hodgkins, Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To determine the response rate and response duration for favorable and unfavorable histology Non-Hodgkin's lymphoma (NHL) treated with Menogaril.

2) To define the qualitative and quantitative toxicities of Menogaril administered in a phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of non-Hodgkin's lymphoma with at least one site of bidimensionally measurable disease. Patients must have failed and recovered from potentially curable treatment. Patients with a cumulative dose of Adriamycin > 250 mg/m² are not eligible for this study. allowable prior chemotherapy depends on disease type. Patients will be stratified according to histology: unfavorable histology NHL vs favorable histology NHL.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was temporarily closed for interim analysis on November 1, 1989. It was reopened for the second stage of accrual on April 15, 1990 due to response. Accrual has been relatively slow. A total of fifty patients have been entered on the study (29 high grade and 21 low grade histology). Toxicity has been acceptable and consistent with expectations, with the primary hematologic toxicity being granulocytopenia; and the observed non-hematologic toxicities including gastrointestinal toxicity alopecia, cardiotoxicity and allergic reaction. There has been less cardiotoxicity observed on this study than has been observed with traditional anthracyclines.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8516 Status: Ongoing
 Title: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBom vs MACOP-B
 in Patients with Intermediate or High-Grade Non-Hodgkin's Lymphoma.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-Hodgkin's lymphoma, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare 'n a randomized Group-wide setting the complete response rate, response duration and survival of patients with intermediate and high-grade non-Hodgkin's lymphoma treated with one of four combination chemotherapy regiments: CHOP, m-BACOD, ProMACE-CytaBOM, or MACOP-B.

2) To compare the toxicities of each regimen in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: At the end of 1989, 755 patients were registered to this study. The accrual goal has been extended to 1,000 patients. Toxicity has been acceptable, with a 2-8% fatality.. There are no changes planned for this study, and closure is expected in approximately one year.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8520 Status: Ongoing
 Title: Cis-Diamminedichloroplatinum II: Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, epidermoid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine the response rate in patients with advanced epidermoid carcinoma of the penis treated with cis-platinum, methotrexate, and bleomycin.

2) To evaluate the toxicity of this three-drug combination.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8530 Status: Completed
 Title: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Glucocorticoid Receptors, Phase II.

Start Date 7 Nov 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To estimate the response rate and duration with high dose prednisone in patients with refractory myeloma.

2) To measure glucocorticoid receptors in multiple myeloma.

Technical Approach: All patients must have a histologic diagnosis of multiple myeloma. Eligible patients must have had prior chemotherapy or hormonal therapy for myeloma and progression of disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Gupta has left the Group and moved to Pittsburgh. Data on the Prednisone, Glucocorticoid receptor study is now all in the Statistical Office and Ms. Donna Stock-Novack is currently conducting analysis. A final report on this study will be made by Ms. Stock-Novack at the Fall 1990 meeting of the Southwest Oncology Group after which a manuscript will be submitted for publication.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8568 Status: Ongoing
 Title: Combined Modality Therapy for Advanced Stage III Breast Cancer (T3b any N, T3aN2-3, or any T4).

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast cancer, stage III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To evaluate by serial biopsy and flow cytometry whether or not an increase of the percentage of cells in S+G₂+M can be induced in patients with locally advanced breast cancer by synchronization with a high physiologic dose of estradiol before chemotherapy is applied.

2) To obtain information by flow cytometry and serial biopsy when this increase in S+G₂+M occurs.

3) To evaluate the toxicity of an aggressive program of hormonal synchronization, chemotherapy, radiation therapy and surgery on patients with T3b any N, T3aN2-3, T3aN, or T4 breast cancer lesions.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Thirty-eight patients have now been accrued to this study. The accrual to the ER-positive portion is now complete and the study will be closed. The study demonstrates that estrogen treatment of patients with locally advanced breast cancer results in an increased S phase fraction. However, the absolute increase in S phase fraction is not dramatic. A study will be considered which tests the concept of initial tamoxifen followed by estrogen rescue to determine if the cell kinetics can be altered in a more favorable way.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8573 Status: Ongoing
 Title: Treatment of Limited Small Cell Cancer with Concurrent Chemotherapy
 Radiotherapy and Intensification with High Dose Cyclophosphamide.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, small cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To estimate the response rate and survival of patients with limited small cell lung cancer when treated with concurrent chemo-radiotherapy followed by chemotherapy and late intensification with high dose cyclophosphamide.

2) To assess the toxicity of this treatment program.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8590 Status: Ongoing
 Title: Phase III Study to Determine the Effect of Combining Chemotherapy With Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Squamous cell carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To test whether the addition of chemotherapy to surgery and radiotherapy prolongs disease-free survival and survival between the two study groups.

2) To test whether the addition of chemotherapy to surgery and radiotherapy increases local control rates at the primary site and/or the cervical neck nodes.

3) To determine if the patterns of failure have been changed with the addition of chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The results of this study for resectable patients, which is administered by RTOG, have not been presented to publisher to date. The current status of the Head and Neck Cancer Intergroup is uncertain and is under review at the NCI. Meetings are scheduled for this summer and fall with the NCI to address this matter.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8591 Status: Ongoing
 Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma of colon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): To assess the effectiveness of levamisole alone and levamisole plus 5-fluorouracil as surgical adjuvant regimens for resectable colon cancer by comparison with untreated controls.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study was discussed by Dr. Macdonald. This is the 5-FU levamisole study which has been widely reported and is discussed on page 15 of the GI Committee agenda.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8594 Status: Completed
 Title: A Phase III Trial of Cis-Platin Alone or in Combination with Doxorubicin, Vinblastine, and Methotrexate in Advanced Bladder Cancer.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LIC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): To determine if cisplatin in combination with doxorubicin, vinblastine and methotrexate is more effective than cisplatin alone in the treatment of patients with advanced bladder cancer in terms of objective response rate, response duration and survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The upcoming presentation at ASCO of the cisplatinum vx. MVAC in advanced bladder cancer patients was discussed. MVAC turns out to be superior to platinum alone as measured by an increase in median survival. The response rates also were considerably higher and in fact what was most remarkable about this now closed intergroup trial is the relative inactivity of cisplatinum.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8598 Status: Ongoing
 Title: Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus.

2) To determine if the patters of recurrence for patients treated with the combination of chemotherapy and radiation differs from those patients treated with radiation alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: A total of 34 patients have been accrued on this study from the Southwest Oncology Group. One-hundred and eleven total cases were entered as of November 1989. All the other cases were from RTOG. No treatment results are available. Of those, 78 patients have been evaluated for acute toxicities. The toxicity is generally acceptable with three patents having Grade IV chemotherapy toxicity and nine patients having Grade III chemotherapy toxicity. The study will remain open until replacement neo-adjuvant esophageal studies are available.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8600 Status: Ongoing
 Title: A Randomized Investigation of High Dose versus Standard Dose Cytosine Arabinoside With Daunorubicin in Patients With Acute Non-Lymphocytic Leukemia, Phase III.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, acute, non-lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) 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.

2) To compare the durations of complete remission and of disease-free survival among patients who each receive one of three combinations of induction and consolidation regimens.

3) To determine the comparative toxicities of these three programs of induction and consolidation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study continues to accrue well. Dr. Weick presented an update on this study and anticipates that accrual will be completed by the end of the year.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8608 Status: Completed
 Title: Mitoxantrone Plus Cis-Platinum in Patients With Advanced Breast Cancer, Phase I-II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To evaluate the response rate and remission duration of the combination of Mitoxantrone and cis-platinum used as second-line therapy for metastatic breast cancer.

2) To evaluate the toxicity of this drug combination in these patients.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: We are awaiting a manuscript from Dr. Craig for a final report.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8610 Status: Completed
 Title: Prospective Randomized Clinical Trial of the Capillary Cloning System for Patients with Extensive Small-Cell Lung Cancer, Phase III.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer Small-Cell Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Ongoing

Objective(s): 1) To evaluate the ability of the capillary cloning system to improve upon patient response and survival when compared to a standard regimen (Vincristine + adriamycin + cyclo-phosphamide)(VAC) by selecting patient-specific regimens. These individual patient regimens will be formulated from the best two or three drugs which are effective against the patient's small-cell lung cancer in vitro.

2) To assess whether a cloning system has a place in the clinical care of the patient with extensive small-cell lung cancer.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study closed early, therefore, no manuscript will be possible, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8614 Status: Completed
 Title: Chemotherapy of Gastric Cancer with VM-26

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Gastric Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To determine the toxicity of VM-26 therapy in patients with advanced gastric cancer.

2) To determine the response rate in patients with advanced gastric cancer.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Seventeen patients have been accrued, thirteen are evaluable. The toxicity reveals two drug related deaths and two Grade IV toxicities related to leukopenia. This study will remain open for accrual. Response data is not available.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8616 Status: Ongoing
 Title: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With and Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): To determine if the addition of ifosfamide to doxorubicin and dacarbazine significantly changes the response rate, survival, and toxicity.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The randomized portion of this study was closed in May 1989 after having accrued 338 eligible patients to the comparison of Adria/DTIC/ifosfamide with Adria/DTIC. This study remains open for patients with osteogenic sarcoma, Ewing's sarcoma, and rhabdomyosarcoma. There have been 41 ineligible patients registered. Most of these patients were ineligible because of inadequate baseline documentation or out of range lab values. (ALU3 entered 160 patients and the Southwest Oncology Group entered 224. Two major treatment deviations occurred. Both of these involved the delivery of concomitant radiotherapy. Seven treatment related deaths have been documented in the 191 evaluated patients receiving Adria/DTIC/ifosfamide. All of these deaths were related to myelosuppression. One patient on Adriamycin/DTIC had a fatal pulmonary embolus. Responses to this study are still being evaluated. Response and survival information will be presented at the upcoming ASCO meeting.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8621 Status: Ongoing
 Title: Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare initial combined chemo-hormonal therapy with initial hormonal therapy with respect to survival.

2) To compare initial chemo-hormonal therapy using tamoxifen with that using DES with respect to survival.

3) A secondary goal is to compare combined chemo-hormonal therapy with initial hormonal therapy with respect to response in patients with measurable disease.

Technical Approach: Patients must have clinical or histologic confirmation of recurrent or disseminated breast cancer, with tumor positive for estrogen receptor or progesterone receptor. Patients with completely dissected disease or with a life threatening visceral disease will be ineligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Because of poor accrual due to the fact that most breast cancer patients today have already been previously treated with tamoxifen as an adjuvant, this trial has been amended to be a two-arm trial comparing DES versus DES + chemotherapy as second-line therapy for metastatic breast cancer. This amendment has been approved by the NCI and will be activated in the near future.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8624 Status: Ongoing
 Title: A Phase III Randomized Trial of Combinatin Therapy for Multiple Myeloma.

Start Date FY 1979	Est Comp Date:
Principal Investigator: Timotny J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare the effectiveness of three chemotherapy induction schedules for the induction of remission in previously untreated patients with multiple myeloma. The three schedules are: 1)VMCP/VBAP; 2) VAD; 3) VMCP/VBAPP.

2) To compare the value of Intron-A maintenance versus no maintenance for patients proven to achieve remission.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: After further evaluation of data it was determined to continue this study.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8626 Status: Completed
 Title: Study of Recombinant DNA Gamma Interferon in Advanced Cancer of the Pancreas, Phase II.

Start Date FY 1988	Est Comp Date:
Principal Investigator:	Facility:
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center
Dept/Svc:	Associate Investigators:
Department of Medicine/Oncology	
Key Words:	
Cancer, pancreatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To determine the clinical response of recombinant gamma interferon in pancreatic adenocarcinoma.

2) To define the qualitative and quantitative toxicities of recombinant gamma interferon in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8642 Status: Completed
 Title: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma After Surgical Excision of the Primary Lesion.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the overall survival and of disease-free survival among patients who are at high risk for recurrence of melanoma following surgical resection of all known disease, and who are randomized to receive either recombinant human interferon-gamma adjuvant therapy or no adjuvant therapy.

2) To estimate the rates of toxicities among the patients who receive recombinant human interferon-gamma as adjuvant therapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study was temporarily closed 11/15/89. Data Monitoring Committee will be meeting soon to decide on permanent closure and release of study results.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8691 Status: Ongoing
 Title: A Randomized Comparison of Deoxycoformycin versus Alpha Interferon in Previously Untreated Patients With Hairy Cell Leukemia.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, hairy cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review:	16 Oct 89 Results Continue

Objective(s): 1) To compare Deoxycoformycin and Alpha-interferon with respect to frequency of response, time to response and duration of relapse-free survival among unsplenectomized patients with hairy cell leukemia.

2) To compare Deoxycoformycin and Alpha-interferon with respect to improvement in specific patient characteristics.

3) To estimate the rate of response for each treatment when used among patients who have failed to respond to or had unresolvable toxicity from the other treatment.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study has completed its accrual. Accordingly this study has been declared closed as of September 15, 1989. A meeting is planned in the next several months at the National Cancer Institute to analyze the accrued data. If additional patients are needed the study could conceivably be reopened but that is not planned at the present time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8692 Status: Ongoing
 Title: Therapy in Premenopausal Women with advanced, ER Positive or PgR
 Positive Breast Cancer: Surgical Oophorectomy vs. the LH-RH Analog, Zoladex:
 Phase III, Intergroup.

Start Date 14 Oct 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare the time to treatment failure and survival of medical castration using Zoladex with surgical castration in premenopausal women with advanced, ER + or PgR + breast cancer.

2) To compare the response rate of the two treatments.

3) To assess the response rate to surgical castration in patients failing to respond to or relapsing on Zoladex, and the response rate to Zoladex in patients failing to respond to or relapsing on surgical castration.

4) To compare toxicities of medical castration and surgical castration.

5) To assess the value of post-treatment hormone levels (LH, FSH and estradiol) in predicting response to medical castration.

6) To assess the effect of long-term Zoladex treatment on hormone levels (LH, FSH and estradiol) in responding patients.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This trial has now accrued 67 patients and it compares medical castration with Zoladex with surgical castration in ER-positive premenopausal patients with advanced breast cancer. Obviously this trial is difficult to do because these patients are not common and it is difficult to do studies comparing surgical versus non-surgical treatments. Nevertheless, the study is progressing and it is now averaging about three patients per month. Thus, we will tentatively continue to keep the trial open for accrual. If accrual drops below this level, then the trial will be either modified or stopped. The only toxicities reported to date are menopausal symptoms which are somewhat greater in the Zoladex arm in the form of hot flashes.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8693 Status: Completed
 Title: Adjuvant Therapy of Primary Osteosarcoma: A Phase III Randomized Intergroup Study.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine whether the intensity of adjuvant chemotherapy affects its success in terms of local recurrence, disease-free survival and overall survival in patients who have primary osteosarcoma of the extremities and who are randomized to either surgery followed by adjuvant chemotherapy with three drugs or surgery followed by adjuvant chemotherapy with six drugs.

2) To determine the influence of clinical prognostic variables on disease outcome.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study will be permanently closed because of low accrual. Only four patients have been registered to the trial.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8694 Status: Ongoing
 Title: A comparison of Pentostatin and Alpha-Interferon in Splenectomized Patients With Active Hairy Cell Leukemia.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, hairy cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the frequency of response between pentostatin and a-IFN treatment in patients with hairy cell leukemia who following splenectomy manifest active or progressive disease.

- 2) To compare time to response between these two treatments.
- 3) To compare the response duration between these two treatments.
- 4) To determine whether pentostatin salvages non-responders to a-IFN treatment and whether a-IFN salvages non-responders to pentostatin treatment.
- 5) To compare the toxicity of the two treatments.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is not reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8695 Status: Ongoing
 Title: (GOG 85) A Randomized Comparison of Hydroxyurea versus 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes.

Start Date	FY 87	Est Comp Date:
Principal Investigator:(vice Burke)	Facility:	
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center	
Dept/Svc:	Associate Investigators:	
Department of Medicine/Oncology		
Key Words:		
Carcinoma, Cervix		
Accumulative MEDCASE	Est Accumulative	
Cost:	OMA Cost:	
Number of Subjects Enrolled During Reporting Period:	0	
Total Number of Subjects Enrolled to Date:	0	
Date of Periodic Review 16 Oct 89	Results	Continue

Objective(s): 1) To determine whether hydroxyurea or the combination of 5-Fluorouracil and cisplatin is superior as a potentiator of radiation therapy in advanced cervical carcinoma.

2) To determine the relative toxicities of hydroxyurea versus the combination of 5-fluorouracil and cisplatin when given concurrently with radiation therapy.

Technical Approach: Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix, Stages II-B, III-A, III-B and IV-A with negative para-aortic nodes are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: The Southwest Oncology Group joined in with the Gynecologic Oncology Group protocol 85 on Jul 15, 1987. As of December 12, 1989, 28 of the registrations were from 12 Southwest Oncology Group institutions. The distribution of stages was as follows: II/B, 58%, III, 38%, AND IV-A, 4%.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8697 Status: Ongoing
 Title: Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P)TH or CMFH Intergroup.

Start Date FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) Investigate the induction efficiency and impact on time to treatment failure and survival of CAF vs CAF-TsAVbH used in a rotating schedule.

2) Investigate the value of CMF(P)TH vs no maintenance treatment in duration of complete response and survival.

3) Evaluate on-study disease characteristics and patient discriminants with respect to their prognostic use of the above objectives.

