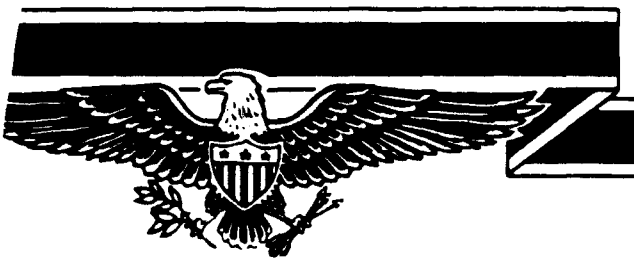
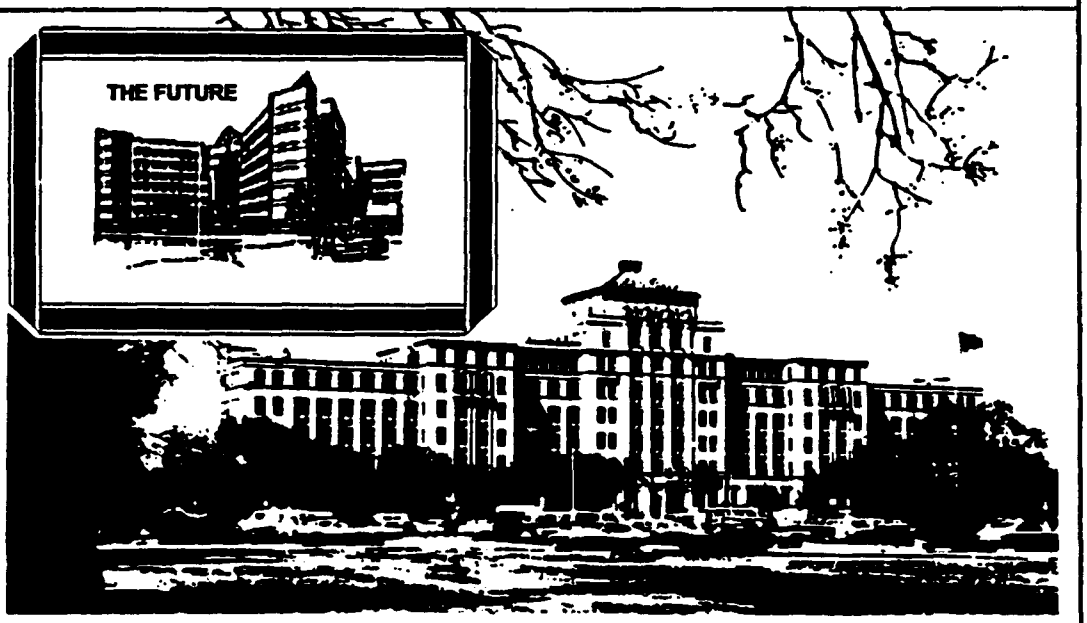
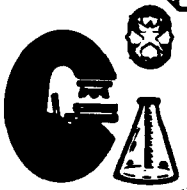


DEPARTMENT OF CLINICAL INVESTIGATION

ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1992
VOLUME 2





BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-9-89 Status: Completed

Title: Cardiac Response to Semistarvation and Refeeding.

Start date: 5 May 89	Estimated completion date:
Principal Investigator: John A. Ward, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Eleanor A. Young, Ph.D., UTHSC-SA
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To participate in a comprehensive study of the effect of semistarvation (SS) and refeeding (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 SS and RF in a systematic, controlled animal model, the rat. 3) To monitor cardiac function serially by screening electrocardiograms for arrhythmias.

Technical approach: Animals were fed a high-fat (30%) diet until they weighed 480 to 540 g. They were then randomized into one of 9 diet groups. Both the control (C, 70 kcal/day) and the semistarvation (SS, 14 kcal/day) diets met the protein, vitamin and mineral requirements for the rat. Diet groups consisted of 0 to 3 weeks of C, 1 to 3 weeks of SS, 1 week SS followed by 1 week C and 2 weeks SS followed by 1 week C. Animals were anesthetized with sodium pentobarbital and ECGs were recorded at the starting and ending days for each diet regimen. Data were analyzed with one way ANOVA and a SNK test at the 0.05 level of confidence.

Progress: Results of study indicated there was a decrease in heart rate in rats on a semistarvation diet that was reversed by refeeding. While significant changes in heart weight, DNA and protein/DNA ratio suggest a direct effect of semistarvation on the heart, the most likely cause of bradycardia was a decrease in sympathetic activity. It would be necessary to monitor autonomic tone to test this hypothesis. In so doing, the effects of handling the animals and anesthesia should be avoided by using telemetry or a

tethering system to gather data from the animals over extended periods of time in their home cages.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-10-89 Status: Terminated

Title: Flow Cytometric Analysis of Guinea Pig Dorsal Root Ganglion Cells.

Start date: 5 May 89	Estimated completion date:
Principal Investigator: Eleanor Ayala, MT	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Janice Grassel, MT David G. Burleson, COL, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 determinations of the percent populations of large, intermediate, and small cells and the biochemical contents of the cells.

Progress: Cultured mouse neuroblastoma cells were sized both manually and with the coulter Zm. Size distributions were similar to those of isolated DRG cells and ranged from 6-41 microns and 10-45 microns by optical and electronic measurements respectively. The FACS instrument was available only once for sorting the mouse cells. However, a Coulter multisizes instrument with software specifically developed for cell size analysis has been marketed and is being well used in tumor cell analysis. Such an instrument would greatly benefit this protocol which has been suspended pending the availability of this instrument.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Richard E. Peterson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 (NMEPs).

Technical Approach: To study the effects of hypocarbia, hypercarbia, hypotension, and hypothermia upon the NMEP, eight hogs were subjected to changes in PCO2 (10 mm Hg increments, range 30 mm - 70 mm Hg), graded hypotension (MAP lowered in 10 mm Hg increments range 90 mm - 30 mm Hg), and hypothermia to 3° C.

To study the effects of the commonly used inhaled anesthetic, 14 hogs were subjected to 1/4 MAC (minimum alveolar concentration) increments (up to 1 MAC) of Halothane, Isoflurane, and Enflurane as well as N_2O (50% and 70%).