Technical Approach: Patients must have histologically documented mammary carcinoma with clinical and/or laboratory evidence of metastatic or recurrent disease. Patients must have measurable disease. All patients with ER negative tumors are eligible unless they have responded to prior hormone manipulation therapy. ER positive or ER unknown patients are eligible only if they have had prior therapeutic hormone manipulation and did not respond to this therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: The intergroup trial in ER-negative metastatic breast cancer continues accrual. Seventy-six patients have been registered from the Southwest Oncology Group and a total of over 200 patients have been registered. According to the ECOG Statistical Office, this trial will be ready for closure by December of this year. The only Grade 4 toxicities observed are hematologic and they have been equally distributed between the two arms.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8710 Status: Ongoing
 Title: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Cancer, Advanced Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare the survival of those patients with locally advanced bladder cancer treated with cystectomy alone to those treated with M-VAC followed by cystectomy in a randomized Phase III neoadjuvant trial.

2) To quantify the "tumor downstaging" effect of neoadjuvant M-VAC in patients with locally advanced bladder cancer.

Technical Approach: All patients must have histologically proven diagnosis of T₂-T_{4a}, N₀, M₀ transitional cell carcinoma of the bladder without mixed histology. All patients must have adequate kidney, liver, and bone marrow function, a performance status of 0-1, and be judged potentially curable.

Therapy will follow the schema outlined in the study protocol.

Progress: The 104 patients registered represent one-third of the ultimate accrual goal for this trial and toxicity problems, according to Dr. Grossman, have not been a problem to date. The study remains open.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8711 Status: Ongoing
 Title: A Study of Reproductive Function in Patients with Testicular Cancer.

Start Date	FY 88	Est Comp Date:
Principal Investigator:	Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc:	Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	Cancer, Testicular	
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 16 Oct 89 Results Continue		

Objective(s): 1. To evaluate the natural history of seminal fluid and hormonal parameters noted in Stage A testicular cancer patients treated by orchiectomy alone.

2. To evaluate the effects of a) orchiectomy plus platinum based combination chemotherapy or radiation therapy and b) retroperitoneal node dissection on the seminal fluid and hormonal parameters of Stage A, B, or C testicular cancer patients.

3. To estimate the median time to return to ejaculatory function following orchiectomy and retroperitoneal node dissection.

4. To study the effect of testicular cancer on sexual/ reproductive functioning.

Technical Approach: Each patient must have histologically proven diagnosis of testis cancer for which he has undergone an orchiectomy. Patients must be registered within three weeks of their surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Stanisc reported on the follow-up of this trial and although 80 patients have been registered there are not enough in any given subset to do an analysis. There seems to have been a slight decrease in actual accrual to this study and Dr. Stanisc encouraged increasing patient enrollment including patients who will only be observed. Additionally, Dr Stanisc pointed out that about 25% of the patients failed to have baseline semen analysis, making any future analysis more difficult. Again, Dr. Stanisc stressed that there are at least 5 subsets of patients being analyzed, those who are observation only patients, those who have received radiation therapy, those who have received chemotherapy, those with retroperitoneal lymph node dissection (RPLND), and those with RPLND plus chemotherapy.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8714 Status: Ongoing
 Title: Evaluation of Amonafide in Colorectal Carcinoma, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To evaluate response to amonafide in previously untreated patients with colorectal carcinoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have biopsy proven bidimensionally measurable adenocarcinoma arising from the colon or rectum. Patients may have had previous surgical therapy or previous radiation therapy. Patients must not have received any prior chemotherapy or no more than one prior biologic regimen.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available for this study at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8717 Status: Completed
 Title: Evaluation of Amonafide and Didemnin-B in the Treatment of Ovarian Cancer.

Start Date	FY 88	Est Comp Date:
Principal Investigator:		Facility:
Timothy J. O'Rourke, LTC, MC		Brooke Army Medical Center
Dept/Svc:		Associate Investigators:
Department of Medicine/Oncology		
Key Words:		
Cancer, Ovarian		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0	
Total Number of Subjects Enrolled to Date:	0	
Date of Periodic Review	16 Oct 89	Results Continue

Objective(s): 1) To conduct a randomized Phase II trial of two treatment regimens, amonafide and Didemnin-B and to evaluate tumor response to each of these agents in patients with metastatic or recurrent epithelial carcinoma of the ovary who have failed on higher priority treatment protocols.

2) To assess the qualitative and quantitative toxicities of each of these treatment regimens.

Technical Approach: Patients must have histologically proven incurable advanced metastatic or recurrent epithelial Stage III or IV carcinoma of the ovary. Pathology review is required to verify eligibility. Patients must have bidimensionally measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was temporarily closed on April 1, 1989, after accruing 30 patients. Because of ineligible patients, the study was reopened on November 15, 1989, so that the initial accrual goal of 15 patients per arm could be met. As of May, 1990, sufficient patients have been entered onto both arms of the study so that we are certain that there are no responders in at least 14 evaluable patients treated with either Amonafide or Didemnin-b. Of the twelve patients evaluable for toxicity on Amonafide, ten have experienced Grade 4 hematologic toxicities. Eleven patients were evaluable for toxicity on the Didemnin-b arm; there has been one Grade 4 toxicity (elevated bilirubin). The study will be closed to further accrual.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8719 Status: Ongoing
 Title: Evaluations of Didemnin B or Ifosfamide/Mesna in Endocrine Resistant Prostate Cancer and of Ifosfamide/Mesna in Patients without Prior Endocrine Manipulation. Phase II

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): To determine the response rate, response duration and toxicity of trimetrexate given on a daily x 5 schedule every three weeks to patients with hepatoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The didemnin-B arm has been closed due to the need to find a better dose, although 18 patients were registered there is little information about them to make any real Phase II judgment. This is also true of accrual at this point for ifosfamide as well. This study remains open for ifosfamide only.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8720 Status: Completed
 Title: Evaluation of Amonafide in Pancreatic Adenocarcinoma

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Pancreatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To evaluate response to amonafide in patients with pancreatic adenocarcinoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have a verified diagnosis of pancreatic adenocarcinoma. Patients must have objectively measurable lesion(s) excluding CNS metastases. Prior chemotherapy is not permitted and only one prior biologic regimen.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8721 Status: Ongoing
 Title: A Phase II Trial of Trimetrexate in the Treatment of Esophageal Cancer.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Esophageal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine the response rate, response duration and toxicity of trimetrexate given on a daily x 5 schedule every three weeks to patients with esophageal cancer.

Technical Approach: Patients must have a biopsy proven epidermoid carcinoma that is measurable. Patients may have had previous surgical therapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Brown presented this study. This is a Phase II study for previously untreated patients. Twenty patients have been accrued and response data are not available. Toxicity was generally acceptable with mild suppression being the major toxicity, although there was one drug related death listed as other. Dr. Brown commented on the slow accrual to this protocol. He pointed out that previously treated patients are not eligible for this study and with the wide spread use of neo-adjuvant therapy this makes accrual quite difficult. Attempts will be made to discuss this with the NCI to allow one previous treatment for such patients. The study will remain open.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8723 Status: Completed
 Title: Evaluation of Amonafide in Disseminated Malignant Melanoma Phase II.

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Melanoma, Disseminated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To evaluate response to amonafide in patients with Disseminated Malignant Melanoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have pathologically verified malignant melanoma. Only patients with Stage IV disease are eligible. Patient must not have received prior chemotherapy and only one prior biologic regimen is permitted.

Therapy will follow the schema outlined in the study protocol.

Progress: This Phase II trial of amonafide accrued a total of 21 eligible patients. There were no complete or partial responses, with a 95% confidence interval of 0% -16%. Ten patients experienced hematologic toxicities with six experiencing Grade 3 or worse. Another major toxicity experienced was nausea and vomiting. This study is now closed. Amonafide will not be pursued further in malignant melanoma.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8725 Status: Completed
 Title: Evaluation of Amonafide in Cervical Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Cervical	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To evaluate response to amonafide in patients with metastatic or recurrent epithelial carcinoma of the cervix who have failed on higher priority treatment protocols.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach:

Therapy will follow the schema outlined in the study protocol.

Progress: This study was temporarily closed on June 15, 1989 after accruing 15 patients. Six experienced Grade 4 hematologic toxicities. There were no responders. The study will be permanently closed. The manuscript is in a first draft of preparation by Dr. Malviya.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8726 Status: Completed
 Title: Evaluation of Amonafide in Refractory and Relapsing Multiple Myeloma.

Start Date 15 July 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To assess the antitumor activity of amonafide in patients with refractory and relapsing multiple myeloma by estimation of the response rate and the remission duration.

2) To assess the qualitative and quantitative toxicities of amonafide administered in a Phase II study.

Technical Approach: Patient must have a histologic diagnosis of multiple myeloma, have prior exposure to therapy on SWOG 8624 and have failed therapy, or have received only a single prior chemotherapy regimen. Three weeks must have elapsed since prior chemo- or radiotherapy. Patients must be past the nadirs from previous therapy and have a performance status of 2 or better. They must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Hanson indicated that he is just starting to prepare the manuscript on this Phase II agent.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8728 Status: Completed
 Title: Evaluation of Didemnin-B in Metastatic Adenocarcinoma of the kidney, Phase II.

Start Date 22 Jan 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Kidney, Adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To evaluate the likelihood of response in patients with advanced renal cell carcinoma in order to assess whether Didemnin-B should be advanced to further studies.

2) To evaluate the qualitative and quantitative toxicities of Didemnin-B.

Technical Approach: All patients must have a histologically confirmed diagnosis of advanced adenocarcinoma of the kidney not curable by surgery. Disease must be bidimensionally measurable. All patients must have adequate kidney, liver, and bone marrow function. Patients must have a performance status of 0-2.

Patients may not have received prior chemotherapy. One prior hormonal or immunotherapy is permitted, but objective evidence of progression of disease following prior treatment is needed.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8729 Status: Completed
 Title: A Phase II Trial of Low Dose Pala and High Dose 5-FU as a Short Term Infusion in the Treatment of Adenocarcinoma of the Pancreas.

Start Date 8 Apr 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, Pancreas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To evaluate response to a new regimen consisting of 24-hour infusion of high dose (effector) 5-FU and low dose (modulator) PALA in patients with advanced pancreatic adenocarcinoma.

2) To assess the qualitative and quantitative toxicities of the regimen.

Technical Approach: Patients must have verified advanced pancreatic adenocarcinoma that is objectively measurable.

Patients must have a central venous access placement (Hickman catheter or Infusaport) prior to starting therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Macdonald discussed this study in Dr. Ardalan's absence. Twenty-seven patients have been accrued and there has been one partial response. There also was one drug related death. This patient experienced severe diarrhea and nausea and vomiting.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8733 Status: Ongoing
 Title: Evaluation of Operable Bladder Cancer Patients with Pre-Operative Irradiation + 5-FU Alone, Phase II, a Pilot Study for Patients Ineligible for SWOG-8710.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Cancer, Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) Operable Patients: To evaluate the complete downstaging rate in patients with bladder cancer who are treated with pre-operative 5-FU/radiation. to assess the efficacy of treating patients with no histologic evidence of residual tumor following irradiation and 5-FU with additional irradiation and 5-FU without cystectomy. To assess the efficacy of treatment in patients who are not free of disease after initial treatment with 5-FU/radiation with radical cystectomy.

2) Inoperable Patients: To estimate the response rate of patients treated with 5-FU and radiation. To assess the qualitative and quantitative toxicities of this regimen in the treatment of bladder cancer.

Technical Approach: Patients must have primary or recurrent bladder cancer confined to the pelvis and no evidence of spread beyond the regional lymph nodes at or below the level of the bifurcation of the iliac vessels. Patients must not have any prior pelvic irradiation, or prior malignancies which are active, or synchronous non-bladder malignancies other than basal or squamous cell carcinoma of the skin or any other carcinoma in situ. Patients with prior inactive malignancies are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There are 18 patients registered with a total accrual goal of 40. No other report was provided.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8735 Status: Completed
 Title: A Phase II Study of Recombinant Human Interferon-Alfa and Recombinant Human Interferon-Gamma in Previously Untreated Patients with Chronic Myelogenous Leukemia.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia Myelogenous, Chronic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To develop an appropriate dose for alternate day therapy with recombinant human alfa and gamma interferon, in previously untreated patients with chronic myelogenous leukemia (CML).

2) To estimate whether such a regimen is of sufficient effectiveness and of sufficiently limited toxicity to justify its investigation in further trials. The effectiveness of the regimen will be measured by the rates of hematologic, cytogenetic, and molecular remission it produces.

3) To evaluate effectiveness and toxicity of such a regimen once an appropriate dose is developed.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: The report by Dr. Dabich disclosed difficulties with toxicity using the combination of alpha and gamma interferon. These problems are of sufficient magnitude and the efficacy sufficiently disappointing that the decision was made to close SWOG-8735. The NCI will be informed of this decision.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8736 Status: Ongoing
 Title: Treatment of Localized Non-Hodgkin's Lymphoma: comparison of
 Chemotherapy (CHOP) to Chemotherapy plus Radiation Therapy.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To establish the complete response rate (CR%), CR duration, survival and toxicity of chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) (eight cycles) versus CHOP (three cycles) plus radiation therapy in a cooperative group setting for patients with localized diffuse large cell lymphoma (DLC).

2) To determine if the difference in CR rates of combined treatment (less chemotherapy alone translates into longer survival with less toxicity.

3) To determine if subgroups (based on location, histology, age, stage) have significant prognostic importance with regard to CR%, time to progression, survival and toxicity.

4) To establish CR%, time to progression and survival for localized histologies other than diffuse large cell lymphoma .

Technical Approach: All patients must have biopsy proven Stage I or IE or non-bulky Stage II or IIE non-Hodgkin's lymphoma. Patients must have intermediate or high grade histology other than lymphoblastic lymphoma. No prior chemotherapy or radiation therapy is allowed. Patients with known AIDS syndrome or HIV associated complex are not eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has had an average accrual of eight patients per month with a total of 160 patients accrued on the study. This is higher than was anticipated. There has been no significant, unanticipated toxicity. As a result of Revision #7 on this study (December 1, 1989), in which the treatment port is to be indicated on the site diagram and approved by Dr. Cassidy, the radiotherapy compliance ratio has improved.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8737 Status: Ongoing
 Title: Phase III AZQ 24-Hour Infusion Versus BCNU for Adult High Grade Gliomas.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Gliomas, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the activity of 24-hour infusion AZQ versus a BCNU control for adult, high grade, supratentorial gliomas. Primary endpoints for evaluation will be survival and time to progression. Secondary endpoints, when evaluable, will be partial and complete response rates as determined by contrast enhanced CT scan. Identification of a 50% increase in survival over control is sought.

2) To develop a data base on current surgical practices with protocol patients and to study further the prevalence and management of pulmonary toxicity from BCNU.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Accrual to this trial has continued to improve with the March 1990 update demonstrating 97 patients registered on the study. Forty-six have been randomized to receive AZQ infusion and 44 randomized to receive BCNU. The additional seven patients have been registered on the radiation therapy portion of the study with randomization to AZQ versus BCNU to follow. Toxicity evaluations are present on 22 patients in the AZQ and 26 patients in the BCNU arm. Twelve patients on AZQ have experienced toxicities of Grade III and IV with no fatalities. The toxicities predominantly are leukopenia, granulocytopenia and thrombocytopenia. Other toxicities include allergies, with one possible anaphylactoid reaction. An adverse drug reaction was filed regarding this toxicity. Seven patients have experienced Grade III or IV toxicity on the BCNU arm. Grade IV toxicities include leukopenia, thrombocytopenia and granulocytopenia. There has been pulmonary toxicity observed with patients discontinuing treatment because of pulmonary fibrosis with no fatalities observed. At present with the improved accrual rate, it seems clear that the Southwest Oncology Group can enter the 200 patients necessary to evaluate the scheduling of AZQ as a treatment for high grade brain tumors.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8738 Status: Completed
 Title: Treatment of Extensive Non-Small Cell Lung Cancer: Standard Dose Cisplatin Versus High-Dose Cisplatin in Hypertonic Saline Alone Versus High-Dose Cisplatin/Mitomycin-C.

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Non-Small Cell, Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare standard dose cisplatin chemotherapy to high-dose cisplatin in hypertonic saline alone to high-dose cisplatin/mitomycin C in a randomized study, with stratification for known important prognostic factors, with regard to response rate, response duration and survival duration.

2) To compare the toxicities of these three chemotherapy regimens in patients with extensive non-small cell lung cancer.

Technical Approach: Patients with metastatic disease are eligible. this includes patients with metastases to the lung. This does not include patients whose only metastases are to the ipsilateral hilar nodes and/or mediastinal nodes, or to the supraclavicular nodes only. All patients must have pathologically demonstrated advanced non-small cell lung cancer of the following histologic types: squamous cell, adenocarcinoma or large cell carcinoma. All patients must have bidimensional (perpendicular diameters) objectively measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Planned interim survival analysis, as performed by Dr. Crowley and presented by Dr. Gandara, indicates a very low probability that the high dose cisplatin arm could be superior to the standard. Both of the arms containing high dose cisplatin are significantly more toxic. Therefore, this study will be closed prior to reaching its initially projected accrual goals.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8741 Status: Ongoing
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in
 Patients with Refractory Carcinoma of the Breast.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma Breast, Refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with refractory carcinoma of the breast.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This trial is temporarily closed with 19 patients registered. Thus far there have been no responses. If, after a few more months when additional data on some of the last few patients registered has been obtained, and no responses have occurred, the trial will be permanently closed. Mild leukopenia and an increase in the PTI have been the only minor toxicities observed.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8742 Status: Completed
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Metastatic Sarcoma.

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Sarcoma, Metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To obtain preliminary evidence of antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with metastatic sarcomas.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have pathologically verified soft tissue sarcoma or bony sarcoma which is surgically nonresectable, metastatic to a site or sites distant from the primary lesion. All patients must have bidimensionally measurable disease.

Patients with lymphoma("reticulum sarcoma"), Kaposi's sarcoma and mesothelioma are ineligible.

Patients treated with zero or one previous chemotherapy regimen are eligible. Those who have been treated with previous biologics or immunotherapy are ineligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Since the opening of this protocol five patients have been randomized to the trial.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8743 Status: Completed
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Metastatic Colorectal Adenocarcinoma.