Progress: Last phase of protocol completed March 1992. Currently undergoing data entry and statistical analyses.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-12-89 Status: Completed

Title: Bronchalveolar Lavage as a Diagnostic Tool in Bacterial Pneumonia of Young Piglets.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Stephen Inscore, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): William Ehler, D.V.M.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: $10,000,00 (AFSGO)

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Protol was completed at Wilford Hall Medical Center on Sep 91. A total of twelve (12) pigs was utilized out of the twenty (20) pigs originally authorized. One (1) pig was procured by the BAMC DCI and the remaining 11 pigs was procured by the WHMC CID by mutual agreement of the respective clinical investigative activities. No follow on study is planned. An abstract is in preparation for submission to the American Thoracic Society 1993 annual meeting.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-14-89 Status: Completed

Title: Study of Feral Domestic Cats (Felis domestica) for Lyme Spirochetes at Fort Sam Houston and Camp Bullis, Texas.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Nelson R. Powers, MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Preventive Medicine Service	Associate Investigator(s): Erik Torring, CPT, VC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: A sample of 167 feral cats were collected from June 1989 to October 1991, serum samples were drawn from 142 cats collected from June 1989 to December 1990. Serum was tested by IFA for antibodies to Borrelia burgdorferi, 36% were found with reactive titers (>1:64). Examination of feral cats; 157 from June 1989 to October 1991 for ectoparasites - Ctenocephalides felis and Pulex irritans (n = 1006) disclosed that none were found to have B. burgdorferi spirochetes. None of the 167 feral cats showed clinical signs of Lyme borreliosis.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-2-90 Status: Terminated

Title: The Development of Adenocarcinoma of the Colon with a Two-Stage Vesico Colonic Anastomosis.

Start date: 17 Nov 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: This protocol was not being used due to a lack of time and the principal instructor's time was greatly limited.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: A-4-90	Status: Ongoing

Title: Botulinum Toxin Detection by Mouse Bioassay.

Start date: 7 Feb 90	Estimated completion date:
Principal Investigator: Michael Gray	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pathology and ALS	Associate Investigator(s): David Culak
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Only one sample was run but each sample uses multiple animals.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: David Culak	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pathology and ALS	Associate Investigator(s): Michael R. Gray
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 .03 ml 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: Materials prepared in 1991 are still available. Because this protocol supports the production of materials for a diagnostic test, it may not utilize animals each year, only as needed.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-7-90 Status: Ongoing

Title: Clinical Investigation on the Biodegradation of Lactide-Based Polymers in Rabbits.

Start date: 7 Mar 90	Estimated completion date:
Principal Investigator: Allan L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): Kevin Murphy, CPT, MC Danny Williams SSG Rene Cardona
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 eight 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: All implants removed. Mechanical testing complete. Histologic slides prepared - to be reviewed.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-9-90 Status: Ongoing

Title: Biosynthesis of Polyclonal Anti-peptide Antibodies in Rabbits.

Start date: 1 Jun 90	Estimated completion date:
Principal Investigator: Gerald Merrill	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Four rabbits were immunized with synthesized peptides conjugated to poly-L-lysine to render them immunogenic. Three rabbits were immunized with a peptide corresponding to the amino terminal segment (residues 1-17) of rhodanese. The remaining rabbit was immunized with the tether sequence (residues 142-156) of rhodanese. In both cases, the peptide-poly-L-lysine conjugates were added to trehalose dimycolate and monophosphoryl lipid A (immune adjuvants) in oil-in-water micelles to aid in the immunization. Each rabbit was immunized every 2-4 weeks by IP and/or SC injections of immunogens. Prior to each immunization 2-10 ml of blood was obtained from each rabbit via cardiac puncture to screen for the presence of serum anti-peptide antibodies. The sera were screened by direct immunoassays in which either peptide or intact rhodanese was immobilized to microtiter plates as the capture antigen. Immunizations were continued for a period of 18 weeks.

Progress: Three animals were immunized with rhodanase amino terminal peptide crosslinked to poly-L-lysine via multiple IM and SC immunizations. After 14 weeks, only very low titers of antibodies were obtained. One animal produced an acceptable titer to an internal rhodanese peptide when immunized with the

15 amino acid peptide prepared and conjugated as was the amino terminal peptide. This wera was utilized in a study in which antibodies were used to A-9-90 (continued)

demonstrate conformational differences between a recombinant and native purified rhodanese forms (J. Protein Chem. 1992). Four rabbits are currently receiving immunizations. Two rabbits are presently being immunized with intact rhodanese (to be used for a positive control sera). Both rabbits have antibodies demonstrable at a 1:5000 dilution. The titer is being increased by booster immunizations. Two other rabbits are receiving immunizations with CPN60, a heat shock protein which has been shown to aid in the refolding (and presumably the initial folding of rhodanese). Both rabbits have titers to the antigen, bu the antisera appears to have significant non-specific antibodies that also react to the antigen. Additional booster immunizations have been producing an increased titer of specific antibodies so that the non-specific effect can be minimized by use of the antisera at increased dilutions.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/ Anesthesiology	Associate Investigator(s): Danny Williams SSG Rene Cardona
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: $1,848.00

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Phase 1-3 has been completed. The addendum for plan 4 has been approved (adenosis groups) and scheduled to start. The first phase (groups 1-3) manuscript is in the submission process.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-15-90 Status: Ongoing

Title: Hemodynamic Effects of Dobutamine in a Porcine Hemorrhagic Shock Model.

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: MAJ David W. Mozingo, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s): James M. Lamiell, LTC, MC David W. Mozingo, CPT, MC Glen E. Gueller, SFC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 pCO_2 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: Of the 35 animals used, 15 experiments were completed (i.e., the animals survived the induced shock long enough to collect all data points and/or all recording equipment functioned properly). These data are currently being analyzed to determine if more animals are required to attain adequate statistical comparison between groups.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Timothy K. Dixon, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): William Boykin, MAJ, MC Ian M. Thompson, MAJ, MC Eric S. Zeidman, MAJ, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Initial injection of MBT (murine bladder tumor) resulted in poor tumor growth in the majority of animals. This necessitated euthanizing the animals before meaningful data could be collected.

Trial Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Steven C. Lynch, CPT, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC Steven M. Dresner, MAJ, USAF, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative CMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 $1x10^4$ 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 ($1x10^8$ 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: Data are being analyzed.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-1-91 Status: Terminated

Title: High Frequency Ventilation Rescue of Venous Air Embolism.

Start date: 11 Dec 90	Estimated completion date:
Principal Investigator: David W. Mozingo, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine if high-frequency ventilation (HFV) offers any advantage over conventional mechanical ventilation after venous air embolism (VAE).

2) To establish the safety of high-frequency ventilation for treatment of life threatening VAE.

Technical Approach: Animals are placed on either volume or high frequency percussive ventilation after a hemodynamically significant venous air embolus.

Progress: Initial trials showed no survival benefit for animals ventilated by VDR ventilation during massive air embolism.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-3-91 Status: Completed

Title: Fascia Augmentation: A Comparison Between Autologous Fascia and Injectable Collagen.

Start date: 7 Jan 91	Estimated completion date:
Principal Investigator: David C. Teller, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): The pilot portion of this study will be to initially evaluate and perfect the techniques of obtaining suitable fascia from New Zealand White Rabbits and Preparing this fascia for injection into the donor rabbit.

The second portion is to compare the augmentation effects of prepared fascia to the commercially available collagen injection.

Technical Approach: The pilot study in this project will be to harvest fascia from the leg of the rabbit in a sterile manner. The pilot portion of the study will be performed to perfect the harvesting of the fascia, the preparation of the fascia for injection into the back, and the intradermal injection technique. Once the technique is perfected, 0.1 ml of the prepared gel will be injected into the dermis of the rabbit's back in 5 identified locations. The prepared gel injection samples will be compared at set intervals to similar intradermal injections of the commercially available bovine collagen, the vehicle for the commercial collagen, and to normal saline as a control.

Progress: The project has been completed. We found out that it would be impractical to produce our own collagen especially if autologous tissue. This was due to a large amount of tissue too small but of collagen produced. Also we found it was very difficult to process fascia into an injectable form. RESULTS: No difference in usage, however.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-4-91 Status: Completed

Title: What are the Effects of Hemorrhagic Shock on Myocardial Contractility and Function?

Start date: 12 Mar 91	Estimated completion date:
Principal Investigator: (vice Ho'.ck) Charles P. Kingsley, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) Create a clinically relevant, reproducible model of hemorrhagic shock in anesthetized swine.

2) Determine the role of myocardial contractility on the compensatory and decompensatory phases of hemorrhagic shock.

3) Measure the changes in regional blood flow, serum lactate, serum pH and endothelin levels during the compensatory and decompensatory phases of shock.

Technical Approach: Thirty anesthetized swine will be instrumented to obtain hemodynamic data and pressure dimension loops to calculate endsystolic elastance, a reflection of myocardial contractility. Serial serum pH, lactate and endothelin levels will be collected to determine the effects of shock on these parameters. The effects of shock on peripheral and splanchnic blood flows will be followed by the use of ultrasonic flow probes.

Progress: The research continues-the study has been difficult to complete secondary to changes in the protocol, and also due to inability of the investigators to obtain lab time or time away from the OR. Endothelin appears to cause a significant increase in afterload and there is a trend indicating that myocardial contractibility is affected significantly.

Detail Summary Sheet

Date: 25 Nov 91 Protocol Number: A-5-91 Status: Ongoing

Title: Alkalinization of Lidocaine and its Effect on Plasma Levels in Guinea Pigs.

Start date: 9 Apr 91	Estimated completion date:
Principal Investigator: Samuel C. Sayson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To determine whether alkalinization of lidocaine will affect plasma lidocaine levels obtained at predetermined times following intramuscular injection.

Technical Approach: The protocol has been modified to involve intraperitoneal injections of 2% lidocaine into rabbits. The volume of local anesthetic was too great to be injected into IM or intrapleural sites. Rabbits are used as the lidocaine assay require extracted blood volumes that were poorly tolerated by the guinea pig; therefore larger animals (rabbits) were chosen. The central artery of the rabbit ear was cannulated to extract samples used for plasma assay.

Progress: With the current protocol, 6 animals are in control and 5 animals are in the study group. At least 6 animals have been eliminated under this revised protocol as no lidocaine could be ID'd by the assay. We speculate that the trauma of cannulation and injection of an unsedated animal caused significant vasoconstriction as to minimize absorption of the lidocaine. However the results are promising. Concentrations of the local anesthetics (based on means) are notably greater (1.5x) in the alkalinized group, as to be predicted by the more neutral-charged alkalinized lidocaine. Unfortunately, because of the wide variability of the collected data points, the data failed to achieve statistical significance (based on ANOVA for multiple samples).

We feel that our findings are of reportable significance if we can overcome the apparent degree of variability in absorbance between subjects. We believe

that sedating each animal with ketamine (fixed dose per kilogram) prior to artery cannulations and injection of lidocaine may minimize any catecholamine-induced vasoconstriction.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-7-91 Status: Ongoing

Title: The Effect of Epidurally Administered Local Anesthetics on Differential Sensorimotor Neural Blockade Using Near-Field Cortical and Spinal Evoked Responses in Rabbits.

Start date: 29 Aug 91	Estimated completion date:
Principal Investigator: Joseph P. Ducey, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Paul Mongan, CPT, MC William Strong, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To determine the selectivity (sympathetic, sensory and motor) of neural blockade produced by commonly used local anesthetics introduced into the epidural space.

2) To establish a dose-response relationship for sympathetic, sensory and motor blockade using epidurally administered local anesthetics in the rabbit.

Technical Approach: Five different local anesthetics in varying concentration will be studied: lidocaine, bupivacaine, etidocaine, 2-chloroprocaine, and mepivacaine. Combined somatosensory and motor evoked potential monitoring will be used to assess the onset, extent and conclusion of sensory and motor neural blockade. The different anesthetics will be compared in their ability to produce differential blockade by comparing the ratio of concentrations required to produce sensory and motor block.

Progress: Data for the effects of bupivacaine and lidocaine on somatosensory and motor evoked potentials are complete. Data has been collected from 2 eperiments using chloroprocaine. Statistical comparisons have not yet been performed. Though MEP's are clearly more resistant to local anesthetic effects than SSEP's.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: A-92-01	Status: Ongoing

Title: Nasal Tip fixation: A Comparison of Suture Materials

Start date: 14 Nov 91	Estimated completion date:
Principal Investigator: MAJ Paul J. Davey, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept of Surgery/Otolaryngology	Associate Investigator(s): LTC Kweon I. Stambaugh, MC LTC Clifford J. Hixon, VC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): Object of study is threefold. The primary interest of this study is to evaluate various suture materials used to fixate alar cartilages and other nasal tip structures (one). To do this requires development of an animal model system for the suture evaluation (two), and an anatomic/histologic study of the healing process involved (three), with specific attention to the time frame of healing, strength of healing tissue, and relation of the various tissue involved in the healing process.

Technical Approach: A single incision will be made on the outer anterior ear surface and the cartilage exposed, incised, and sutured with the test suture material. 6-0 Nylon, vicryl, and chromic gut suture materials will be tested (i.e., 3 suture materials x 1 suture material per ear x 6 ears per suture material for a total of 18 ears) in 9 rabbits. This is followed by a healing period of 4, 8, and 12 weeks. The ears will be sampled by excising approximately 1/3 of the sutured cartilage at each of the 3 time points. The samples will then be processed for microscopic evaluation.

Progress: Progress report unavailable at this time.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: A-92-02	Status: Ongoing

Title: Effect of Typically Applied Crystalline L-Lysine

Start date: 12 Mar 92	Estimated completion date: 2 Jan 93
Principal Investigator: Eleanor Ayala, MA	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): MAJ Earl Grant, Jr., MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To determine whether topical applications of crystalline L-lysine enhance the rate of would contraction and rate of reepithelialization of punch biopsies using a hairless guinea pig model.

Technical Approach: Four male, 250-300g, euthymic hairless Hartley guinea pigs will be used. There is only one experimental group and all animals will be assigned to that group, given a number, and weight. All animals will be anesthetized and prepped for aseptic skin biopsies. There will be eight skin biopsy sites/guinea pig (four test sites and four contralateral control sites). All wounds will be blotted dry with sterile gauze.