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with gastric adenocarcinoma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have histologically confirmed diagnosis of colorectal adenocarcinoma. They must have metastatic or recurrent disease incurable by surgery or radiation therapy and bidimensionally measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Whitehead discussed this study and pointed out that 25 patients were accrued and no responses occurred. There was mild coagulopathy noted. The study will be presented at the American Society of Clinical Oncology Meetings in May.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8744 Status: Ongoing
 Title: A Phase II Study of Recombinant tumor Necrosis Factor (rTNF) In
 Patients With Refractory Multiple Myeloma.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple, refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with refractory and relapsing multiple myeloma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: As of the meeting, a total of nine patients have been registered on rTNF with the protocol having been open for two years. One patient who had been progressing prior to therapy achieved disease stabilization on rTNF. The study will remain open for further case accrual at least until the next meeting.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8750 Status: Completed
 Title: Pilot Study to Examine Cytogenetic Abnormalities in Patients with Acute Leukemia, Ancillary

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Acute, Ancillary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To develop the capability for group-wide cytogenetic studies in leukemia within the Southwest Oncology Group with performance of studies at an institutional level followed by a central review of the data.

2) To organize a panel of expert cytogenetics within the Southwest Oncology Group that will form the core of the central cytogenetic review process.

3) To estimate the percentage of cases that are properly prepared and for which the central review confirms the local analysis.

4) To compare the cytogenetic abnormalities present in individual patients with acute leukemia registered on companion therapeutic protocols over this one year pilot period.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There is no new data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8752 Status: Completed
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients With Endometrial Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with endometrial cancer.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Four patients have been registered into this study as of Sep 30, 1989. Three of the four patients have been found to be ineligible, two due to non-endometrial primary cancer and the third had a second primary tumor and received two prior hormonal therapy regimens. The remaining patient experienced Grade 2 chills/fever, elevated alkaline phosphatase, and Grade 1 anemia, granulocytopenia, and weight loss. Because of the poor accrual to this study, it will be closed permanently.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8754 Status: Completed
 Title: Evaluation of Didemnin B in Disseminated Malignant Melanoma, Phase II.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, Phase II Disseminated, Malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To evaluate the response rate of disseminated malignant melanoma treated with didemnin B.

2) To assess the qualitative and quantitative toxicities of didemnin B administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This Phase II trial of Didemin B was closed after entry of 14 patients due to an unacceptable toxicity associated with the second course of therapy (anaphylaxis/severe allergic reaction). No responses were observed and Didemnin B will not be pursued further in malignant melanoma.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8760 Status: Completed
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Gastric Adenocarcinoma.

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Gastric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with gastric adenocarcinoma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have histologically confirmed diagnosis of gastric adenocarcinoma. Patients must have bidimensionally measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Macdonald briefly reviewed this study in Mr. Muggia's absence. Twenty-nine patients have been accrued. There has been no response but, only approximately 12 patients are currently evaluable for response. The analysis of this study continues and the study is closed.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8788 Status: Ongoing
 Title: Phase III Evaluation of "High Dose" versus "Standard Dose" Cisplatin
 Combined with Bleomycin and VP-16 for Advanced Metastatic Testicular Cancer.

Start Date 11 Mar 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To examine the value of "high dose" cisplatin (CDDP) versus "standard dose" CDDP in the regimen CDDP plus VP-16 plus bleomycin in advanced metastatic testicular cancer.

Technical Approach: all patients must have a histologic diagnosis of either advanced stage disseminated germ cell tumor, advanced extra gonadal germ cell tumor, or advanced metastatic testicular cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8789 Status: Ongoing
 Title: A Randomized Study of Etoposide + Cisplatin and Etoposide + Carboplatin (CBDCA) in the Management of Good Risk Patients With Advanced Germ Cell Tumors.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumor, advanced germ cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): To determine in a randomized trial the differences in response, toxicity, time to relapse and survival between two active chemotherapy regimens, etoposide + cisplatin and etoposide + carboplatin, for good risk patients with germ cell tumors.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This Memorial Sloan Kettering study in good risk testis cancer patients has accrued a total of 140 patients, 34 of them from the Southwest Oncology Group. Toxicities have been fairly predictable with the greatest degree of myelosuppression seen in the carboplatin arm. Response rates are very close with 84 and 86% response rates. The study remains open with a total accrual goal being 240 eligible patients.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8790 Status: Ongoing
 Title: A Randomized Trial of Adjuvant Intraperitoneal Recombinant Interferon Alpha-2 in Stage III Ovarian Carcinoma in Patients who have no Evidence of Disease after Surgery and Chemotherapy.

Start Date	FY 88	Est Comp Date:
Principal Investigator:	Timothy J. O'Rourke, LTC, MC	Facility:
Dept/Svc:	Department of Medicine/Oncology	Associate Investigators:
Key Words:	Carcinoma, Ovary	Richard O. Giudice, MAJ, MC
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:		0
Total Number Of Subjects Enrolled to Date:		0
Date of Periodic Review		16 oct 89 Results continue

Objective(s): 1) To assess the efficacy of alpha-2 interferon as an adjuvant to surgery and chemotherapy upon overall disease-free survival as well as number of relapses and site of relapse in patients with no evidence of disease but at substantial risk for subsequent recurrence.

Technical Approach: Patients must have a histologically confirmed diagnosis of Stage III ovarian carcinoma and must be found to be disease-free at second look surgery after treatment on SWOG 8412 or SWOG 8501; or after treatment on any other regimen that contains at least six courses of cisplatin or carboplatin.

Therapy will follow the schema outlined in the study protocol.

Progress: There were 28 patients registered on study as of May, 1989. Ten patients are evaluable for toxicity. There was one incidence of Grade 4 diarrhea. Three patients had Grades 1 & 2 flu-like symptoms; Grade 2 pain at the catheter site, and Grade 1 insomnia and fatigue. The study remains open for accrual; however, if the accrual does not increase to at least 16 patients per six months and/or the study is not joined by a second cooperative group, it will be closed shortly.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8791 Status: Ongoing
 Title: (INT-0087) "Adjuvant Trial of Soft Tissue Sarcomas, Phase III."

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcomas, Phase III Soft Tissue	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To assess whether adjunctive chemotherapy with adriamycin, DTIC, and ifosfamide/mesna can improve the survival and disease-free survival of selected patients with soft tissue sarcomas.

2) To establish a repository of frozen sarcoma tissue to be used for ancillary genetic and flow cytometric analysis of these tumors.

Specific goals of genetic analysis are to determine the alterations and expression of proto-oncogenes, kinases, growth factors, and growth factor receptors in Grade III adult sarcomas, to correlate these findings with various clinical parameters, and to determine if they provide independent prognostic information above that provided by stage and histologic type.

The goals of flow cytometric analysis are to determine the various patterns of ploidy and the proliferative activity of Grade III adult sarcomas and to correlate these findings with various clinical parameters. It is anticipated that with sufficient data, a model predicting survival may be derived from a combination of DNA ploidy patterns, size and location both for patients receiving and not receiving chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This intergroup study was opened in March 1989. To date it has accrued only two patients. An amendment to eliminate the requirement for biopsy specimens to be submitted for flow cytometric and genetic analysis was made in May 1989, but accrual has not improved. This study remains open pending further discussion with other intergroup participants.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8792 Status: Ongoing
 Title: Phase III Study of Alfa-n1 (Wellferontm) as Adjuvant Treatment for Resectable Renal Cell Carcinoma

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, renal cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): To assess in a controlled fashion the effectiveness of interferon alfa-n1 (Wellferontm) as a surgical adjuvant in patients with renal cell carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This initial ECOG study now has 161 registered patients of the 240 needed. Anticipated closure is in 1991. No serious toxicities were reported.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8793 Status: Ongoing
 Title: Randomized Phase III Evaluation of Hormonal Therapy versus Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To determine the time to progression and survival, in patients with histologically confirmed Stage D1 prostate cancer following prostatectomy and pelvic lymphadenectomy treated immediately with hormonal therapy.

2) Determine whether the effects of early hormone therapy on local control of D1 prostate cancer.

Technical Approach: Patients must have histologically confirmed diagnosis of adenocarcinoma of the prostate (not including "endometrioid" carcinoma). Patients must have pathologic D1 disease. Histological confirmation of pelvic node involvement is required for a patient to be considered to have Stage D1 disease. Confirmation must be obtained by formal pelvic node dissection.

Therapy will follow the schema outlined in the study protocol.

Progress: A collaborative effort with the Eastern Cooperative Group study EST-3886 in which hormonal therapy is compared to observation alone in D1 patients with adenocarcinoma of the prostate. Accrual is extremely slow with only 29 patients and at this rate, the anticipated closure date would be almost another decade. It was elected to keep this open for at least another cycle of meetings to see if accrual will improve. Ultimately a decision will need to be made as to whether or not this study can be continued although clearly it is a study originating in ECOG. It should be noted that Dr. Messing of ECOG and Dr. Sarosdy will discuss the possible use of other forms of hormonal therapy in addition to or in substitution for current orchiectomy.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8794 Status: Ongoing
 Title: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy.

Start Date 16 Oct 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Carcinoma, Prostate	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	2
Total Number of Subjects Enrolled to Date:	6
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare in a randomized study, the disease-free survival rates in completely resected patients with pathologic stage C (T3N0M0) carcinoma of the prostate assigned to be treated with adjuvant external beam radiotherapy to that in patients assigned to receive no adjuvant therapy.

2) To assess the qualitative and quantitative toxicities of patients with pathologic stage C (T3N0M0) carcinoma of the prostate when treated with external beam radiotherapy.

Technical Approach: Patients must have undergone radical prostatectomy and pelvic lymphadenectomy with a histologically proved diagnosis of pathologic stage C (T3N0M0) carcinoma of the prostate. Patients must be able to begin treatment within 14 weeks after radical prostatectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Thompson reported that this is extremely important to use only pathological stage C patients for this trial. At this time there are 55 patients on the study and Dr. Thompson emphasized that the quality of life adjunctive trial, SWOG-8994, would result in an extra half credit for any patient registered on this study.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8795 Status: Ongoing
 Title: Randomized Prospective Comparison of Bacillus Calmette-Guerin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder, with DNA Flow Cytometric Analysis, Phase III.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Bladder Superficial, Transitional Cell Or	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): The overall objective of this protocol is to compare the efficacy and toxicity of two commonly used intravesical treatments for recurrent transitional cell carcinoma. The treatments to be evaluated are Mitomycin-C (MMC), and Tice substrain of Bacillus Calmette-Guerin (BCG).

- 1) The primary objective of this study is to compare the efficacy of MMC in preventing recurrence of superficial stage Ta and T1 transitional cell carcinoma of the bladder with that of BCG.
- 2) To compare the survival and cause-specific survival of patients randomized to each treatment arm.
- 3) To compare the toxicity of each treatment with respect to local effects of cystitis, bladder contraction, and hematuria as well as systemic effects including hypersensitivity, infection, bone marrow suppression, and others.
- 4) To compare treatments with respect to the pathologic grade and stage of recurring tumors.
- 5) To compare treatments with respect to differences in flow cytometry histogram findings of tumors before treatment and at the time of recurrence.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: To date, 160 patients have been entered and the toxicity analysis shows that the BCG patients had some form of toxicity 65% of the time with 47% of mitomycin patients having some type of toxicity. Accrual is about 20 patients per month and 30 per month are needed to accomplish the goal of accrual in a timely fashion. Dr. deVere White gave a brief update on SWOG-8507 flow cytometric data and commented that on SWOG-8795 the current accrual totals 96 cases for analysis.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8796 Status: Ongoing
 Title: Combination Chemotherapy for Advanced Hodgkin's Disease, Phase III Intergroup.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Hodgkin's Disease, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	3
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To compare the effectiveness of the MOPP/ABV Hybrid with sequential MOPP -> ABVD in patients with advanced or recurrent Hodgkin's disease and to determine which regimen is superior with respect to the following parameters: A) complete response rate; B) duration of complete response; C) freedom from progression; D) survival.

2) To prospectively correlate doses of chemotherapy administered with clinical outcome.

3) To analyze and compare the toxicity and patient tolerance on each of the above two treatment programs.

Technical Approach: Patients must have histologic confirmation of Hodgkin's disease (Ann Arbor classification). All patients entered must have the tissue from which the diagnosis of Hodgkin's disease was made sent to the SWOG Pathology Office for review and classification immediately following registration.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no new reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8804 Status: Completed
 Title: Evaluation of Cis-Platinum and DTIC in Inoperable Stage III and Stage IV Melanoma, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Melanoma, Inoperable	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): To evaluate the response rate and efficacy of DTIC and cisplatin in combination for patients with inoperable Stage III or Stage IV melanoma.

Technical Approach: Patients must have measurable, histologically confirmed metastatic melanoma with disseminated (Stage IV) or inoperable regional (Stage III) disease. Patients must have adequate renal, hepatic, and hematologic function, and a performance status of 0-2.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no new reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8805 Status: Ongoing
 Title: Neoadjuvant Cisplatin and VP-16 plus Concurrent Chest and Optional Brain Irradiation for Patients with Stage III Non-small Cell Lung Carcinoma, A Phase II Pilot.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Lung Stage III, Non-Small Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to 2	
Date of Periodic Review 16 Oct 88 Results Continue	

Objective(s): 1) To assess the feasibility and toxicity of treating patients with Stage III non-small cell lung cancer with cisplatin and VP-16 for two cycles, concurrent with a program of continuous, fractionated chest and optional whole brain irradiation, followed by surgical resection.

2) To assess the objective response rate, resectability rate, and proportion of patients free of microscopic residual disease after such an approach.

3) To assess whether immunocytochemical analysis and/or DNA analysis (ploidy, proliferative fraction) define subset(s) of patients who benefit from this combined modality approach, and to potentially assess the impact of chemoradiotherapy on the ploidy of the tumor.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Sixty patients have been registered to date. See the attached table for a detailed breakdown of toxicity and results to date. The study remains open and should meet accrual goals within 12 months.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8806 Status: Completed
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in
 Patients with Advanced Bladder Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Bladder, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with advanced bladder cancer.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There is no new reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8808 Status: Ongoing
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in patients with Chronic Myeloid Leukemia

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: leukemia, chronic myeloid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To obtain preliminary evidence of the antitumor effect of recombinant tumor necrosis factor (rTNF) administered to patients with chronic myeloid leukemia.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8809 Status: Ongoing
 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.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphomas, malignant, low grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy $\pm$ radiation therapy, to those who receive induction therapy alone.

2) To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MOPP (Day 1-8).

3) To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study has accrued 147 patients, with an average of 8-10 patients entered per month. This study has encountered difficulty in retaining patients due to the study design with a second randomization. Only 40% of the first 50 patients entered on study have gone on to the second randomization; this is much fewer than anticipated. On the ProMACE-MOPP chemotherapy, two fatal toxicities have been reported. One patient had pulmonary infiltrates, possibly treatment related, and the other had adult respiratory distress syndrome. Grade 4 toxicities have included leukopenia, granulocytopenia, thrombocytopenia, infection, pneumocystic pneumonia, anemia, mucositis, nausea, pancytopenia, and adult respiratory distress syndrome. The study has been amended for patients with residual disease present in the bone marrow following six cycles of ProMACE-MOPP. These patients will receive two additional cycles of treatment, and then be evaluated. In addition, the study was amended to assure adequate hydration with the administration of methotrexate. The study has also been amended so that a positive bone marrow within the last six months will no longer need to be repeated within 42 days prior to registration if the patient has received no interim treatment. It is hoped that these changes will increase this study's accrual and retention of patients.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8810 Status: Ongoing
 Title: Six courses of 5-Fluorouracil and Cis-platinum with Correlation of Clinical Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) Evaluate, following three and six courses of treatment the likelihood of increased numbers of patients achieving complete response rates when given three additional courses of the same regimen.

2) Evaluate the qualitative and quantitative toxicities of 5-fluorouracil and cisplatin following three and six courses of treatment.

3) Evaluate by serial biopsy and flow cytometry the correlation of the cellular DNA parameters of degree of aneuploidy (DNA index) and proliferative activity (SPF) with patient clinical characteristics, tumor morphology, cytotoxic response, disease free interval and survival.

Technical Approach: Patients must have a histologically confirmed diagnosis of advanced unresectable squamous cell carcinoma of the head and neck Stages T4, NO-3, MO or T2-3, N2-3, MO. Each patient will be examined by a multi-modality team prior to entry on study. Patients must be staged as having measurable disease within one week prior to entry on study.

Therapy will follow the schema outlined in the study protocol.

Progress: Results from this study (as well as SWOG-8803 and other data from studies at Wayne State University) will be presented at ASCO. The flow cytometry analysis from these studies indicates that DNA diploid tumors or tumor components are unresponsive to intermittent cisplatinum-containing cytotoxic therapy but, due to their growth characteristics, demonstrate better local control and survival following surgery.

Detail Summary Sheet

Date: 1 Oct 90	Proj No: SWOG 8812	Status: Ongoing
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."		
Start Date FY 1989	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:	
Key Words: Cancer, Limited Small Cell, Lung		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 1		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 16 Oct 89 Results Continue		

Objective(s): 1) Patients with limited stage small cell lung cancer (SCLC) will receive induction chemotherapy (cisplatin + VP-16 + GM-CSF) and concurrent chest radiotherapy. This study is designed to answer two questions:

Induction/Consolidation.

- To compare the days of neutropenia (absolute granulocyte counts <500/ u1), the days of leukopenia (leukocyte counts <1,000/ u1), the incidence and severity of infections, the incidence and duration of fever, the days on antibiotics, and the days of hospitalization between patients receiving GM-CSF and those not receiving GM-CSF.

- To evaluate the toxicities of GM-CSF in patients randomized to receive it.

2) Maintenance.

- To evaluate the ability of rHuIFN Alpha-2a to prolong remission duration and survival.
- To evaluate the toxicities of rHuIFN Alpha-2a.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No more lethal toxicity has been seen since the amendment was issued reducing drug dosage. Accrual is satisfactory and the study will continue.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8814 Status: Ongoing
 Title: Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF.

2) To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This adjuvant trial in postmenopausal ER-positive patients comparing tamoxifen versus CAF plus tamoxifen versus CAF followed by tamoxifen has been open approximately one year and it is averaging approximately 20 patients per month, which is half of its estimated accrual. Thus far, there are 169 patients registered. At the meeting we discussed reasons for possible low accrual and most of them stem from the problem of randomizing a patient to a regimen that does not contain chemotherapy with one that does. There was also discussion about whether the tamoxifen alone arm should be closed in view of the NSABP trial that suggests an advantage for the combination. However, in view of the other trials that do not show an advantage, we felt that this study should remain as is for the present time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8816 Status: Ongoing
 Title: Study of 13-cis Retinoic Acid (Accutane) Plus rIFN-alpha A (Roferon-A) in Mycosis Fungoides, Phase II.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Fungoides, Mycosis, Phase II	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) To evaluate the response rate of mycosis fungoides (cutaneous T-cell lymphoma) treated with the drug combination of 13-cis Retinoic Acid (Accutane) plus rIFN-alpha A (Roferon-A).

2) To assess the qualitative and quantitative toxicities of the regimen in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: As of May 2, 1990, five patients have been entered on this study. The protocol was revised on November 1, 1989 to allow photographs for documentation of disease measurement. Investigators are urged to involve dermatologists at their institution in the active treatment of these patients.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8819 Status: Ongoing
 Title: Central Lymphoma Repository Tissue Procurement Protocol

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associ Investigators:
Key Words: Lymphoma, central Tissue, repository	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Ongoing	

Objective(s): 1) To acquire fresh snap-frozen lymphoma tissue to establish a central lymphoma tissue repository.

2) To establish a standard set of procedures for routine acquisition, banking, and study of lymphoma tissues within the cooperative group.

3) To use repository tissue to establish clinical correlations via presently activated phenotyping studies and future projected molecular studies assessing specimen DNA and RNA status.

4) To determine if pretreatment phenotype or genotype predict patient outcome with respect to complete response rate, time to progression, and survival using prospective trial designs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: 107 snap frozen cases have been submitted to the repository to date. 103 have been analyzed with 50 assays being performed on each lymphoma. These submissions have come from a total of 21 institutions with 80% coming from Arizona, Oregon, Cleveland Clinic, Galveston, San Antonio, New Mexico and Loyola. The goals of this study include: 1) establishing lineage and 2) histocompatibility, and 3) predicting outcome based on these tests. Fifty-one genotypes have been completed, and BCL-2 appears to be significant. In addition, those patients who lack histocompatibility antigens appear to have a shorter median survival. Host response is also significant. Relapse tends to occur when T-TIL drops below 6%. This study has reinforced the importance of urging pathologists to freeze the specimens at the diagnostic procedure. It is also important that institutions ensure the eligibility of specimens by submitting tissue samples rather than marrow.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8828 Status: Ongoing
 Title: A Phase II Trial of Carboplatin (CBDCA) In Relapsed or Refractory Acute Myeloid Leukemia

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: leukemia, refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the complete remission rate of carboplatin (CBDCA) in patients with relapsed or refractory acute myeloid leukemia (AML).

2) To assess the qualitative and quantitative toxicities in patients with relapsed AML treated with carboplatin.

3) To identify the pattern of treatment failure by the criteria of Priesler.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8829 Status: Ongoing
 Title: Evaluation of Amonafide in the Treatment of CNS Tumors Phase II.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumors, CNS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) The objectives of this phase II study of amonafide in patients with cancer in the central nervous system are to:

- evaluate the response rate and duration of response in order to assess whether amonafide should be advanced to further studies and

2) Evaluate the qualitative and quantitative toxicities of amonafide.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Brown reported that the study had accessioned 23 patients, 15 astrocytomas and 8 in the other tumor category. At present 19 of these are likely to be eligible. Toxicity information was reported on 16 evaluated patients; leukopenia and thrombocytopenia of Grade III and IV were seen. A pulmonary embolism was seen in one patient which was nonfatal. The study will remain closed pending evaluation of response, but at present no responses were reported and thus it is likely the study will close permanently.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8833 Status: Ongoing
 Title: Phase II Investigation of Chlorambucil and Fludarabine Monophosphate in Relapsed or Refractory Chronic Lymphocytic Leukemia.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Chronic Lymphocytic,	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To estimate the maximum tolerated dose (MTD) of Fludarabine monophosphate (FAMP) when given in combination with chlorambucil for patients with relapsed or refractory chronic lymphocytic leukemia (CLL).

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study has been accruing patients on schedule. Dr. Elias has reported that dose level 2 seems tolerable and we have gone on to dose level 3 while we are evaluating the second cycle of therapy at dose level 2. This study will provide the doses for the combined use of fludarabine and chlorambucil in the upcoming three armed intergroup study which we plan to join with CALBG and ECOG.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8834 Status: Ongoing
 Title: A Phase II Evaluation of Fazarabine in Central Nervous System Tumors

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: tumors, CNS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) Evaluate the likelihood of response in order to assess whether fazarabine should be advanced to further studies.

2) Evaluate the qualitative and quantitative toxicities of fazarabine.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study evaluating a drug provided by a foreign drug company will be coordinated through Access Biotechnology which will make the necessary arrangements with the drug company. Concerns were raised regarding the total number of patients needed to answer the question based upon time to progressive disease. As currently designed, this will require approximately 120 patients. Efforts to contact the Brain Tumor Cooperative Group and Radiation Therapy Oncology Group to perform an intergroup study will be explored.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8835 Status: Ongoing
 Title: Intraperitoneal Mitoxantrone vs. Intraperitoneal FUDR in Ovarian Cancer Patients with Minimal Residual Disease After Second-Look Surgery. A Randomized Phase II Pilot.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Ongoing	

Objective(s): 1) To establish toxicity parameters for treatment regimens given intraperitoneally.

2) To evaluate the time to disease progression, sites of disease progression, and relapse rate of ovarian cancer patients with minimal residual disease after second-look surgery in the setting of a randomized phase II trial.

3) To evaluate the survival durations of patients on the two study arms.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There were 31 patients entered on study as of April, 1990. Among the 12 patients evaluable for toxicity on the mitoxantrone arm, the Main Grade 3 toxicities were abdominal pain and/or fullness/pressure. Since the study was amended on 5/15/89 to decrease the mitoxantrone dose to 10 mg/m² every other week, the gastrointestinal symptoms have decreased markedly. Of six catheter problems experienced by patients on the mitoxantrone arm, four occurred in nine patients treated at the 20 mg/m² dose. Two patients experienced Grade 4 thrombocytopenia on the FUDR arm and one patient each also experienced Grade 4 diarrhea and Grade 4 leukopenia. The study remains open to accrue at least 37 evaluable patients on each arm of the study.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8842 Status: Ongoing
 Title: Dihydroxyazacytidine in Malignant Mesothelioma, Phase II.

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review Results	

Objective(s): 1) To assess the response rate and survival of patients with unresectable malignant mesothelioma treated with Dihydroxyazacytidine (DHAC, NSC-264880).

2) To further evaluate the toxicity of DHAC given by continuous infusion.

3) To prospectively evaluate the use of CA-125 as a tumor marker in mesothelioma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Since the opening of this protocol five patients have been randomized to the trial.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8851 Status: Ongoing
 Title: Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer --Intergroup.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor-Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (Z + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T.

2) To compare the relative toxicities of these 3 regimens.

3) To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This trial has recently been activated. It currently has accrued 48 patients from the Southwest Oncology Group. This trial is being managed by the Eastern Cooperative Oncology Group and evaluates medical castration versus compete castration with Zoladex plus tamoxifen compared to chemotherapy alone. Thus far there are no unexpected toxicities.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8854 Status: Ongoing
 Title: Prognostic Value of Cytometry Measurements of Breast Cancer DNA from Postmenopausal Patients with Involved Nodes and Receptor Positive Tumors: A Companion Protocol to SWOG 8814.

Start Date: FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Ongoing

Objective(s): 1) To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG-8814.

2) To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is an ancillary study to the current postmenopausal node-positive, ER-positive adjuvant study and it is evaluating flow cytometry as a prognostic factor in this group of patients. There is no data available on this study yet.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8857 Status: Ongoing
 Title: Alternating Cisplatin/VP-16 with Continuous CAV and Consolidation
 Chemotherapy for Extensive Small Cell Lung Cancer with PCI for Complete
 Responders.

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: small cell lung cancer, extensive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To assess response rate (especially rate of CR) and toxicity of a "dose intensive" approach to induction chemotherapy in which cisplatin/VP-16 is alternated with cyclophosphamide, adriamycin and vincristine; consolidation therapy will be given to responders with one cycle of each induction regimen, coupled with prophylactic brain irradiation in CR patients.

2) To measure survival in patients so treated.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The study is accruing well with no problems to date.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8859 Status: Ongoing
 Title: DNA Flow Cytometric Analysis in Patients with Prostate Cancer

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: prostate cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To determine if ploidy analysis of prostate cancer by routine clinical flow cytometry (FCM) technique can predict response/survival/recurrence of patients registered to SWOG 8890 better than pathologic grade (Gleason) and stage (pathologic and clinical)

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8861 Status: Ongoing
 Title: Evaluation of Quality of Life in Patients with Clinical Stage A2 or B Adenocarcinoma of the prostate enrolled on SWOG-8890.

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: prostate, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To compare these primary aspects of quality of life, according to treatment assignment: 1.11) Treatment specific symptoms, 1.12) Physical functioning, 1.13) Emotional functioning.

2) To compare four secondary quality of life variables, according to treatment assignment: 1.21) General symptoms, 1.22) Role functioning, 1.23) Social functioning, 1.23) Global perception of quality of life.

3) To assess the feasibility of collecting quality of life data from patient report, self-administered questionnaires over a five year period in a cooperative setting.

4) The comparison of quality of life measurements between treatment arms will complement the analysis of survival data for patients registered to SWOG 8890 and become a critical consideration if no difference is demonstrated in survival between the treatment arms.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8890 Status: Ongoing
 Title: Radical Prostatectomy versus Radiation Therapy for Clinical Stage A² and B Adenocarcinoma of the Prostate (N⁰M⁰).

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: prostate, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To compare the effectiveness of external radiation therapy versus radical prostatectomy with respect to survival. Comparisons of time to first evidence of treatment failure, time to death from prostate cancer and impact of treatment on quality of life will be secondary issues.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: It should be noted that SWOG 8890 has finally opened and evaluates the role of radiation therapy and radical prostatectomy in early prostate cancer patients.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8891 Status: Ongoing
 Title: Low-Grade Glioma Phase III: Surgery and Immediate Radiotherapy vs Surgery and Delayed Radiotherapy.

Start Date FY 1989	Est Comp Date:
Principal Investigator:	Facility:
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center
Dept/Svc:	Associate Investigators:
Department of Medicine/Oncology	
Key Words:	
Glioma, Low-Grade, Phase III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89	Results Continue

Objective(s): 1) In adult patients with low-grade supratemporal glioma, to compare the effect on survival of radiation therapy (RT) administered immediately after pathological diagnosis with RT administered on progression as measured by clinical and/or radiographic (CT scan) and/or MRI.

2) To compare quality of survival in patients receiving immediate RT with that in patients receiving delayed RT.

3) In a cohort of adult patients with low-grade glioma whose disabling neurologic signs and symptoms require that they be treated with RT immediately, to evaluate biological and clinical variables which might predict prognosis.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study continues to have poor accrual with only one patient registered from the Southwest Oncology Group. Accrual from other groups appears to be slow with the Brain Tumor Cooperative Group entering 25 patients and the Radiation Therapy Group two patients in the year since the study was activated. No significant toxicity from radiation therapy has been reported by any group.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8892 Status: Ongoing
 Title: A Study of Radiotherapy With or Without Concurrent Cisplatin in
 Patients with Nasopharyngeal Cancer, Phase III

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Nasopharyngeal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Dec 99 Results Continue	

Objective(s): 1) To compare the complete response rate, time to treatment failure, overall survival and pattern of recurrence.

2) To assess the qualitative and quantitative toxicities

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Giri reported on the intergroup nasopharyngeal study. It is experiencing extremely poor accrual, but accrual has begun to increase over the last two months. This study may be closed unless significant improvement occurs quickly.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8894 Status: Ongoing
 Title: A Comparison of Bilateral Orchiectomy with or without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D₁ Prostate Cancer

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology Svc	Associate Investigators:
Key Words: cancer, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): 1) To compare bilateral orchiectomy + flutamide versus bilateral orchiectomy alone according to: 1) Survival, 2) Progression free survival, 3) Qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: It was noted that this was still clearing many human subjects committees and effective May 15, 1990, ALL Southwest Oncology Group patients (that are able to understand English) registering to SWOG-8794 must also register to SWOG-8994.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8896 Status: Ongoing
 Title: Phase III Protocol for Surgical Adjuvant therapy of Rectal Carcinoma:
 A Controlled Evaluation of A: Protracted Infusion 5-Fluorouracil as a
 Radiation Enhancer and B: 5-FU Plus Methyl-CCNU Chemotherapy.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, rectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To compare the local recurrence rates, rates of distant metastasis, disease-free survival, and overall survival in patients having potentially curative resections of modified Astler Collier B₂₋₃ and C₁₋₃ rectal carcinoma treated with sequential chemotherapy and radiotherapy using 5-FU as a radiation enhancer given either by simple IV bolus administration or by Protracted Venous Infusion (PVI) concomitant with radiation therapy.

2) To compare the same study endpoints for the same group of patients who either receive Methyl-CCNU as a component of the systemic therapy regimen or do not receive Methyl-CCNU as a component of the systemic chemotherapy regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Dr. Macdonald presented this study briefly. This is the intergroup adjuvant study which will be closed shortly with the advent of a new rectal adjuvant study. There is not data on efficacy of the four arms in SWOG-8896. The new study will test various chemotherapy regimens in conjunction with 5-FU + radiation and resective rectal cancer. The chemotherapy regimens includes 5-FU only, 5-FU + Levamisole, 5-FU + Leucovorin, and 5-FU + Leucovorin and Levamisole.

Detail Summary Sheet

Date: 1 Oct 90	Proj No: SWOG 8897	Status: Ongoing
Title: Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients, and a Natural History Follow-up Study in Low-Risk, Node Negative Patients (Intergroup).		
Start Date FY 1989	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:	
Key Words: Cancer, Breast, Node Negative		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 20		
Total Number of Subjects Enrolled to Date: 20		
Date of Periodic Review 16 Oct 89 Results Continue		

Objective(s): 1) To compare disease-free survival (DFS) and overall survival(s) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles.

2) To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients.

3) To compare the relative toxicity of the therapies.

4) To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only.

5) To evaluate the disease free survival and survival of low risk invasive breast cancer determined by receptor status, tumor size and % of S phase treated by local therapy only.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: More than 600 patients have been registered and we are averaging approximately 120 per month, greater than the expected 90 per month. There are no unexpected toxicities from the chemotherapy arms.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8899 Status: Ongoing
 Title: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Low-Dose Leucovorin Plus 5-FU Plus Levamisole Following Curative Resection in Selected Patients with Duke's B or C Colon Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colon, Duke's B/C	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To assess the effectiveness of 5-FU + low-dose Leucovorin, and 5-FU + high dose Leucovorin as surgical adjuvant therapy for resectable colon cancer, when compared to surgery alone.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is the intergroup study and was discussed by Dr. Macdonald. There are currently 436 patients enrolled in this study. The four arm study has not shown untoward toxicity and accrual is approximately 1-- per month. The estimated accrual for this study on an intergroup basis is 2,600 patients.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8900 Status: Ongoing
 Title: A Phase II Pilot of VAD and VAD/Verapamil for Refractory Myeloma.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, Refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Contin	

Objective(s): 1) To estimate the response rate and resp. duration of chemotherapy alone (VAD) and chemotherapy plus the chemo-fer, verapamil (VAD/V), in patients who have failed previous combination therapy.

2) To investigate the toxicities of these two treatments.

3) To evaluate the presence and prognostic significance of Ki-67 and P-glycoprotein in multiple myeloma.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Dr. William Dalton presented this two arm study of VAD versus VAD/Verapamil for patients with refractory or relapsing myeloma. At the time of the meeting, a total of 48 patients of the planned 100 registrations have been registered with equal numbers on VAD and VAD/Verapamil. Potential unusual toxicities of either Dexamethasone or the addition of Verapamil were discussed. These appear to be infrequent events and the use of VAD on SWOG-8624 has not been associated with significant unusual toxicity and the few instances of bone pain or additional GI toxicity with VAD/Verapamil will require further evaluation to see how frequent they are. There is preliminary evidence that these regimens are active in the treatment of myeloma and relapse and the studies will continue as scheduled.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8905 Status: Ongoing
 Title: Phase II/III Study of Fluorouracil (5FU) and its Modulation in
 Advanced Colorectal Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colorectal, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To determine and compare response rates and toxicities of 5-fluorouracil given by different schedules and/or with biochemical modulators to patients with advanced colorectal cancer.