Progress: Annual report due by July 1993.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: A-92-03	Status: Ongoing

Title: Effects of Desflurane on Neurogenic Motor Evoked Potentials in Swine

Start date: 15 Jun 92	Estimated completion date:
Principal Investigator: MAJ Michael P. Hosking, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): CPT Paul D. Mongan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): a) To determine the effects of desflurane on neurogenic motor evoked potential (NMEP) monitoring. b) To evaluate and characterize any dose related changes in the neurogenic motor evoked response associated with desflurane.

Technical Approach: One (1) experimental group consisting of 8 animals will be studied. Each animal will act as its own experimental control. After induction of anesthesia and placement of all monitoring electrodes a fifteen minute equilibration period will be observed to allow a return of physiologic variables to baseline. A baseline NMEP will then be recorded. Desflurane will then be administered in 0.25 MAC (MAC in swine is 9.4%) increments up to a maximum of 1.5 MAC, or until loss of the NMEP signal. A fifteen minute equilibration period will be allowed after the end tidal concentration of desflurane is stable at the desired level. A NMEP will then be recorded, and the concentration of desflurane increased to the next MAJ interval. An Axon Sentinel clinical evoked potential averager will be used to generate, amplify, and record NMEPs. NMEPs will be generated with a square wave pulses at a constant current of 25 mAmp delivered at a rate of 4.8/sec with a duration of 200 s. One hundred sweeps will be acquired through a band pass of 10-1500 Hz and averaged. Impedance will be maintained at less than 5000 ohms. The resulting signals will be observed on the oscilloscope and recorded on magnetic discs. All NMEPs will be recorded in triplicate and measured for amplitude and latency.

Progress: Annual report due by July 1993.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-92-04 Status: Completed

Title: Effect of Nitric Oxide Synthetase Inhibition in a Porcine Septic Shock Model

Start date: 21 May 92	Estimated completion date:
Principal Investigator: MAJ Frank M. Robertson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Critical Care Service	Associate Investigator(s): MAJ David P. Ciceri, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): a) To establish a porcine septic shock model for continued use her at Brooke Army Medical Center. b) To investigate the metabolic and physiologic effects of nitric oxide (NO) synthetase inhibition with N-nitro-L-arginine (NNLA) and determine if this can reverse the shock state. c) To document blockade of the arginine-nitric oxide-nitrate pathway by measuring N15 labeled nitrate excretion after a primed trace infusion of N15-arginine.

Technical Approach: A total of 16 animals will be studied. These will be divided into 3 groups as described in study protocol. After preparation, a 30 minute equilibration period will be allowed. Data will then be collected hourly starting at time=0 (TO) for 6 hours. After preparation, animals in groups 1 and 2 will be given a primed trace infusion of N15-arginine (20 mol/kg IV followed by 0.2 mol/kg/min IV via the femoral vein catheter) to allow characterization of NO metabolism. All animals will be resuscitated with normal saline via the femoral vein catheter to maintain a normal pulmonary capillary wedge pressure (PCWP).

Progress: Protocol A-92-04 is now completed and we are currently analyzing the large volume of data obtained. The attached abstract highlights just a few of the significant findings. Further conclusions await completion of the statistical analysis.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-92-06 Status: Ongoing

Title: The Effect of Slow Calcium Channel Blockade on Citrate Toxicity During Simulated Massive Transfusion in Swine

Start date: 18 Nov 92	Estimated completion date:
Principal Investigator: CPT Jack Chavez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): LTC Joseph P. Ducey, MC CPT Samuel Sayson, MC MAJ Paul D. Mongan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): a) To establish a procine model for citrate cardiotoxicity. b) To establish a dose-response relationship between citrate dose (administered by continuous infusion) and cardiac performance. c) To determine the effect of preexisting calcium channel blockade on the dose-response relationship between citrate dose and cardiac performance.

Technical Approach: After inducation of general anesthesia, all monitoring devices will be placed. Continuous intraoperative monintoring will include, ECG, arterial blood pressure (arterial line), central venous pressure, pulmonary artery pressure, rectal temperature, Sp02 and end-tidal C02. Upon initiation of the citrate infusions, the following date will be collected at 10 minute intervals for 60 minutes.

Progress: Results will not be available until late fall of 1993.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: A-92-08 Status: Ongoing

Title: The Effects of Desmopressin on Myocardial Contractility in Swine

Start date: 16 Nov 92	Estimated completion date:
Principal Investigator: CPT Samuel Sayson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): CPT Jeffrey Baeuerle, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To determine the effect of DDAVP on contractility.

Technical Approach: Ten animals will be used in this study. After induction of general anesthesia, all monitoring devices will be placed. Continuous intraoperative monitoring devices will be placed. Continuous intraoperative monitoring will include ECG, arterial blood pressure (arterial line), central venous pressure, pulmonary artery pressure, rectal temperature, SPO2, and end-tidal CO2. In addition, cardiac output, pulmonary artery wedge pressure, and pressure-diameter loops will be obtained at 0 (baseline, prior to any DDAVP therapy), 5, 15, 30, 45, 60, and 75 minutes after the initiation of DDAVP treatment.

Progress: Results will not be available until late fall of 1993.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-9-86 Status: Ongoing

Title: Orthopaedic Microsurgery - A Training Protocol.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator: Allan L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedic	Associate Investigator(s):
Key words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 66.30

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review results: Continue

Objective(s): To train Orthopaedic Residents and maintain Orthopaedic Staff expertise at BAMC in the techniques used in 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 microneurorraphy, and the fourth phase will teach the technique of ree tissue transfer using microvascular anastomoses.

Progress: Ongoing training for microsurgery. Due to the age of the protocol and the need to conform to regulatory requirements, the protocol was revised.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-10-86 Status: Ongoing

Title: Supervised Basic Abdominal and Vascular Surgical Experience.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator(vice Rosenthal) Michael J. Walters, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/General Surgery	Associate Investigator(s): Robert Solenberger, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 910.00

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review 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: Continuing laboratory training in laparoscopic and open surgical procedures. Due to the age of the protocol revision was necessary to comply with regulatory requirements.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: T-11-86	Status: Terminated

Title: Microsurgery Training Protocol for Plastic Surgery Staff, Residents and Rotators.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator: Robert N. Young, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Plastic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 347.00

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review results: Continue

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: Terminated. Nothing has been done on protocol since principal investigator PCS'd.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-13-86 Status: Ongoing

Title: Swine Model for Technical Procedure Training of Emergency Medicine Residents.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator: Kevin G. Rodgers, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 2,450.00

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 89 Review 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: Technical procedure training for Emergency Medicine residents continues to be a requirement by the Residency Review Committee (RRC) for accreditation. These labs are scheduled monthly and also benefit rotating students, interns and residents from other services.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-3-87 Status: Ongoing

Title: Abdominal Surgical Experience - Gynecology Service.

Start date: 19 Feb 87	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: $420.00

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review results: Continue

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

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

Progress: Monthly teaching sessions for medical students, interns and OB/GYN residents in surgical techniques, suturing, GI and GU procedures they are required to be familiarized wityh. To conform with regulatory requirements, the protocol was recently revised.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-4-87 Status: Ongoing

Title: Canine Utilization for Rigid Endoscopic Training.

Start date: 2 Mar 87	Estimated completion date:
Principal Investigator: Sylvester Ramirez, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review results: Continue

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 is a training protocol for training residents in laryngoscopy, esophagoscopy, bronchospy and foreign body management. Over the last couple of years, we have not used any animals from BAMC since Wilford Hall had animals available. We still want to continue the protocol as is.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-1-88 Status: Ongoing

Title: Oculoplastic Seminar and Laboratory and Wound Closure.

Start date: 7 Mar 88	Estimated completion date:
Principal Investigator: Donald A. Hollsten, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Ophthalmology	Associate Investigator(s):
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review 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. Protocol recently underwent major revisions in order to conform with regulatory requirements.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-3-89 Status: Terminated

Title: Pediatric Intubation Training Utilizing the Feline Model.

Start date: 15 Sep 89	Estimated completion date:
Principal Investigator: Stephen C. Inscore, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review results: Continue

Objective(s): To teach physicians and other health care professional 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: Protocol terminated. Superseded by Protocol T-92-02.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: T-2-90	Status: Terminated

Title: Urologic Microsurgery - A Training Protocol.

Start date: 14 Mar 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 13 Mar 91 Review results: Continue

Objective(s): To train Urology residents at BAMC the techniques used in microsurgery.

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

Progress: Terminated. This protocol was not being used due to a lack of time and the principal instructor's time was greatly limited.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-92-1 Status: Ongoing

Title: Sensormedics Model 3100 High Frequency Oscillatory Ventilator Training using a Swine Model

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Howard Heiman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): This training protocol is designed to teach physicians and other health care professionals the basic knowledge required to use and and operate a Sensormedics Model 3100 HIgh Frequency Oscillatory Ventilator.

Technical Approach: As outlined in the training protocol.

Progress: Have not used recently due to the principal instructor PCS'ing. The service does want to maintain this protocol.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: T-92-02	Status: Ongoing

Title: Pediatric Endotracheal Training Utilizing the Ferret Model

Start date: 20 May 92	Estimated completion date:
Principal Investigator: Stephen C. Inscore, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): This protocol is designed to teach physicians and other health care providers the basic knowledge and psychomotor skills required for efficient endotracheal intubation in children.

Technical Approach: Protocol designed to increase physician confidence in intubation skills and increase the efficiency with which invasive airway management is accomplished in emergencies.

Progress: Annual protocol review is scheduled for 26 July 1993.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: T-92-03	Status: Ongoing

Title: A Field Anesthesia Machine and the OHMEDA PAC Drawover Vaporizer

Start date: 1 Oct 92	Estimated completion date:
Principal Investigator: Douglas Anderson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): This training protocol is designed to provide anesthesiologists, nurse anesthetists and other health care professionals with clinical experience in the use of anesthesia equipment designed for field medical conditions.

Technical Approach: This protocol is designed to provide the operator with the experience and confidence required to provide anesthetic care to patients with this equipment.

Progress: Annual review of training protocol is scheduled for July 1993.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: T-92-04 Status: Ongoing

Title: Emergency Medicine Trauma Skills Laboratory Using the Goat

Start date: 19 Nov 92	Estimated completion date:
Principal Investigator: Marco Coppola, CPT, MC	Facility: Darnall ACH, Ft Hood, TX
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): Training protocol is designed to refresh Advanced Trauma Life Support (ATLS)-Emergency Medicine residents with basic skills in trauma resuscitation as required by the American Board of Emergency Medicine.

Technical Approach: This lab will provide the Emergency physicians and residents the training required in life-saving resuscitative procedures and will in turn provide optimal life saving care to critical patients.

Progress: Annual review of training protocol is scheduled for July 1993.

Date: 1 Oct 92 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:
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 19 Oct 92 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 TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

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

Progress: This study is closed to new patient accrual, open for follow up purposes only. Two hundred twenty-one patients were entered to this study. There have been no benefits for FAM noted.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 7808 Status: Ongoing

Title: Combined Modality Treatment for Stages III and IV. Hodgkin's Disease MOPP # 6.

Start Date FY 79	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 19 Oct 92 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 in the protocol.

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

Detail Summary Sheet

Date: 1 Oct 92 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 19 Oct 92 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.

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

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

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8216/38 Status: Ongoing

Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date FY 85	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 M. 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: 3
Date of Periodic Review 19 Oct 92 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 follow up purposes only.

Detail Summary Sheet

Date: 1 Oct 92 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 83	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 19 Oct 92 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 follow up purposes only.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8294 Status: Ongoing

Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer.

Start Date FY 83	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 19 Oct 92 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.

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

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

Detail Summary Sheet

Date: 1 Oct 92 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 85	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 19 Oct 92 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).

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

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

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8309 Status: Ongoing

Title: Autologous Marrow Transplantation for the Treatment of Non-Hodgkin's Lymphoma, 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:
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: 4

Date of Periodic Review 19 Oct 92 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 92 Proj No: SWOG 8312 Status: Completed

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 84	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 19 Oct 92 Results Completed

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 92 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 84	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: 9
Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for postoperative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one 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 study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 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 85	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: 1
Total Number of Subjects Enrolled to Date: 4
Date of Periodic Review 19 Oct 92 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 continues to accrue patients but has not reached its accrual goal of 190 patients quite yet. We will need to keep this study open for several more months.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8393 Status: Ongoing

Title: MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma.

Start Date FY 84	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: 1

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 19 Oct 92 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: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8406 Status: Ongoing

Title: Evaluation of Esorubicin (4' Deoxydoxorubicin) in Malignant Lymphoma, Phase II.

Start Date FY 85	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 19 Oct 92 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 92 Proj No: SWOG 8417 Status: Completed

Title: Evaluation of two Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III.

Start Date FY 85	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 19 Oct 92 Results Completed

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 has reached its accrual goals and can be closed to new patients registration. Study SWOG-8419 (the consolidation arms) will remain open until accrual goals are met.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8501 Status: Completed

Title: Intraperitoneal Cis-Platinum/Intravenous Cyclophosphamide in Patients with Non-Measurable (Optimal) Disease Stage III Ovarian Cancer, Phase III Intergroup.

Start Date FY 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:
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 19 Oct 92 Results Completed

Objective(s): 1) To carry out a Phase III randomized trial of intermediate dose intraperitoneal cis-platinum (100 mg/M^2) plus intravenous cyclophosphamide versus intermediate dose intravenous cis-platinum (100mg/M^2) 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: As of April 1, 1990, more than 500 patients had been accrued into this trial. IP cisplatin has been well tolerated with a trend toward less granulocytopenia and ototoxicity compared to patients treated on the intravenous cisplatin arm. The study hs been extended to approximately May 1992 to accrue an additional 100 patients so that the two treatments can be compared statistically with respect to patients who have $\leq$ 0.5 cm residual sized tumor masses.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8507 Status: Ongoing

Title: Maintenance versus no Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phase III.