2) To compare patient survival on the different 5-FU regimens.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study was discussed by Dr. Gail Leichman in Dr. Muggia's absence. Sixty-five patients have been accrued to this study. The Group was reminded that this study will accept non-measurable patients for treatment. Currently only ten percent of patients have non-measurable patients are placed on this study. It was also pointed out that the non-measurable patients were the patients in whom the North Central Cancer Treatment Group, in a similar study, showed survival benefit. No significantly adverse toxicity was reported, although there was one septic death which occurred after granulocytopenia had been resolved. There was one adverse drug reaction due to inadvertent overdosage. There was no evidence of excessive cancellations from this study which had been a concern because of the randomization between pumps and no pumps and intravenous catheters and no intravenous catheters.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8906 Status: Ongoing
 Title: Evaluation of Merbarone in Hepatoma, Phase II

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: hepatoma, merbarone	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the response rate and response duration of hepatomas treated with merbarone given as a five day continuous intravenous infusion, every 21 days.

2) To evaluate the qualitative and quantitative toxicities of merbarone administered on this schedule.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were three patients accrued and no toxicities or response data is available. The study remains open.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8910 Status: Ongoing
 Title: Evaluation of Low Dose Continuous 5-Flourouracil (5-FU) and Weekly Cis-Platinum (CDDP) in Advanced Adenocarcinoma of the Stomach

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: stomach, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate response to low dose continuous 5-FU and weekly cis-platinum in patients with advanced adenocarcinoma of the stomach.

2) To assess the qualitative and quantitative toxicities of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Five patients have been accrued. There is no toxicity or response data available. The study remains open.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8911 Status: Ongoing
 Title: Evaluation of Piroxantrone in Refractory Carcinoma of the Breast,
 Phase II

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: breast, carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the response rate of refractory carcinoma of the breast to treatment with piroxantrone.

2) To evaluate the toxicities of piroxantrone in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8912 Status: Completed
 Title: Evaluation of Fazarabine in Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Head/Neck, Squamous Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) Evaluate the response rate of recurrent squamous cell carcinoma of the head and neck when treated with fazarabine.

2) Assess the qualitative and quantitative toxicities of bolus fazarabine administered on a daily x 5 schedule.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Dr. Kuebler reported that this study has just been closed due to lack of any detectable activity in this tumor in the 14 patients studied.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8917 Status: Ongoing
 Title: 5-Flurouracil, Leucovorin and Roferon-A in Advanced Colorectal Cancer, Phase II Pilot

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: cancer, colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further study.

2) To evaluate the qualitative and quantitative toxicities of this regimen.

Technical Approach:

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8915 Status: Ongoing
 Title: A Phase II Study of 6-Thioguanine Administered as 120-Hour Continuous Infusion for Refractory or Recurrent Small Cell Carcinoma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: small cell lung, carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review:	Results:

Objective(s): 1) To assess response rate of 6-Thioguanine used in patients with refractory (progression while on treatment) or recurrent small cell lung cancer

2) To assess the qualitative and quantitative toxicities of this drug administered as a 120 hour continuous infusion in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8921 Status: Ongoing
 Title: Phase II Trials of Cyclophosphamide, IL-2, DTIC/IL-2 and
 DTIC/Cisplatin/Tamoxifen in Stage IV Melanoma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: melanoma,	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the response rates in patients with disseminated malignant melanoma treated with one of three regimens: cyclophosphamide (CY) and IL-2; dacarbazine (DTIC) and IL-2; or DTIC, cisplatin (CDDP) and tamoxifen (TAM).

2) To assess the qualitative and quantitative toxicities associated with each of the three regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This three part simultaneous Phase II trial of DTIC + IL-2, cytoxan + IL-2 and DTIC + DDP + Tamoxifen was activated in March 1990. To date, seven patients have been registered.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8925 Status: Ongoing
 Title: Evaluations of Cisplatin + VP-16 Followed by Mitotane at Progression if No Prior Mitotane or Cisplatin + BP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Metastatic Adrenal Cortical	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 89 Results Continue	

Objective(s): 1) To evaluate the response and response duration of patients with:

- adrenocortical carcinoma treated with combination chemotherapy consisting of cisplatin and etoposide, and
- of those who receive mitotane after progression on the above chemotherapy (if no prior treatment with mitotane).

2) To evaluate the qualitative and quantitative toxicities of these therapies.

3) To evaluate and compare tumor morphology of patients with this rare tumor.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There is no new reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8926 Status: Ongoing
 Title: Evaluation of Low Dose Continuous Infusion 5-Fluorouracil in Patients with Advanced and Recurrent Renal Cell Carcinoma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: renal cell, carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) Evaluate the likelihood of response in order to assess whether LDCI-5-FU should be advanced to further studies.

2) Assess the qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8929 Status: Ongoing
Title: Evaluation of Merbarone in Patients with Advanced Renal Cell Carcinoma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: renal cell, carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the response rate of advanced renal cell metastatic or recurrent, treated with Merbarone.

2) To assess the qualitative and quantitative toxicities of merbarone administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8930 Status: Ongoing
 Title: Phase II Trial of Piroxantrone for Advanced or Metastatic Soft-Tissue Sarcomas

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: soft tissue, sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To assess the activity of piroxantrone in the treatment of locally advanced or metastatic soft tissue sarcoma.

2) To evaluate the qualitative and quantitative toxicities of piroxantrone administered in this disease.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study has been approved for activation by CTEP and will be activated. It will remain as second priority to the Merbarone study until the Merbarone study until the Merbarone protocol is complete.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8931 Status: Ongoing
 Title: Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: breast, cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	Results

Objective(s): 1) To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16 week multi-drug chemotherapy regimen.

2) To compare toxicities of adjuvant CAF and a 16 week multi-drug regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8932 Status: Ongoing
 Title: Evaluation of Piroxantrone in Patients with Recurrent and Metastatic Squamous Cell Carcinoma of the Head and Neck, Phase II.

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: head and neck, squamous cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To assess the response rate of patients with recurrent and metastatic squamous cell carcinoma of the head and neck to treatment with piroxantrone

2) To evaluate the toxicities of piroxantrone in this patient population

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8939 Status: Ongoing
 Title: Evaluation of Merbarone in Colorectal Cancer, Phase II

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: cancer, colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the response rate and response duration of colorectal carcinoma treated with Merbarone given as a five day continues intravenous infusion, every 21 days.

2) To evaluate the qualitative and quantitative toxicities of Merbarone administered on this schedule.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8942 Status: Ongoing
 Title: High Dose Etoposide, Cyclophosphamide and Either Fractionated Total Body Irradiation or Carmustine Combined with Autologous Bone Marrow Rescue for Refractory or Relapsed Non-Hodgkin's Lymphoma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: lymphoma, non-hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate in a group-wide setting the complete response rate and survival of patients with either "sensitive" or "resistant" relapsed or refractory Non-Hodgkin's lymphoma treated with high dose VP-16, cyclophosphamide, and fractionated total body irradiation or VP-16, cyclophosphamide and BCNU (for patients receiving any prior mediastinal RT) combined with an autologous bone marrow transplant.

2) To assess the non-hematopoietic toxicities of these regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This recently activated limited institution study uses a regimen developed at City of Hope. It has had good activity in pilot studies.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8943 Status: Ongoing
 Title: Evaluation of Merbarone in Advanced Soft Tissue Sarcomas, Phase II

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: soft tissue, sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review Results	

Objective(s): 1) To assess the response rate of advanced soft tissue sarcomas treated with Merbarone.

2) To evaluate the qualitative and quantitative toxicities of Merbarone administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol,

Progress: Eight patients have been registered with 4 of those registrations being in the last 30 days.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8944 Status: Ongoing
 Title: A Phase II Study of Carboplatin (CBDCA) in Refractory Multiple Myeloma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: myeloma, refractory multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To assess the efficacy of carboplatin in terms of response ($\leq$ partial response) in patients with multiple myeloma refractory to standard therapy with VAD or VMCP-VBAP, i.e. displaying primary resistance or acquired resistance following a previous response to such regimen.

2) To assess the toxicities associated with carboplatin in terms of myelosuppression infectious complications and other organ toxicities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This Phase II study is newly activated in the Southwest Oncology Group, and two patients have been registered on study within the past 30 days. It is too soon to have either toxicity or response data available on this study.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8947 Status: Ongoing
 Title: Central Lymphoma Serum Repository Protocol

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: lymphoma, central	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review Results	

Objective(s): 1) To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies.

2) To utilize the Southwest Oncology Group clinical database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Dr. Slamon's HTLV-1 serology was disapproved by the NCI while the establishment of the repository was approved. This study now needs proposals for serum markers or assays to utilize the repository.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8952 Status: Ongoing
 Title: Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study
 Comparing ABVD vs MOPP/ABV Hybrid

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: advanced hodgkins	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities.

2) To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups.

3) To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There has been one registration on this study. Patients must have histologically documented, newly diagnosed, untreated Hodgkin's disease Stage III₂A, III₁B, IVA or IVB; Hodgkin's disease recurrent after definitive radiotherapy for primary localized Hodgkin's disease considered non-salvageable by additional radiotherapy.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8954 Status: Ongoing
 Title: Evaluation of the L-17M Protocol in the Management of Patients with Lymphoblastic Lymphoma, Phase II, Pilot.

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To assess the response rate and response duration of lymphoblastic lymphoma treated with the L-17M protocol.

2) To assess the qualitative and quantitative toxicities of the L-17M protocol administered in a Phase II study.

3) To assess the immunophenotypic characteristics of adult lymphoblastic lymphoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study uses a design of induction, consolidation and maintenance which has been used before in ALL. The consolidation period is shorter than that of the L-10M design. All stages of lymphoblastic lymphoma are eligible for this study, and patients will be stratified according to "good" or "poor" risk. Tissue submissions to the tissue repository (SWOG-8819) will be particularly important for this study because of the similarity between the phenotypes of lymphoblastic lymphoma and ALL. This study has been added to the list of companion studies for SWOG-8819.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8957 Status: Ongoing
 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 Pilot

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: cancer, head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the feasibility of administering three courses of chemotherapy to resected patients who have received cisplatin and radiation therapy post-operatively.

2) To evaluate the qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This feasibility study evaluating the feasibility and toxicity of this regimen for future use in the next Intergroup resectable protocol was recently activated. It is now open for patient accrual.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8994 Status: Ongoing
 Title: Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794.

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: prostate, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To compare these primary aspects of quality of life, according to treatment assignment: 1.11) Treatment specific symptoms; 1.12) Physical functioning; 1.13) Emotional functioning.

2) To compare three secondz y quality of life variables, according to treatment assignment: 1.21) General symptoms; 1.22) Global perception of quality of life; 1.23) Social functioning.

3) The comparison of quality of life measurements between treatment arms will complement the analysis of survival data for patients registered to SWOG-8794 and become a critical consideration if no difference is demonstrated in survival between the treatment arms.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: It was noted that this was still clearing many human subjects committees and effective May 15, 1990, ALL Southwest Oncology Group patients (that are able to understand English) registering to SWOG 8794 must also register to SWOG 8994.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8997 Status: Ongoing
 Title: Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: cancer, testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

- Objective(s): 1) To determine the objective response rate and duration of remission of BEP compare to VIP combination chemotherapy.
- 2) To determine the toxicity of VIP compared to BEP combination chemotherapy.
- 3) To confirm the efficacy and toxicity of intravenous Mesna as a urothelial protective agent.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is for poor risk patients. The southwest Oncology Group joined this effort in August of 1989 and has registered 14 of the total 90 patients entered to date. The study is accruing about four patients per month and with a target accrual of 300 it would take potentially another four or five years to complete. However, Dr. Ed Messing from ECOG thinks that the protocol will actually be closed in 1991. There have been two lethal toxicities reported, one in the non-Bleo arm from myelosuppression and one in the Bleo arm related to the pulmonary toxicity of that agent.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 8999 Status: Ongoing
 Title: Evaluation of Radiation Treatment Following Surgical Resection of Solitary Brain Metastasis

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: metastasis, brain	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate response rate, duration of response, neurological improvement and survival of patients with solitary brain metastases treated with surgery and radiotherapy.

2) To evaluate the pattern of failure in patients treated with surgery and radiotherapy (CNS vs systemic progression).

3) To assess the accrual rate and evaluate the feasibility of conducting a future randomized trial.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The accrual on this study remains very low with only three patients being entered in the last eight months. Reasons for possible low accrual were discussed and it seems clear that further attempts at advertising and encouraging enrollment are needed. This is particularly true in view of the plan to open a randomized study evaluating the contribution of radiation therapy to surgery in the management of solitary brain metastases.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 9001 Status: Completed
 Title: A Phase II Study of Alpha Interferon Plus 5-Fluorouracil in Patients with Advanced Renal Cell Carcinoma

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: renal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review Results	

Objective(s): 1) To evaluate the response rate of advanced renal cell carcinoma to treatment with combination alpha interferon and 5-Fluorouracil.

2) To evaluate the toxicity of the treatment program used.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The study was closed by SWOG due to problems with drug procurement. No patients were accrued to this study.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 9011 Status: Ongoing
 Title: High Dose Etoposide, Cyclophosphamide, and Either Fractionated Total Body Irradiation or Carmustine Combined with Autologous Bone Marrow Rescue for Refractory or Relapsed Hodgkin's Disease

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: bone marrow, hodgkins disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate in a group-wide setting the complete response rate and survival of patients with either "sensitive" or "resistant" relapsed or refractory Hodgkin's disease treated with high dose VP-16, cyclophosphamide, and fractionated total body irradiation or VP-16, cyclophosphamide and BCNU (for patients receiving any prior mediastinal RT) combined with an autologous bone marrow transplant.

2) To assess the non-hematopoietic toxicities of these regimens in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study uses the same regimen as SWOG 8942, except that it will focus on Hodgkin's disease. It is expected that the majority of these patients will receive BCNU rather than TBI.

Detail Summary Sheet

Date: 1 Oct 90 Proj No: SWOG 9013 Status: Ongoing
 Title: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery vs Surgery alone for Patients with Local Regional Disease, Phase III-Intergroup

Start Date FY 1990	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: squamous carcinoma, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, vs pre- and post- operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern.

2) To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality.

3) To compare the local and distant control rates with the two approaches and to define the pattern of failure.

4) to compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 7799 Status: Ongoing
 Title: Rare Tumor Registry for Childhood Solid Tumor Malignancies.

Start Date 25 Sep 81	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid tumor malignancies	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: One patient remains on this study. No reportable data are available.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8104 Status: Ongoing
 Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start Date 27 Jan 83	Est Comp Date:
Principal Investigator	Facility
Paul J. Thomas, M.D., COL, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	Allen R. Potter, LTC, MC
Key Words:	
Neuroblastoma	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Three patients remain on the study. Although the study was closed 8 Mar 90, it remains open for follow-up only.

Detail Summary Sheet

Date: 26 Sep 90	Proj No: POG 8304	Status: Completed
Title: SIMAL #4. Combination Chemotherapy for Remission Induction and Maintenance for: 1) Recurrent Childhood Lymphocytic Leukemia After Elective Cessation of Therapy; 2) Children with Occult Testicular Leukemia After 3 Years of Continuous Complete Remission.		
Start Date 27 Jan 84	Est Comp Date:	
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC	
Key Words: Leukemia, lymphocytic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review 0 Jul 90 Results Closed		

Objective(s): 1) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in children with ALL, who relapse 6 months or greater, after elective cessation of chemotherapy.

2) To evaluate the effectiveness of prophylactic intrathecal chemotherapy, during the second remission.

3) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in patients with testicular leukemia.

4) To determine the effectiveness of two regimens of cyclic maintenance chemotherapy in children with isolated CNS relapse.

Technical Approach: Patients less than 21 years of age with pathologic verification of leukemic relapse at any site more than six months after elective cessation of initial therapy are eligible. Children with their first CNS relapse are also eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed 15 May 1990.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8315 Status: Completed
 Title: Laboratory Study and Subclassification of Non-Hodgkin's Lymphoma.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Jul 90	Results Closed

Objective(s): 1) To provide a mechanism for the group wide study of biologic characteristics of lymphoma cells, by acquisition and coordination of data from reference laboratories.

2) To seek correlates of biologic characteristics, with histopathology, clinical presentation, and end results of protocol therapies.

3) To attempt the development of a comprehensive classification of childhood NHL which is both clinically and biologically relevant.

Technical Approach: Patients less than 21 years of age with tumor tissue or cells available for study who are simultaneously being entered on open, front-end POG treatment protocols for NHL are eligible for this study.

Progress: Two patients have been entered on study with satisfactory samples for classification. This study was replaced by POG 8600 and closed 9 May 1990.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8340 Status: Ongoing
 Title: Allogeneic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study

Start Date 12 Aug 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC,	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics/Medicine	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC John J. Posch, Jr. Barbara Reeb
Key Words: Transplantation, bone marrow, autologous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 22	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To determine the response rate and duration of patients aged > 1 year with metastatic (Stage D) neuroblastoma to intensive chemotherapy and fractionated total body irradiation followed by allogeneic or autologous bone marrow transplantation (BMT) performed in first clinical remission.

2) To determine the response rate and duration using the same regimen in patients with Stage D neuroblastoma who fail to respond to, or recur after, conventional chemotherapy.

3) To determine the toxicity of the above regimen.

Technical Approach: This pilot study tests the efficacy and toxicity of high dose melphalan and fractionated total body irradiation supported by allogeneic or autologous BMT for neuroblastoma in first clinical remission or following relapse.

Bone marrow aspiration and therapy will follow the schema outlined in the study protocol.

Progress: Twenty-two patients have been transplanted. There have been 4 early deaths, 17 successful engraftments, and 1 partial engraftment. Overall disease free survival is 7/22 (32%). Disease free survival for patients transplanted when in complete response 3/8 (38%) and 4/14 (29%) for patients transplanted not in complete response.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8398 Status: Ongoing
 Title: Up-front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Childhood

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svr Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine the toxicity and complications, short and long term, of alternating intensive chemotherapy pairs in children with acute lymphocytic leukemia of poor prognosis. The intensive chemotherapy pairs are: 6-MP/MTX; VM-26/Ara-C; and Daunomycin/Ara-C.