Start Date FY 86	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 M. Thompson, MAJ, MC
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 19 Oct 92 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 92 Proj No: SWOG 8509 Status: Ongoing

Title: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II.

Start Date FY 86	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 M. Thompson, 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: 8
Date of Periodic Review 19 Oct 92 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 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, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8515 Status: Ongoing

Title: Evaluation of Menogaril in Non-Hodgkins Lymphoma, 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:
Key Words: Non-Hodgkins, Lymphoma	
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 19 Oct 92 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/m^2 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 is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 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 86	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: 0
Total Number of Subjects Enrolled to Date: 13
Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To compare in 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: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 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 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: Ian M. Thompson, MAJ, MC
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 19 Oct 92 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: This study will be closed in a year or so. There have been some responses seen.

Detail Summary Sheet

Date: 1 Oct 92 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 86	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 19 Oct 92 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 92 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 85	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 19 Oct 92 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: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 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 85	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 19 Oct 92 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: Study remains open for followup.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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: 2

Date of Periodic Review 19 Oct 92 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 patterns 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: Study remains open for followup.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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: 5
Date of Periodic Review 19 Oct 92 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 is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8621 Status: Ongoing

Title: Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast 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:
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: 1
Date of Periodic Review 19 Oct 92 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: This trial continues to accrue slowly. Four patients were registered in the last 30 days with 57 patients total. Because of very slow accrual, this trial will now be closed. Toxicity has been acceptable although three patients have had Grade 4 hypercalcemia and one patient had Grade 4 leukopenia. This study is closed.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8624 Status: Completed

Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma.

Start Date FY 79	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: 3
Date of Periodic Review 19 Oct 92 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: a)VMCP/VBAP; b) VAD; c) VMCPP/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: There is no reportable data at this time. This study is closed.

Detail Summary Sheet

Date: 1 Oct 92 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 FY 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:
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 19 Oct 92 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.

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

Progress: Ninety one patients have now been registered to this important intergroup trial. It will remain open. It is accruing about three patients per month. An interim analysis, as planned, will be done in October of this year. There have been no toxic deaths and no unexpected toxicities to Zoladex.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8694 Status: Completed

Title: A comparison of Pentostatin and Alpha-Interferon in Splenectomized Patients With Active Hairy Cell Leukemia.

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:
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 19 Oct 92 Results Completed

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: This study needs to accrue at least another 50 or so patients to reach its accrual goal.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8697 Status: Completed

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:
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: 1
Date of Periodic Review 19 Oct 92 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 protocol.

Progress: This study is coordinated by the Eastern Cooperative Oncology Group. It is now closed and is being analyzed for publication. This study is closed.

Detail Summary Sheet

Date: 1 Oct 92 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 M. 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: 1
Date of Periodic Review 19 Oct 92 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 T_2-T_{4a}, N_0, M_0 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: This trial is still open to patient accrual which is relatively poor at this time. A total of 130 patients have been entered on study. The accrual goal is 290.

Detail Summary Sheet

Date: 1 Oct 92 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: Ian M. Thompson, 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 19 Oct 92 Results Continue

Objective(s): 1. To evaluate the natural history of semenal 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: One hundred thirty patients have been entered. Accrual goal is 300. Approximately 3.2 patients per month have been observed. At this rate,

accrual will be reached in June, 1995.

Detail Summary Sheet

Date: 1 Oct 92 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 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 M. Thompson, MAJ, MC
Key Words: Cancer, Prostate	
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 19 Oct 92 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: A total of 19 patients with Didemnim B and 30 patients with ifosfamide/Mesna have been entered on this trial. Approximately six ot these patients received ifosfamide/Mesna on the Phase II untreated arm. The Didemnim B study will now be expanded to include the new dose level. Since some responses were seen, the protocol will continue onto the second stage of accrual.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8730 Status: Completed

Title: Evaluation of Amonifide in Esophageal Cancer.

Start Date FY	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, Esophageal	
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 19 Oct 92 Results Completed

Objective(s): 1) To evaluate response to amonafied in patients with esophageal cancer. 2) To assess the qualitative and quantitative toxicities of amonafide.

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

Progress: There is no reportable data at tnis time.

Detail Summary Sheet

Date: 1 Oct 92 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 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, Bladder	
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 19 Oct 92 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 treating 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 with prior inactive malignancies are eligible. Therapy will follow the schema outlined in the protocol.

Progress: Thirty-four patients have been entered so far; seven with operable disease and 27 with inoperable disease. Three complete responses were seen in the seven patients with operable disease. Toxicity primarily involves Grade I

thrombocytopenia, but mostly diarrhea which has not been very severe.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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: 5
Date of Periodic Review 19 Oct 92 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: Two hundred and seventeen patients have been entered on this study. There are no major problems with the study. Accrual continues as expected.

No fatal toxicities have been observed.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8737 Status: Ongoing

Title: Phase III AZQ 24-Hour Infusion Versus BCNU for Adult High Grade Gliomas.

Start Date FY 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:
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: 5

Date of Periodic Review 19 Oct 92 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: As of April 1991, 240 patients have been registered on this randomized Phase III trial. Patient data will be evaluated, with final analysis completed in the next several months.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8750 Status: Ongoing

Title: Pilot Study to Examine Cytogenetic Abnormalities in Patients with Acute Leukemia Ancillary.

Start Date FY 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:
Key Words: Leukemia, Acute, Ancillary	
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 19 Oct 92 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 one this one year pilot period.

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

Progress: This study continues to be open and will remain open until it is replaced in the next month or so by SWOG 9007 which will be the Group-wide cytogenetics study. Manuscripts have been accepted by Cancer Genetics and Cytogenetics, Leukemia, and Genes, Chromosomes and Cancer.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8788 Status: Completed

Title: Phase III Evaluation of "High Dose" vs "Standard Dose" Cisplatin Combined with Bleomycin and VP-16 for Advanced Metastatic 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: Ian M. Thompson, 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 19 Oct 92 Results Completed

Objective(s): 1) To examine th 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 germcell tumor, advanced extra gonadal germ cell tumor, or advanced metastatic testicular cancer. Therapy will follow the schema outlined in the protocol.

Progress: This study has closed. It accrued quite well. Preliminary data indicates no differences, but a final manuscript is pending.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8789 Status: Completed

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 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:
Key Words: Tumor, advanced germ cell	
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 19 Oct 92 Results Completed

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: There is no news available at this time. The study accrued quite well and rapidly. There appears to be no difference between the arms; however, the toxicity information is required.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8790 Status: Completed

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: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Ovary	
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 19 Oct 92 Results Completed

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 protocol.