Technical Approach: To be eligible for this study, patients must be registered on POG 8600. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on the study.

Detail Summary Sheet

Date: 16 Sep 90 Proj No: POG 8451 Status: Ongoing
 Title: Intergroup Rhabdomyosarcoma Study III

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To compare various forms of therapy of rhabdomyosarcoma based on favorable and non-favorable histology.

Technical Approach: Patients under 21 years of age with the diagnosis of rhabdomyosarcoma or undifferentiated sarcoma, type indeterminate, or extraosseous Ewing's sarcoma, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient died after multiple relapses of the tumor. One patient continues to do well.

Detail Summary Sheet

Date: 26 Sep 90	Proj No: POG 8493	Status: Ongoing
Title: Infant Leukemia Protocol		

Start Date 26 Mar 85	Est Comp Date:
Principal Investigator (vice Thomas)	Facility
Allen R. Potter, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Leukemia	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To establish the qualitative and quantiative toxicity of this regimen in infants and to determine criteria for dose modificalton in infants.

2) To obtain an estimate of survival and disease-free survival in infants <12 months of age treated with intensive chemotherapeutic regimen.

Technical Approach: Patients with ALL (or undifferentiated leukemia) <12 months of age at diagnosis are eligible. All patients must comply with immunologic and cytogenetic criteria for diagnosis according to POG front line ALinC classification studies and must be registered on that study as well as this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8495 Status: Ongoing
 Title: A Phase I Study of Hyperfractionation in Brain Stem Gliomas in Children

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain stem gliomas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To test the feasibility of treating children with brain stem gliomas with hyperfractionated (twice daily) radiotherapy.

2) To study the immediate and late side effects of such treatment.

3) To test the feasibility of escalation of the dose of radiotherapy in this situation.

4) To monitor the response of the patients in terms of tumor regression, disease free interval, and length of survival.

Technical Approach: Patients >3 and <21 years of age with a previously untreated tumor arising in the mesencephalon, pons, including the cerebellar peduncles and floor of the IVth ventricle, and medulla oblongata and with a life expectancy of greater than 6 weeks, shall be eligible for inclusion in this study. Therapy will follow the schema outlined in the study protocol.

Progress: One patient was transferred here for follow-up.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8532 Status: Ongoing
 Title: Treatment of Intracranial Ependymomas

Start Date 31 May 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Ependymoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To estimate the occurrence of subarachnoid seeding in children with well differentiated, IVth ventricular ependymoma following resection and posterior fossa irradiation.

Technical Approach: Patients ≥ 24 months and ≤ 21 years with histologically confirmed primary intracranial ependymomas or ependymoblastoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient alive with disease has relapsed in spinal cord.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8552 Status: Ongoing
 Title: A Case-Control Study of Childhood Rhabdomyosarcoma

Start Date 31 May 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To evaluate the relationships between environmental exposures and childhood rhabdomyosarcoma (RMS).

- 2) To evaluate associations between gestational factors and childhood RMS.
- 3) To evaluate the role of genetic factors in the etiology of childhood RMS.
- 4) To develop new methods for using subjects from collaborative cancer clinical trials for etiologic research.

Technical Approach: This is a case-control study of childhood RMS which will identify its cases from a large national collaborative clinical trial. The study will reexamine several promising hypotheses suggested by the preliminary study of RMS.

Progress: This study was closed 9 May 1990 but remains open for follow-up.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8561 Status: Completed
 Title: Phase II Study of 6-Mercaptopurine Administered as an Intravenous Infusion for Malignant Solid Tumors and Acute Leukemia

Start Date 2 Aug 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid Tumors Acute leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Closed	

Objective(s): 1) To determine response rate of children with advanced malignatn disease for whom no effective anti-cancer therapy is known to treat-ment with 6-mercaptopurine (6-MP) administered as a 48 hour IV infusion.

2) To further assess the toxicity in a larger group of children.

Technical Approach: Patients must be $\leq$ 21 years of age with a measurable solid tumor or acute leukemia with either an M3 marrow or extra medullary disease. The diagnosis must be confirmed by appropriate histologic examination.

Progress: No patients have been entered into this study. Study closed 1 September 1989.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8600/01/02 Status: Ongoing
 Title: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia in Childhood (AlinC #14) - A Pediatric Oncology Group Phase III Study

Start Date 28 Mar 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphoid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To test the concept that intensive asparaginase (ASP) therapy, designed to maintain low asparagine levels for the first six months of maintenance will improve the outcome of patients with standard risk acute lymphocytic leukemia (ALL) when added to pulses of intermediate dose methotrexate (MTX), as compared to intensification with IDM alone.

2) To study the effectiveness in standard risk patients of intensification with a potentially synergistic or additive drug pair, i.e., IDM plus AraC, as compared to that of intensification with IDM pulses alone.

3) To determine if administering a pulse of IDM + AraC at 3 week intervals during the first 4 months of complete remission in children with ALL is superior to administering the same number of IDM + AraC pulse at 23-week intervals during the first 2 years of complete remission in children with ALL with either "lower" or "higher" risk of relapse.

4) To obtain further information on the immediate and delayed toxicity of the continuation of chemotherapy program that incorporates these combinations of MTX and AraC or MTX and ASP in moderately high doses.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient was removed from the study due to diabetes secondary to chemotherapy.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8615 Status: Ongoing
 Title: A Phase III Study of Large Cell Lymphomas in Children and Adolescents:
 A Comparison of Two Treatment Regimens - ACOP+ vs AOP

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To determine the influence of alkylating agent (cyclophosphamide) 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 elimination of involved field and cranial radiation in the treatment of large cell lymphomas.

3) To evaluate the adequacy of one year of total therapy for advanced large cell Non-Hodgkin's lymphoma (NHL).

4) To study clinical pathologic patterns and biologic characteristics of large cell lymphomas in children and adolescents.

Technical Approach: Previously untreated patients under 21-years of age, available for periodic follow-up are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8616 Status: Ongoing
 Title: Intensive Chemotherapies for Stage III Diffuse Undifferentiated Lymphoma
 (DU NHL Burkitt and Non-Burkitt)

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To achieve chemotherapeutic cure (two-year disease-free survival) in a majority of patients with Stage III DU NHL.

2) To determine if a new regimen, Total Therapy B, is superior to high-dose Cytosan, high-dose methotrexate for patients with Stage III DU NHL.

3) To study potential interaction between treatment and LDH.

Technical Approach: Previously untreated patients under 21 years of age with a diagnosis of diffuse, undifferentiated non-Hodgkin's lymphoma, small non-cleaved cell (Burkitt or non-Burkitt), Stage III by Murphy's system will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8617 Status: Ongoing
 Title: Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, acute lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To estimate the complete remission (CR) rate in patients with Stage IV diffuse undifferentiated non-Hodgkin's Lymphoma (DU NHL) and B-Cell acute lymphocytic leukemia (B-ALL) with a new schedule of administration of 3 active agents: "split-dose" cyclophosphamide (cyclo) - Adriamycin (Adria) + vincristine (VCR).

2) To estimate the chemotherapeutic cure rate in Stage IV DU NHL and B-ALL with a brief (6 month) intensive rotational chemotherapy program designed to confer greater protection against central nervous system (CNS) disease and marrow relapse.

3) To estimate the reinduction rate and disease-free survival rate for patients in relapse with non-lymphoblastic lymphoma.

Technical Approach: Patients must be under 21 years of age at time of initial diagnosis in order to be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on study had an initially good response but relapsed after about six months and died. No new patients have been entered since that time.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8622 Status: Completed
 Title: Evaluation of Retinoic Acid in Pediatric Patients with Non-lymphocytic Leukemia

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, non-lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Closed

Objective(s): 1) To determine the effectiveness and further assess the toxicity of 13-cis retinoic acid (RA) in the treatment of children with acute non-lymphocytic leukemia (ANLL).

2) To explore the association of RA-induced differentiation in vitro with the response to RA in vivo if there is evidence of response in patients with ANLL.

Technical Approach: Patients under 21 years of age at time of diagnosis who have ANLL in bone marrow relapse who have been resistant to other forms of therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date. This study was closed 7 November 1989.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8625/26 Status: Ongoing
 Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA₁ Hodgkin's Disease in Pediatric Patients

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Thomas)	Facility
Allen R. Potter, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Hodgkin's disease	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 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 or remission and eventual survival (with one cycle = 1 course MOPP and 1 course of ABVD) 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: Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have completed treatment and continue to do well. One patient transferred in is off therapy with no evidence of disease.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8631 Status: Ongoing
 Title: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs Standard Dose Irradiation - A Phase III Study.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Medulloblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To determine patterns of recurrence, disease free survival, and survival in patients with favorable prognosis medulloblastoma who receive a neuraxis dose of 2340 rad compared to those who recieve 3600 rad.

2) To study the quality of survival obtained by decreasing the dose of radiotherapy to cerebrum and spinal cord.

3) To evaluate prospectively the central nervous system (CNS) functions of these children with IQ tests, CT scans, neurological examinations, psychometric testing and neuroendocrine tests.

Technical Approach: Patients >36 months and <21 years of age at diagnosis are eligible. Patients must have no evidence of dissemination beyond the posterior fossa confirmed by myelogram, chest x-ray, bone scan, bone marrow and CSF exam, i.e. M0.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8633/34 Status: Ongoing
 Title: Treatment of Children 3 years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) 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 <2 years old.

2) To estimate the response (CR or PR) to two cycles of cyclophosphamide and vincristine in children with measurable tumor at the initiation of chemotherapy.

3) To estimate the objective response rate (CR, PR, SD) and disease control interval with this multi-agent chemotherapy regimen.

8634 - To estimate the response rate, disease control interval, recurrence-free survival and survival of those children who, after having progression of disease on chemotherapy (#8633), are subsequently treated with surgery and radiation therapy or radiation therapy alone.

Technical Approach: Inclusion-exclusion criteria and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date. POG 8633 has been closed; however, POG 8634 remains open.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8638 Status: Completed
 Title: Randomized Phase II Study of Carboplatin (CBCDA) vs CHIP in the Treatment of Children with Progressive or Recurrent Brain Tumors

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Closed
Objective(s): 1) To determine the effectiveness of Carboplatin (CBCDA) and CHIP in the treatment of children with progressive or recurrent brain tumors.	

2) To compare the toxicities associated with the use of each agent.

Technical Approach: To be eligible for this study, the patient must be ≤ 21 years of age at initial diagnosis, with a recurrent or progressive brain tumor, and who has not been entered on more than one phase II new agent study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date. Study closed 9 April 1990.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8650 Status: Ongoing
 Title: National Wilms' Tumor Study - 4: Stage I/Favorable or Anaplastic
 Histology

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Wilms' tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To gain a better understanding of the Wilms' tumor by gathering detailed information regarding gross and histologic morphology and to correlate this information with treatment and clinical outcome.

Technical Approach: Patients will be randomized according to stage and histology.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered as a "followed" patient because the primary was non-resectable. Two additional patients were transferred here as "followed" patients. Two patients have died and one relapsed 10 years off therapy.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8651 Status: Ongoing
 Title: Osteosarcoma #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Non-Metastatic Osteosarcoma.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): To determine whether chemotherapy administered prior to and after the definitive surgery of the primary tumor can improve the disease-free and/or overall survival of patients with non-metastatic osteosarcoma of the extremity or resectable bone when compared to the traditional approach of surgical treatment of the primary tumor followed by adjuvant chemotherapy.

Technical Approach: To be eligible for this study, the patient must be under 30 years of age, have no prior history of cancer and no prior therapy other than biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8653/54 Status: Ongoing
 Title: A Study of Soft Tissue Sarcomas Other than Rhabdomyosarcoma and Its Variants

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To determine whether adjuvant chemotherapy with vincristine, Adriamycin, cyclophosphamide, and actinomycin D (VACA) increases 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 postoperative radiation.

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

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8661 Status: Completed
 Title: Evaluation of CHIP in Malignant Solid Tumors, A Phase II Study

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Closed	

Objective(s): 1) To evaluate the response rate to CHIP in patients with recurrent malignant tumors resistant to conventional therapy.

2) To evaluate the toxicity of CHIP in these patients.

Technical Approach: To be eligible for this study, the patient must be <21 years of age, have a life expectancy of ≥4 weeks and absence of significant uncontrolled infection.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date. This study was closed 9 April 1990.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8691 Status: Ongoing
 Title: T-Cell #3 Pilot Study

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To determine the toxicity and complications associated with the administration of this intensive chemotherapy regimen to children with T-cell leukemia and advanced stage T-cell lymphoma.

2) To determine the feasibility of using this chemotherapy regimen as the backbone of a randomized groupwise T-cell study evaluating intensive L-asparaginase therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been entered. One patient achieved remission but relapsed after about one year. The other patient remains on therapy with good response. One patient on therapy was transferred-in.

This study has been closed to new entries; however, it remains open for follow-up and continued therapy of the one patient who has responded.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8695 Status: Completed
 Title: A POG Pilot Study of Front Loading Chemotherapy in Children with Increased Risk Medulloblastoma

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Medulloblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Closed

Objective(s): 1) To evaluate the feasibility and acute toxicity of chemotherapy prior to radiation therapy in the treatment of newly diagnosed children with medulloblastoma who are at increased risk for recurrence.

2) To measure tumor response to the entire chemotherapy regimen of cis-platinum, vincristine, and high-dose cyclophosphamide prior to irradiation.

3) To evaluate the feasibility of a centralized rapid neuroradiology review of pre-study CT scans and myelograms in determining patient eligibility.

Technical Approach: To be eligible for this study, patients must be >3 years and <21 years of age and must have presence of advanced medulloblastoma.

Therapy will follow the schema outlined in the study protocol.

Progress: No patient have been entered to date. This study was closed 9 January 1990.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8696/97 Status: Completed
 Title: Treatment of Hepatoblastoma (HB) with Surgery and Chemotherapy and Radiation Therapy

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hepatoblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Closed	

Objective(s): 1) To obtain preliminary data on the natural disease course of patients with carefully staged, completely resected, "favorable histology" hepatoblastoma, given no further therapy after surgery.

2) To obtain preliminary data on the toxicity of a combination of cis-platin, vincristine and 5-fluorouracil (DDP/VCR/5-FU) in the treatment of patients with hepatoblastoma.

3) To assess tumor response to DDP/VCR/5-FU in those patients with Stage III and IV hepatoblastoma.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed 6 October 1989.

Detail Summary Sheet

Date: 26 Sep 90	Proj No: POG 8704	Status: Ongoing
Title: T-Cell #3 Protocol - A POG Phase III Study		

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To estimate the disease-free survival of a multiagent chemotherapy regimen designed to be particularly effective for patients with T-cell derived lymphoid malignancies in children with advanced stage lymphoblastic lymphoma and T-cell acute lymphoblastic leukemia.

2) To determine the efficacy of adding intensive high-dose L-asparaginase to the backbone chemotherapy regimen in an attempt to improve disease-free survival.

Technical Approach: Patients <21 years and >12 months with a diagnosis of ALL or patients age <21 years with a diagnosis of lymphoblastic lymphoma will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients with lymphoblastic leukemia were entered. Both achieved a satisfactory remission; one remains on therapy and one is off therapy.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8710 Status: Ongoing
 Title: Protocol for Second Induction and Maintenance in Childhood Acute
 Lymphoblastic Leukemia (SIMAL #5)

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas)	Facility
Allen R. Potter, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 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.

Technical Approach: Therapy will follow the schema outlined in the study proto-
 col

Progress: One patient was enrolled. This patient died during induction.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8719 Status: Ongoing
 Title: Trial of Shortened Therapy without Maintenance for the Treatment of
 Localized Non-Hodgkin's Lymphoma

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Potter) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 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 8314.

2) To maintain a high cure rate with minimum toxicity for children with localized non-Hodgkin's lymphoma in favorable sites.

Technical Approach: Patients <21 years of age at time of diagnosis will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8725 Status: Ongoing
 Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) +/- Low Dose
 Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIA₂, IIIB, and
 IV Hodgkin's Disease in Pediatric Patients.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine, in a randomized study, whether the addition of low dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone.

To determine whether TNRT will significantly increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone.

To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Two patients entered and one was transferred-in. All are now off therapy.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8726 Status: Completed
 Title: Alpha-Interferon in Histiocytosis X and Other Non-Malignant Histiocytic Disease, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Histiocytosis X	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Closed

Objective(s): 1) To evaluate the response rate of patients with histiocytosis X and related diseases to treatment with alpha interferon (-IFN).

2. To determine the toxicities of -IFN in children with histiocytosis X and related diseases.

Technical Approach: Eligible patients must have biopsy-proven diagnosis of reactive histiocytosis and must be <21 years of age at time of protocol entry.

Therapy will follow the schema outlined in the study protocol.

Progress. No patients entered. Study closed 8 December 1989.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8731 Status: Ongoing
 Title: Phase II Study of Low-dose "Continuous" Oral Methotrexate in the
 Treatment of Children with Progressive or Recurrent Brain Tumors.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): To determine the effectiveness of low-dose "continuous" oral methotrexate in the treatment of children with progressive or recurrent brain tumors and to evaluate the toxicity associate with the use of this agent given in this manner.

Technical Approach: Therapy will follow the schema outlined in the study protocol

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8739 Status: Ongoing
 Title: Evaluation of Alpha Interferon in the Treatment of Recurrent Brain Tumors in Children, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To determine the efficacy of alpha₂-interferon (-IFN) in children with recurrent brain tumors resistant to standard therapy in regard to response rate of different histologic subtypes to -IFN.

2) To further assess the toxicity of -IFN in children.