Progress: This trial has been amended to change its design from a Phase III study to a Phase II randomized trial in order to meet patient accrual goals. As reformatted, 25 fully evaluable patients will be required on each of the three study arms. As of April 1, 1991, 35 patients have entered into this study. In general, intraperitoneal alph-interferon has been well tolerated, with one patient experiencing Grade 4 diarrhea and one patient experiencing Grade 3 fever and chills.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8792 Status: Ongoing

Title: Phase III Study of Alfa-n1 (Wellferon™) as Adjuvant Treatment for Resectable Renal Cell Carcinoma.

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: Ian M. Thompson, MAJ, MC
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: 2
Date of Periodic Review 19 Oct 92 Results Continue

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

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

Progress: This study continues to accrue quite well. It was activated on June 15, 1987, and a total of 110 patients have been entered. Two hundred sixty patients are needed. On average, three patients per month are accrued and hopefully, this study can continue accruing for another three to four years prior to closure.

Detail Summary Sheet

Date: 1 Oct 92 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 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 M. Thompson 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: 2
Date of Periodic Review 19 Oct 92 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 "endometroid" 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.

Progress: This study has been opened for 33 months. A total of 42 registrations have been observed. The accrual goal is 240, and 1.3 patients per month have been entered. Accrual is obviously disappointing, despite the fact that the study is interesting in its objectives. The study is to be continued at the present time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8794 Status: Ongoing

Title: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy.

Start Date FY 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 M. Thompson, MAJ, MC
Key Words: Carcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 14

Date of Periodic Review 19 Oct 92 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 16 weeks after radical prostatectomy. Therapy will follow the schema outlined in the protocol.

Progress: A total of 92 patients have been entered out of 588 required. The average accrual per month is 4.3 patients, which is somewhat less than initially projected. No undue toxicities have been reported so far.

Detail Summary Sheet

Date: 1 Oct 92 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 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 M. Thompson, MAJ, MC
Key Words: Carcinoma, Bladder Superficial, Transitional Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 4
Date of Periodic Review 19 Oct 92 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).

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

Progress: This study continues to accrue rather well. A total of 318 patients with superficial bladder cancer have been entered so far, and accrual continues on toward the accrual goal, 720 patients. An average monthly accrual of 12 patients has been observed since January of this year.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8796 Status: Completed

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:
Key Words: Hodgkin's Disease, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 4
Date of Periodic Review 19 Oct 92 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 sent to the SWOG Pathology Office for review and classification immediately following registration. Therapy will follow the schema outlined in the protocol.

Progress: This study is closed and analysis is continuing by the Eastern Cooperative Oncology Group.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8805 Status: Completed

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 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:
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 Date: 5
Date of Periodic Review 19 Oct 92 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 protocol.

Progress: This study continues, with a plan for closure when it reaches accrual objective of 50 eligible patients in both IIIA and IIIB categories of NSCLC. An abstract describing results in the first 65 patients has been accepted for presentation at ASCO in May.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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: 6
Date of Periodic Review 19 Oct 92 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 ± 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: Two hundred and forty two patients have been entered on this study as of March 23, 1991. Accrued continues at the expected rate. Eighty-nine patients have been randomized between alpha-interferon and observation. An amendment is still being planned to randomized patients with minimal residual disease between interferon and no further maintenance therapy.

Detail Summary Sheet

Date: 1 Oct 92 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: Brocke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
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 19 Oct 92 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: Therapy will follow the schema outlined in the study protocol.

Progress: This protocol was activated by the Southwest Oncology Group on April 1, 1988. Patients will be entered until there are 40 patients who have achieved a partial response at the end of three courses. The conversion from partial response to complete response in these 40 patients will be tested with an additional three courses of 5-FU/CACP.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8812 Status: Completed

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 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:
Key Words: Cancer, Limited 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: 4
Date of Periodic Review 19 Oct 92 Results Completed

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/ ul), the days of leukopenia (leukocyte counts <1,000/ ul), 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.

SWOG 8812 (continued)

Progress: This trial will be amended to stop entry on the GM-CSF arm (initial randomization). In the first 160 eligible patients, the incidence of thrombocytopenia Grade $\geq$3 is 42% on the GM-CSF arm v. 10% on the control arm ($p<.001$), and there is a respective incidence of thrombocytopenia Grade $\geq$4 of 26% v. 5%. Although both leukopenia and granulocytopenia of Grade $\geq$3 are statistically reduced in the arm receiving GM-CSF, this has not been reflected as a reduction in the incidence of infection, number of days hospitalized, or duration of neutropenia. In fact, the group receiving GM-CSF has a higher proportion of days febrile ($\geq$ 101°F), 0.8 v. 0.4 mean days, $p<.01$; and a longer duration of thrombocytopenia (mean of 1.9 v 0.2 days < 25,000, $p<.001$).

Detail Summary Sheet

Date: 1 Oct 92 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 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:
Key Words: Cancer, Breast, Receptor Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 5
Total Number of Subjects Enrolled to Date: 9
Date of Periodic Review 19 Oct 92 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: Four hundred twenty-three patients have now been randomized onto this ER + postmenopausal node-positive trial. Accrual is approximately half of what was expected. There has been one toxic death due to congestive heart failure that was not thought to be Adriamycin induced cardiomyopathy. Other toxicities have been as expected and include granulocytopenia, nausea and vomiting.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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 19 Oct 92 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: This ongoing Phase II study had accrued eight patients as of March 23, 1991. No fatal toxicities have been observed.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8819 Status: Ongoing

Title: Central Lymphoma Repository Tissue Procurement Protocol.

Start Date FY 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:
Key Words: Lymphoma, central Tissue, repository	
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 19 Oct 92 Results Continue

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: One hundred and fifty specimens have been submitted to the Central Lymphoma Tissue Repository. Phenotyping and genotyping studies continue. Multiple abstracts have been submitted. Several papers are now being completed.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8822 Status: Completed

Title: A Phase II Study of Continuous Infusion Recombinant Interleukin-2 in Patients with Malignant Lymphoma.

Start Date FY 91	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: 0

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the response rate of malignant lymphomas to treatment with recombinant human interleukin-2 (rIL-2) given by continuous infusion. 2) To evaluate the toxicity of the treatment program used.

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

Progress: This study has accrued five patients as of March 23, 1991. This study requires prolonged hospitalization for continuous infulsion IL-2. The subcutaneous schedule is not currently available from the NCI. There is no possibility that the accrual goals will be met. This study will be closed.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8828 Status: Ongoing

Title: A Phase II Trial of Carboplatin (CBDCA) in Relapsed or Refractory Acute Myeloid leukemia.

Start Date FY 90	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 Myeloid, 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 19 Oct 92 Results Continue

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 or Priesler.