Technical Approach: To be eligible for this study, patient must be <21 years of age with a biopsy-proven diagnosis of astrocytoma, malignant glioma, brainstem glioma, medulloblastoma or ependymoma with clear evidence of progression or recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8741/42 Status: Ongoing
 Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma in Children >365 Days at Diagnosis

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To evaluate response rates and toxicity of four sequentially administered Phase II chemotherapy agents when given prior to conventional therapy in patients >365 days of age with Stage D (metastatic) neuroblastoma. The specific agents to be studied are: ifosfamide, carboplatin (CBDCA), cis-dichloro-transdihydroxy-bis-platinum (CHIP), and epirubicin.

Technical Approach: Any patient with newly diagnosed metastatic (Stage D) neuroblastoma who is >365 days and <21 years of age, who has receive no previous chemotherapy or irradiation therapy, and who has measurable disease will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients from BAMC entered. One patient transferred here relapsed and died after autologous bone marrow rescue. One patient has died and one is alive on therapy.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8743 Status: Ongoing
 Title: Treatment in 'Better Risk' Neuroblastoma: POG Stge B (All Ages) and POG Stage C, D, and DS (VS) <365 Days

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To prospectively identify patients <365 days of age at diagnosis who will fail to achieve 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.

2) To evaluate the disease-free survival (DFS) and survival in a larger group of patients currently considered to be "better risk" patients with neuroblastoma.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: One patient off therapy with no evidence of disease.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8751 Status: Ongoing
 Title: Low-Dose Methotrexate in the Treatment of Rhabdomyosarcoma, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To determine the response rate of children with rhabdomyosarcoma treated with low-dose methotrexate (LDMTX) given every 6 hours for 8 doses, followed by leucovorin rescue.

2) To determine the type and duration of toxicity of low-dose sustained oral methotrexate.

Technical Approach: To be eligible for entry into this study, patient must be <21 years of age and have biopsy-proven rhabdomyosarcoma unresponsive to standard therapy for which there is no known potentially curative therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8759 Status: Ongoing
 Title: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) 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.

2) To estimate the response rate to Ifosfamide in previously treated patients with osteosarcoma.

3) 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.

4) To study the DNA content of primary and metastatic tumors.

Technical Approach: In order to be eligible for this study, patient must be <30 years of age with no prior history of cancer for Stratum 1 or no prior history of cancer other than osteosarcoma for Stratum 2.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8760 Status: Completed
 Title: Trimetrexate in the Treatment of Childhood Acute Leukemia, Phase II.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Closed	

Objective(s): To determine the remission rate obtained with the administration of trimetrexate to children with acute lymphoblastic or acute myelogenous leukemia which is refractory to standard therapy and to further evaluate the toxicity of trimetrexate in children.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date. Study closed 5 September 1989.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8761 Status: Ongoing
 Title: A Phase II Study of Homoharringtonine for the Treatment of Children with Refractory Non-Lymphoblastic Leukemia

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, non-lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To evaluate the efficacy of Homoharringtonine for the therapy of refractory acute nonlymphoblastic leukemia (ANLL) in children.

2) To assess the toxicity of Homoh. onine in chidren.

Technical Approach: In order to be eligible for this study patients must be <21 years of age with a diagnosis of ANLL. They must have a life expectancy of >4 weeks and evidence of recovery from toxicity of prior therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8763 Status: Ongoing
 Title: Evaluation of Response and Toxicity of Ifosfamide and VP-16-213 in
 Children with Resistant Malignant Tumors

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine the antitumor activity and toxicity of ifosfamide (IFX) plus Etoposide (VP-16) against malignant solid tumors resistant to conventional chemotherapy.

Technical Approach: Eligible patients must be <21 years of age and have documented measurable disease, confirmed with appropriate histologic examination. Patients must have progressive or recurrent disease that is resistant to conventional therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been entered on study. One patient with recurrent Ewing's sarcoma had no response. One patient with recurrent Wilms' tumor had an initial partial response then recurred. One patient with recurrent Wilms' tumor progressed on therapy.

Detail Summary Sheet

Date: 26 Sep 90	Proj No: POG 8764	Status: Ongoing
Title: Chemotherapy Regimen for Early and Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia: Phase II Study		

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regiment 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 resistnace using cDNA probes fot the multidrug-resistant phenotype and obtain an oncogene profile.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 27 Sep 90 Proj No: POG 8788 Status: Ongoing
 Title: Intergroup Rhabdomyosarcoma Study IV Pilot Study for Clinical Group III Disease

Start Date 13 May 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To determine the feasibility of/and toxicity associated with using vincristine-actinomycin D-ifosfamide (VAI) or vincristine-ifosfamide-etoposide (VIE) as induction and continuation chemotherapies.

2) To determine a dose of cyclophosphamide to be used in VAC therapy which will result in myelosuppression comparable to that experienced with the VAI regimen.

3) To determine the feasibility of/and toxicity associated with using a hyperfractionated radiotherapy program following induction chemotherapy in children above and below age 6.

Technical Approach: Patients <21 years of age at diagnosis with Clinical Group III pathologically-proven rhabdomyosarcoma or undifferentiated sarcoma, or extraosseous Ewing's sarcoma are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8820 Status: Ongoing
 Title: VP-16, AMSA+/1 5-Azacytidine in Refractory ANLL, Phase II/III

Start Date: 13 Mar 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Refractory ANLL	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 1) To compare, in a randomized study, the remission rate of VP-16/AMSA versus VP-16/AMSA/5-AZA in children with recurrent or refractory acute non-lymphocytic leukemia (ANLL).

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: Patients $\leq$ 21 years of age at the time initial diagnosis who have either failed to respond to induction therapy or who are in first relapsed are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on this study died of progressive disease.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8821 Status: Ongoing
 Title: AML#3 Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant
 Early in 1st CR for Children with Acute Myelocytic Leukemia.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas)	Facility
Allen R. Potter, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 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.

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/Cytosin preparative regimen and 4-Hydroxycyclophosphamide (4-HC) purged marrow is effective therapy.

To compare, in a randomized study, the results of the above 2 regimens and to correlate the treatment outcome with clinical and laboratory features.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: Four patients sent here for autologous bone marrow transplant. Two have returned to parent institution for follow-up and two are being followed here.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8823 Status: Ongoing
 Title: Recombinant Alpha-Interferon in Childhood Chronic Myelogenous Leukemia, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, myelogenous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed "adult" chronic myelogenous leukemia (ACML) in chronic phase, and for "juvenile" chronic myelogenous leukemia (JCML) occurring within the first two decades.

Technical Approach: Eligible patients must have been $\leq$ 21 years of age at the time of initial diagnosis and must not have received prior anti-neoplastic therapy. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8827 Status: Ongoing
 Title: Treatment of Children with Hodgkin's Disease in Relapse, Phase II

Start Date: 17 Oct 88	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review: 9 Jul 90	Results:

Objective(s): To estimate the response rate of a new combination chemotherapy regimen consisting of cytosine arabinoside, cisplatin, and VP-16 in children who have relapsed Hodgkin's disease and to determine the toxicity associated with this regimen.

Technical Approach: Patients with relapsed Hodgkin's disease who were <21 years of age at time of initial diagnosis are eligible. Patients must not have responded or have relapsed after two or more courses of MOPP and two courses of ABVD, either given together or sequentially. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8828 Status: Ongoing
 Title: Late Effects of Treatment of Hodgkin's Disease, Non-therapeutic Study

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG 8625 and POG 8725. In particular, to focus on known sequelae of Hodgkin's disease and its treatment.

Technical Approach: All patients registered on front-line phase III POG Hodgkin's disease therapeutic studies POG 8625 and POG 8725 after the opening of this study will be eligible and must be registered on this study unless the patient or parent/guardian refuses.

Progress: No patients entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8829 Status: Ongoing
 Title: A Case-Control Study of Hodgkin's Disease in Childhood - A Non-therapeutic Study

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To conduct the first interview case-control study of childhood Hodgkin's disease to learn more about the epidemiology of the disease in children.

Technical Approach: All pediatric oncology patients, less than 15 years of age, with a newly confirmed diagnosis of Hodgkin's disease are eligible. Telephone interview and administration of questionnaire will be conducted.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8832 Status: Ongoing
 Title: Pre-Irradiation Combination Chemotherapy with Cisplatin and ARA-C for Children with Incompletely Resected Supratentorial Malignant Tumors, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Tumors, CNS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): 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 (CNS) tumors.

3) To estimate the feasibility and completeness of second surgical resection in children with incompletely-resected malignant supratentorial tumors after treatment with initial chemotherapy.

Technical Approach: Patients $\geq$ 3 years and $\leq$ 21 years at diagnosis are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8833 Status: Completed
 Title: Pre-radiation Chemotherapy in the Treatment of Children with Brain Stem Tumors - A Phase II Study

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Closed	

Objective(s): To evaluate the response of children with brain stem gliomas to four courses of combination high-dose cyclophosphamide and cis-platinum prior to radiation therapy. Response will be measured by CT and/or MRI scan and neurological exam.

To monitor possible acute and chronic toxicities of the chemotherapy, including neurological and audiological toxicity. To assess unusual irradiation-related toxicity post-chemotherapy.

To Estimate the disease control interval for the population under study following chemotherapy and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered. Study closed 5 September 1989.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8844 Status: Ongoing
 Title: Stage D Neuroblastoma #4: Bone Marrow Transplant in the Treatment of Children > 365 Days at Diagnosis with Stage D Neuroblastoma

Start Date: 12 Dec 88	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To determine whether the outcome of children > 365 days with Stage D neuroblastoma who are treated at institutions offering an autologous bone marrow transplant (ABMT) option to conventional therapy and who have good initial response to conventional therapy, is better than the outcome of similar children who are treated at institutions which do not offer the transplant option.

2) To evaluate the toxicities associated with this protocol.

Technical Approach: Patients >365 days and <21 years at diagnosis previously registered on POG 8741/42 who have completed post-induction evaluation and post-induction surgery are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been enrolled on this study. Two patients relapsed and died; one is too early to report any significant progress.

Detail Summary Sheet

Date: 26 Sep 90	Proj No: POG 8850	Status: Ongoing
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, Phase III		
Start Date: 13 Mar 89	Est Comp Date:	
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Pediatrics	Associate Investigators:	
Key Words: Ewing's sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 1		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 9 Jul 90 Results Continue		

Objective(s): To determine the event-free survival and survival of patients with Ewing's sarcoma and PNET of the bone who are treated with etoposide and ifosfamide in combination with standard therapy, and to compare their EFS and survival rates with those of patients treated with standard therapy alone.

Technical Approach: Patients <30 years of age with newly diagnosed Ewing's sarcoma, PNET of bone, or a diagnosis compatible with primitive sarcoma of bone are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: The one patient entered on this study recently started therapy.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8861 Status: Completed
 Title: The Efficacy of MESNA in Preventing a Recurrence of Cyclophosphamide-induced Hemorrhagic Cystitis

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Cystitis, hemorrhagic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Closed	

Objective(s): To determine whether mesna can prevent the recurrence of acute, cyclophosphamide-induced hemorrhagic cystitis in patients in whom continued therapy with cyclophosphamide is medically indicated.

Technical Approach: Patients who develop hematuria during, or within a 24 hour period immediately following, the administration of cyclophosphamide being administered for a disease in which cyclophosphamide is generally accepted as appropriate therapy are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Study closed 7 November 1989.

Detail Summary Sheet

Date: 26 Sep 90	Proj No: POG 8862	Status: Ongoing
Title: Treatment of First Marrow Relapse and/or Extramedullary Relapse of Childhood Acute T-Lymphoblastic Leukemia and T-Non-Hodgkin's Lymphoma with Combination Chemotherapy including 2'-Deoxycoformycin, Phase II		
Start Date: 12 Jun 89	Est Comp Date:	
Principal Investigator	Facility	
Allen R. Potter, LTC, MC	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Pediatrics		
Key Words:		
T-lymphoblastic leukemia		
T-Non-Hodgkin's lymphoma		
Accumulative MEDCASE	Est Accumulative	
Cost: .	OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review		Results

Objective(s): 1) To assess the toxicity and efficacy of low dose deoxycoformycin (DCF) given as IV bolus injection in prolonging the duration of remission for patients with T-ALL/T-NHL in second remission.

2) To determine the correlation of clinical responses and toxicities with plasma levels of adenosin deaminase (ADA), adenosin (ado) and Deoxyadenosine (dado), dATP/ATP ratios in RBCs, and in vitro sensitivity of leukemia cells to DCF plus dado.

3) To determine the efficacy of IV methotrexate and Iv 6-mercaptopurine in patients with T-ALL and T-NHL.

Tehcnical Approach: Patients < 21 years of age at time of diagnosis in first relapsed documented by aspirate or biopsy are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8863 Status: Ongoing
 Title: High Dose Cytosine Arabinoside in the Treatment of Advanced Childhood Tumors Resistant to Conventional Therapy, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine whether high dose cytosine arabinoside is effective in the treatment of advanced childhood tumors resistant to conventional therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Nov 89	Proj No: POG 8865	Status: Ongoing
Title: Recombinant Alpha-Interferon in Relapsed T-Cell Disease, Phase II		

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: T-cell ALL/Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To determine the response rate to -IFN in children with T-cell ALL/Lymphoma who have failed standard therapy.

2) To correlate the response rate to the presence of interferon receptors, oncogene expression, modulation of oncogene expression by interferon, DNA content, and antiproliferative effect of IFN in vitro on T-cell lymphoblasts.

Technical Approach: Patients <21 years of age at initial diagnosis and in relapse with T-ALL or T-NHL are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8866 Status: Ongoing
 Title: Polyethylene Glycol-Conjugated L-Asparaginase in Combination with
 Standard Agents as Second-Line Induction Therapy for Children with Acute
 Lymphoblastic Leukemia in Bone Marrow Relapse, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To compare, in a randomized trial, the efficacy, toxicity and feasibility of administration of PEG-L-asparaginase versus native L-asparaginase as part of a standard combination chemotherapy re-induction regimen for children with ALL in second relapse.

Technical Approach: Eligible patients must have been <21 years of age at initial diagnosis and must have ALL in second marrow relapse. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8889 Status: Ongoing
 Title: Intergroup Rhabdomyosarcoma Study-IV Pilot Study for Clinical Group IV Disease

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine the feasibility of, and toxicity associated with, using ifosfamide-doxorubicin (ID) as induction chemotherapy and subsequently, as part of maintenance chemotherapy with vincristine-actinomycin D - cyclophosphamide (VAC) for rhabdomyosarcoma and similar sarcomas and to determine the feasibility of/and toxicity associated with hyperfractionated radiotherapy program following induction chemotherapy.

Technical Approach: Patients <21 years of age at diagnosis with pathologically-proven rhabdomyosarcoma or undifferentiated sarcoma, or extraosseous Ewing's sarcoma are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8930 Status: Ongoing
 Title: A Comprehensive Genetic Analysis of Brain Tumors

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To determine prospectively the clinical significance of abnormalities of cellular DNA content, as measured by flow cytometry and to determine the clinical implications of cytogenetic abnormalities in pediatric brain tumors.

Technical Approach: Any patient with a brain tumor who has had tumor tissue submitted for study and who is subsequently registered on a POG frontline therapeutic protocol is eligible for this study.

Progress: No patients have been entered on this study

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8935 Status: Ongoing
 Title: A Study of the Biological Behavior of Optic Pathway Tumors, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principa Investigator Allan R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Optic pathway tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90 Results Continue	

Objective(s): 1) To assess time to progression of optic pathway tumors (OPTs).
 2) To estimate the response rate of radiation therapy in children with OPTs, when measured at 2 years post-irradiation.

Technical Approach: Patients <21 years of age at the time of diagnosis with imaging evidence of intraorbital or chiasmatic mass with or without visual loss are eligible. Within two weeks following surgery, slides will be submitted to pathology for review.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 26 Sep 90 Proj No: POG 8936 Status: Ongoing
 Title: Phase II Study of Carboplatin (CBDCA) in the Treatment of Children with Progressive Optic Pathway Tumors

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Optic pathway tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Jul 90	Results Continue

Objective(s): To assess the response rate to CBDCA in children <5 years of age with optic pathway tumors and to assess the efficacy of CBDCA in delaying progression of disease.

Technical Approach: Patients will be eligible for treatment on this study if they meet the eligibility criteria for POG 8935, if they are <5 years of age and if there is evidence of progressive disease. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 8945 Status: Ongoing
 Title: An Intergroup Protocol for the Treatment of Childhood Hepatoblastoma and Hepatocellular Carcinoma.

Start Date 31 May 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To estimate and compare the response rate and event-free survival of patients with hepatoblastoma which has been incompletely resected or contains unfavorable histologic elements and patients with hepatocellular carcinomas randomized to two different chemotherapeutic regimens cis-platin/adriamycin i.v. continuous infusion and cis-platin/5-fluorouracil/vincristine.

Technical Approach: Patients with either hepatoblastoma or hepatocellular carcinoma are eligible. Previously untreated patients, except for surgery within 14 days of study entry for Stage I and within 7 days of entry for all other patients, with histologically proven hepatoblastoma or hepatocellular carcinoma under 21 years of age are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 9031 Status: Ongoing
 Title: Treatment of Children with High-Stage Medulloblastoma: Cisplatin/VP-16
 Pre- vs Post-Irradiation.

Start Date 24 Aug 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To compare the 2-year event-free survival (EFS) of children with newly-diagnosed high-risk medulloblastoma who are treated with cisplatin and VP-16 pre-irradiation vs post-irradiation.

2) To define the toxicity and activity of pre- and post-irradiation cisplatin/VP-16 in patients with newly-diagnosed high-risk medulloblastoma.

3) To determine whether achievement of a measurable tumor response (PR and CR) to pre-irradiation cisplatin/VP-16 has prognostic significance for children with high-risk medulloblastoma, compared with failure to achieve a measurable response (SD or PD).

Technical Approach: Patients age >3 years and <21 years registered within 4 weeks of initial diagnostic surgery or biopsy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90	Proj No: POG 9046	Status: Ongoing
Title: Molecular Genetic Study of Wilms' Tumor and Nephrogenic Rests		

Start Date 31 May 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To define the patterns of tumor-specific loss of constitutional chromosomal heterozygosity in a large series of Wilms' tumors and associated nephrogenic rests (nephroblastomatosis).

2) To correlate these patterns with clinicopathologic findings, to be able, thereby, to propose a new model of pathogenesis for Wilms' tumor.

3) To physically localize gene mutations and chromosome abnormalities from specific categories of Wilms' tumors on a long-range physical map of the short arm of chromosome 11.

4) To clone genes associated with Wilms' tumor.

5) To establish a bank of molecularly and cytogenetically characterized Wilms' tumors with matched constitutional tissue.

Technical Approach: Any patient <16 years of age, with a previously untreated, histologically proven Wilms' tumor of any histologic subtype or a mesoblastic nephroma, who has had tumor tissue and blood submitted for study, is eligible. Patients diagnosed prior to the opening of this study are also eligible if both unfixed, frozen pre-treatment tumor and a source of constitutional DNA are available.

Study procedures are outlined in the protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90	Proj No: POG 9047	Status: Ongoing
Title: Neuroblastoma Biology Protocol		

Start Date 31 May 90	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To analyze the DNA content of neuroblastoma cells by flow cytometry.

2) To characterize neuroblastoma tumor DNA from POG patients genetically by analysis of N-myc amplification and LOH chromosome 1p.

3) To determine the independent clinical significance of these and other genetic rearrangements compared to more conventional clinical, histologic, and biological variables in predicting either response to treatment or outcome.

4) To develop a reference bank of genetically characterized tumor tissue and DNA that would be available for other current, planned, and future studies of neuroblastoma biology.

Technical Approach: Tumor tissue submitted from diagnostic biopsies or marrow aspirations will be cryopreserved for biologic studies. Eligibility requirements of active neuroblastoma therapeutic studies will require that all patients be concomitantly registered on this study.

Flow cytometry and N-myc studies will be done as outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 9048 Status: Ongoing
 Title: Treatment of Children with Localized Malignant Germ Cell Tumors: A Phase II Study

Start Date 24 Aug 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

- Objective(s): 1) To determine whether >85% of patients with or Stage I malignant testicular germ cell tumors will have long survival when treated with surgery alone, and to estimate a time for which disease recurrence for these patients is very unlikely.
- 2) To determine whether a long-term event-free survival of >85% for children with Stage II malignant testicular germ cell tumors and Stage II ovarian germ cell tumors who are treated with four courses of chemotherapy with cisplatin, etoposide, and bleomycin.
- 3) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s); extension of disease into local tissues; and extent of lymph node involvement.
- 4) To determine whether initial levels and subsequent changes in tumor markers, specifically alpha-fetoprotein, beta-human chorionic gonadotropin, and LDH, correlate with initial response, ultimate outcome, and disease recurrence.

Technical Approach: Eligible patients must have primary germ cell tumors of the testes or ovaries, which are histologically verified to be yolk-sac tumor, embryonal carcinoma, choriocarcinoma, immature teratoma, or teratoma with malignant elements.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 9049 Status: Ongoing
 Title: Study of High-Risk Malignant Germ Cell Tumors in Children.

Start Date 31 May 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To compare the efficacy with respect to survival and event-free survival of two chemotherapeutic regimens high-dose cisplatin, etoposide, and bleomycin or standard-dose cisplatin, etoposide, and bleomycin in the treatment of children with high-risk malignant germ cell tumors.

2) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s), sites of metastasis, and extent of lymph node involvement.

3) To determine whether initial levels and subsequent changes in tumor markers correlate with initial response, ultimate outcome, and the risk of disease progression.

Technical Approach: Patients age <21 years with histologically verified yolk-sac tumor, embryonal carcinoma, choriocarcinoma, dysgerminoma (seminoma), or teratoma with mixed malignant elements are eligible. Chemotherapy must begin within 2 working days of randomization and within 21 days of the most recent diagnostic surgical procedure.

Therapy will follow the Schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 9060 Status: Ongoing
 Title: Intensive QOD Ifosfamide for the Treatment of Recurrent or Progressive CNS Tumors.

Start Date: 1 Aug 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the activity of ifosfamide delivered every other day x 3 in the treatment of children with recurrent or progressive brain tumors.

2) To quantitate the toxicity associated with treatment as above.

Technical Approach: Patients <21 years are eligible if they have had prior histological confirmation of primary intracranial or spinal cord tumor with MRI or CT documentation of progressive or recurrent disease after therapy of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 9061 Status: Ongoing
 Title: The Treatment of Isolated Central Nervous System Leukemia

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the efficacy and toxicity of intensified systemic treatment with delayed craniospinal irradiation for children with acute lymphoblastic leukemia and isolated central nervous system disease.

2) 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.

3) To measure paraments of CNS tissue injury and associate these with the effects of CNS leukemia and treatments.

Technical Approach: Patients with a diagnosis of ALL in first bone marrow remission with isolated, initial CNS relapse are eligible. Patients must be >1 year of age at time of CNS relapse and must not have had prior brain irradiation.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 19 Oct 90 Proj No: POG 9072 Status: Ongoing
 Title: Ifosfamide, Carboplatin, Etoposide (ICE) Treatment of Recurrent/
 Resistant Malignant Solid Tumors of Childhood.

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the antitumor activity and toxicity of ifsof-
 famide (IFOS), etoposide (VP-16) plus escalating doses of carboplatin (CBDCA)
 against childhood malignant solid tumors resistant to conventional chemotherapy.

2) To establish a dose level of carboplatin, when given in the presence of IFOS
 and VP-16, that results in maximum tolerable toxicity, which is predictable and
 reversible.

3) To determine the maximum time of maximum toxicity and time to recovery after
 ICE therapy.

4) To determine if there is cumulative toxicity in the child after administra-
 tion of ICE.

Technical Approach: All patients must be <21 years of age with documented
 measurable disease, confirmed with appropriate histologic examination, are eli-
 gible. Patients must have progressive or recurrent disease that is resistant to
 conventional therapy and must not have been entered on any prior phase I trials.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 20 Status: Ongoing
 Title: A Randomized Comparison of Adriamycin Versus no Further Therapy in
 Patients with Uterine Sarcomas, Stage I and II.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator	Facility
David L. Doering, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review _____	Results _____

Status: Two of the three patients enrolled on this study have died. One patient on study. The study remains open for follow-up only.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 25 Status: Ongoing
 Title: A Randomized Comparison of Melphalan Alone vs. Melphalan Therapy Plus Immunotherapy in the Treatment of Women with Stage III Epithelial Carcinoma of the Ovary.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator	Facility
David L. Doering, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	

Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cos :
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review _____	Results _____

Status: This study remains open for follow-up of the one patient enrolled.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 41 Status: Ongoing
 Title: Surgical Staging of Ovarian Carcinoma.

Start Date FY 79	Est Comp Date:
Principal Investigator	Facility
David R. Doering, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Carcinoma, ovarian	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

2) To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.

3) To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was reopened for follow-up purposes only.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 45 Status: Ongoing
 Title: Evaluation of Vinblastine, Bleomycin and Cis-Platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase II.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review _____	Results _____

Status: This study remains open for follow-up of the one patient enrolled.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 52 Status: Ongoing
 Title: A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus
 Platinol (Cis-Platinum) vs Cyclophosphamide/Platinol in Patients with Optimal
 Stage III Ovarian Adenocarcinoma.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review _____	Results _____

Status: This study remains open for follow-up of the one patient enrolled.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 72 Status: Ongoing
 Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease

Start Date 31 Aug 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the biologic behavior of ovarian tumors of low malignant potential.

2) To evaluate the effectiveness of chemotherapy against this disease; initially, a Phase II study of melphalan.

3) To evaluate the response rate to cisplatin in melphalan failures.

Technical Approach: All patients with ovarian tumors considered to be in the pathology classification of low malignancy potential are eligible. Pre-entry confirmation of diagnosis is required of patients to establish pathologic eligibility. Patients must have undergone adequate surgical staging no later than 8 weeks following the initial surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 73 Status: Ongoing
 Title: A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva
 Treated by Modified Radical Hemivulvectomy.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the relationship of histopathologic parameters (including microstaging of primary malignant melanoma of the vulva) to FIGO staging and ultimate prognosis.

2) To ultimately recommend appropriate therapy for malignant melanomas of the vulva based on histopathologic and microstaging data.

Technical Approach: All patients receiving primary therapy for primary malignant melanoma of the vulva are eligible. Patients must have at least a modified radical hemivulvectomy and must be entered no later than 8 weeks of initiation of primary therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 85 Status: Ongoing
 Title: A Randomized Comparison of Hydroxyurea vs. 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stages IIB, III and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine whether hydroxyurea or the combination of 5-FU and cisplatin is superior as a potentiator of radiation therapy in advanced cervical carcinoma.

2) To determine the relative toxicities of hydroxyurea vs. the combination of 5-FU and cisplatin when given concurrently with radiation therapy.

Technical Approach: Patients with primry, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix, Stages II-B, III-A, and IV-A, with negative para-aortic nodes are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 92 Status: Ongoing
 Title: Treatment of Selected Patients with Stage IB Carcinoma of the Cervix
 After Radical Hysterectomy and Pelvic Lymphadenectomy: Pelvic Radiation
 Therapy vs. No Further Therapy.

Start Date 25 July 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the value of adjunctive pelvic radiation in the treatment of Stage IB carcinoma of the cervix, but with selected high-risk factors.

2) To determine the recurrence-free interval, survival and patterns of failure in these patients.

3) To determine the morbidity of adjunctive pelvic radiation following radical hysterectomy.

Technical Approach: Patients with primary, histologically-confirmed invasive carcinoma of the uterine cervix Stage IB who have undergone radical hysterectomy and lymphadenectomy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 93 Status: Ongoing
 Title: Evaluation of Intraperitoneal Chromic Phosphate Suspension Therapy
 Following Negative Second-Look Laparotomy for Epithelial Ovarian Carcinoma
 (Stage III)

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator	Facility
David L. Doering, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the role of intraperitoneal chromic phosphate suspension (intraperitoneal ³²P) therapy in patients with Stage III epithelial ovarian carcinoma who have no detectable evidence of disease at the second-look laparotomy.

Technical Approach: Patients with primary histologically confirmed epithelial carcinoma of the ovary in clinical remission are eligible. Patients with no persistent or recurrent cancer as assessed by surgical, cytologic and histologic findings at the second-look laparotomy likewise are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 94 Status: Ongoing
 Title: A Phase II Study of Whole Abdominal Radiation in Stage I and II
 Papillary Serous Carcinoma.

Start Date 24 Aug 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To determine the survival and progression free interval of patients with maximally debulked advanced endometrial carcinoma treated with abdominal radiation therapy.

2) To determine the progression free interval and site of recurrence in patients with Stage I and II papillary serous carcinoma of the endometrium treated with abdominal radiation therapy with pelvic boost.

Technical Approach: Patients meeting the inclusion criteria will undergo therapy as outlined in the study protocol.

Proress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 95 Status: Ongoing
 Title: Randomized Clinical Trial for the Treatment of Women with Selected Ic and II(A,B,C) and Selected Stage IAi & IAII and BII Ovarian Cancer (Phase III).

Start Date 24 Aug 90	Est Comp Date:
Principal Investigator	Facility
David L. Doering, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To compare the progression-free interval and overall survival of the two treatment regimens.

2) To determine the patterns of relapse for each form of therapy.

3) To define the relative toxicities of the two treatment approaches.

Technical Approach: Patients meeting the eligibility criteria will be treated in accordance with the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 99 Status: Ongoing
 Title: A Phase III Randomized Study of Surgery vs. Surgery Plus Adjunctive
 Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma.

Start Date 24 Aug 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine if patients with intermediate risk endometrial adenocarcinoma (as defined below), who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy.

2) To evaluate how the addition of pelvic radiotherapy will alter the site and rate of cancer recurrence in these intermediate risk patients.

Technical Approach: Patients with primary histologically confirmed Grades 1, 2, and 3 endometrial adenocarcinoma are eligible. Patients must have had a total abdominal hysterectomy, bilateral salpingo-oophorectomy, selective and para-aortic node sampling, pelvic washings and are found to be surgical Stage I and occult Stage II. Myometrial invasion must be present.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 104 Status: Ongoing
 Title: Intraperitoneal Cis-Platinum/Intravenous Cyclophosphamide vs Intravenous Cis-Platinum/Cyclophosphamide in Patients with Non-Measurable (Optimal Stage III) Ovarian Cancer, Phase III Intergroup.

Start Date 24 Aug 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To carry out a Phase III randomized trial of intermediate dose intraperitoneal cis-platinum plus intravenous cyclophosphamide versus intermediate dose intravenous cis-platinum plus intravenous cyclophosphamide for optimal Stage III ovarian cancer.

2. To evaluate the toxicities and complications of the two combination drug regimens.

3. To determine in the setting of a prospective randomized trial if the human tumor clonogenic assay with a wide range of drug concentration testing can accurately predict pathologic complete response to two-drug combination therapy in the setting of systemic and intraperitoneal drug administration.

Technical Approach: Patients must have a histologically confirmed diagnosis of ovarian carcinoma. Only patients without prior cytotoxic chemotherapy will be eligible for this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 107 Status: Ongoing
 Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus Cisplatin in Patients with Primary Stage III and IV, Recurrent Endometrial Adenocarcinoma, Phase III.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether the addition of cisplatin to doxorubicin offers significant improvement in the frequency of objective response, the duration of progression-free interval, and the length of survival as compared to doxorubicin alone.

Technical Approach: All patients with histologically documented primary Stage III or Stage IV, or recurrent endometrial adenocarcinoma, adenoacanthoma, or adenosquamous carcinoma whose potential for cure by radiation therapy or surgery alone or in combination is very poor will be eligible. Measurements by sonography and/or CT scans are acceptable if the mass is sharply defined.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Oct 90 Proj No: GOG 111 Status: Ongoing
 Title: A Phase III Randomized Study of Cyclophosphamide and Cisplatin vs Taxol and Cisplatin in Patients with Suboptimal Stage III and IV Epithelial Ovarian Carcinoma

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine response rate, response duration and survival in suboptimal Stage III and Stage IV ovarian cancer treated with two different platinum-based combination chemotherapy regimens.

2) To evaluate the relative activity and toxicities of a new combination, cisplatin/taxol, as compared to the standard regimen, cisplatin/cyclophosphamide.

Technical Approach: Patients with established ovarian epithelial cancer, suboptimal Stage III and Stage IV will be eligible. All patients must have optimal surgery for ovarian cancer, with at least exploratory laparotomy and appropriate tissue submitted for histologic examination.

Therapy will follow the schema outline in the study protocol.

Progress: This is a new study

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 8803 Status: Ongoing
 Title: Flow Cytometrically Determined Tumor DNA Content in Advanced Epithelial Ovarian Cancer.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) Can tumor ploidy and cell proliferation be correlated to accepted tumor and host factors, including patient age, tumor histology and grade, stage and amount of residual disease?

2) Can tumor ploidy and cell proliferation be correlated to tumor response, second look laparotomy findings, relapse and survival?

3) Are tumor ploidy and cell proliferation consistent between primary and metastatic sites and stable before and after combination chemotherapy?

Technical Approach: Paraffin blocks from both the primary ovarian tumor as well as 1 to 3 metastatic sites will be analyzed to look at the inter-tumor variability. When one or more paraffin-embedded tumor blocks have been obtained, specimens for flow cytometric determination of tumor cell DNA content and, if possible, cell cycle distribution will be prepared by the modified method of Hedley.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 8809 Status: Ongoing
 Title: Flow Cytometrically Determined Tumor DNA Content in Ovarian Tumors of Low Malignant Potential

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator	Facility
David L. Doering, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether the DNA content of borderline ovarian tumors (carcinoma of low malignant potential) can be correlated with extent/stage of tumor, potential for recurrence, and patient survival.

Technical Approach: Paraffin blocks from both the primary ovarian tumor as well as any metastatic site will be analyzed to look at the inter-tumor variability. When one or more paraffin-embedded tumor blocks have been obtained, specimens for flow cytometric determination of tumor cell DNA content and, if possible, cell cycle distribution will be prepared by the modified method of Hedley.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 90 Proj No: GOG 8810 Status: Ongoing
 Title: Flow Cytometrically Determined Tumor DNA Content in Endometrial Carcinoma.

Start Date 25 Jul 90	Est Comp Date:
Principal Investigator David L. Doering, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the DNA content of primary, recurrent and metastatic endometrial adenocarcinoma, and identify whether the presence of aneuploid cell populations is related to histologic cell type, histologic grade, or stage of disease.

2) To determine whether tumor ploidy is related to the probability of lymph node or distant metastasis, extended progression free interval, or five year survival.

3) To determine whether tumor ploidy is consistent when primary tumors are compared with their metastases.

Technical Approach: Paraffin blocks containing material representative of the primary endometrial adenocarcinoma from either hysterectomy or D&C specimen may be submitted. A minimum surface area of tumor of not less than 1 cm² should be present in the block to assure sufficient neoplasm for flow cytometric studies to be conducted. If metastatic tumor is present in either pelvic or para-aortic lymph nodes, or distant sites, then a block from these sites should also be submitted, if possible. When one or more paraffin-embedded tumor blocks have been obtained, specimens for flow cytometric determination of tumor cell DNA content and, if possible, cell cycle distribution will be prepared by the modified method of Hedley.

Progress: This is a new study.