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

Progress: This study is doing well with 25 patients entered, 18 of whom are evaluable, and there have been five complete remissions. This CR rate in excess of 25% in patients who have relapsed AML using a new agent is encouraging.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8833 Status: Completed

Title: Phase II Investigation of Chlorambucil and Fludarabine Monophosphate in Relapsed or Refractory Chronic Lymphocytic Leukemia.

Start Date FY 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:
Key Words: Leukemia, Chronic Lymphocytic	
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 19 Oct 92 Results Continue

Objective(s): 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 is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8834 Status: completed

Title: A Phase II Evaluation of Fazarabine in Central Nervous System Tumors.

Start Date FY 90	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 19 Oct 92 Results Completed

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: Twenty-two patients have been accessioned on this Phase II study evaluating Fazarabine in recurrent central nervous system tumors. A preliminary analysis discussed at the meeting demonstrates one patient having a partial response by tumor measurements. The toxicity has been mild with only 3 of 16 patients having Grade III granulocytopenia and/or leukopenia and one patient Grade IV toxicity with the study embolus.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8835 Status: completed

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 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:
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 19 Oct 92 Results Completed

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: As of April 1990, 42 patients have been registered on to this trial. It is anticipated that at the present rate of accrual, the study will be closed in early 1992. Thus far, both intraperitoneal treatments have been well tolerated. In particular, IP mitoxantrone at 10 mg/m2 every other week has been associated with minimal chemical peritonitis. Myelosuppression following IP FUdR has been relatively well tolerated.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8842 Status: Ongoing

Title: Dihydroxyazacytidine in Malignant Mesothelioma, Phase II.

Start Date FY 90	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 19 Oct 92 Results Continue

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: This study remains open for patients with prior chemotherapy or a biological regimen. It remains temporarily closed for patients with no prior chemotherapy or biological regimen. Major toxicity has been pleuritis.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
Key Words: Cancer, Breast, Receptor-Positive	
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 19 Oct 92 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 premenopausal node-positive intergroup study is accruing at 20 to 25 patients per month. The Southwest Oncology Group has registered 174 of the more than 400 patients registered. Accrual is going as expected. There have been no toxic deaths. The main toxicities have been nausea, vomiting, and granulocytopenia.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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: 4
Date of Periodic Review 19 Oct 92 Results Continue

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 flow cytometry study and a companion protocol to SWOG-8814. This trial does not involve treatment. One hundred sixty five patients have been registered and the trial will remain open.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8855 Status: Ongoing

Title: A Flow Cytometry Companion Protocol to All Southwest Oncology Group Head and Neck Cancer Protocols Utilizing Chemotherapy as Initial Treatment.

Start Date FY 91	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 19 Oct 92 Results Continue

Objective(s):

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

Progress: There is no reportable data at this time.

Detail Summary Sheet

Date: 1 Oct 92 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 90	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: 0
Total Number of Subjects Enrolled to Date: 6
Date of Periodic Review 19 Oct 92 Results Continue

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: Approximately three-fourths were fully ambulatory and 70% had an increased LDH. Of those currently evaluable for response, there are 3 CR and 19 PR in 28 (68%). There are two drug related deaths from myelosuppression (7&) and 3 others will Grade 4 neutropenia (total of 5, or 18%, with Grade $\geq$4). One patient had Grade 3 thrombocytopenia. Other toxicities have been as expected, and none were Grade $\geq$3. The median time on study is estimated at five months, with a median survival of nine months. These results do not appear sufficiently encouraging to take this regimen into a Phase III trial.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8859 Status: Completed

Title: DNA Flow Cytometric Analysis in Patients with Prostate Cancer.

Start Date FY 90	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 M. Thompson, MAJ, MC
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 19 Oct 92 Results Completed

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: Only two patients have been entered on the companion treatment protocol, SWOG-8890. This continues as projected.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8861 Status: Completed

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 90	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 M. Thompson, MAJ, MC
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 19 Oct 92 Results Completed

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, 1.1)3 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 at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8890 Status: Completed

Title: Radical Prostatectomy versus Radiation Therapy for Clinical Stage A^2 and B Adenocarcinoma of the Prostate (N^oM^o).

Start Date FY 90	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 M. Thompson, MAJ, MC
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 19 Oct 92 Results Completed

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: Only two patients have been entered thus far to this study. Both, of which, are from the University of California, Davis. The issues of poor accrual were very carefully discussed once more. Several institutions have pledged to place a number of patients on this study for the next several months. However, it was decided that if accrual continues to be poor for six more months, the study will be closed, and a new design will be discussed.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8891 Status: Completed

Title: Low-Grade Glioma Phase III: Surgery and Immediate Radiotherapy vs Surgery and Delayed Radiotherapy.

Start Date FY 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:
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 19 Oct 92 Results Completed

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 intergroup trial which is being conducted in cooperation with the Brain tumor Cooperative Group and RTOG, has accessioned 56 patients. The contribution to the study of the Southwest Oncology Group continues to be low and was once again discussed at the meeting. It appears that few of these patients are seen by medical oncologists in the Southwest Oncology Group and many of the radiation therapists in the Southwest Oncology Group Institutions who are participating may be entering patients through RTOG rather than Southwest Oncology Group.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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 19 Oct 92 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: Accrual to this intergroup study has been poor but has begun to increase recently. Twenty-three patients have been registered since the study was activated in May 1989. Only two patients have been evaluated for response and both have data from only the first response assessment time. Both achieved a PR at their first response assessment and further follow-up data is forthcoming to confirm the responses. Three of eight patients evaluated have had Grade 4 toxicity. An article recently printed in the JCO on the RTOG pilot results should generate interest among investigators. The study was amended to base dose modifications on granulocytes.

Detail Summary Sheet

Date: 1 Oct 92 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 D_2 Prostate Cancer.

Start Date FY 90	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 M. Thompson, MAJ, MC
Key Words: Cancer, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7
Total Number of Subjects Enrolled to Date: 21
Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 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: Accrual of 507 patients have been entered. No major toxicities have been reported so far. The study continues to progress without any major problems. The study continues to accrue approximately 35 patients per month. We project a closure date of approximately late 1992.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8895 Status: Ongoing

Title: Phase III Study of the role of Cricopharyngeal Myotomy in the Treatment of Dysphagia following Major Head and Neck Surgery.

Start Date F 91	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	
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 19 Oct 92 Results Continue

Objective(s): 1) The objective of this study is to test the concept that cricophargyngeal myotomy performed in conjunction with the resection of a tumor involving the base of tongue or supraglottic larynx or hypopharynx will increase the frequency of patients with normal swallowing function at six months.

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

Progress: The Ohio State University, JMMC-Brooke Army Medical Center and Wayne State University are the only three Southwest Oncology Group institutions participating in this limited institution intergroup study which is coordinated by RTOG and independently funded by another grant. To date, 60 patients are ineligible, one for positive margins, and the other because the pre-surgical videofluoroscopy was not done.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
Key Words: Carcinoma, rectal	
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 19 Oct 92 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 Coller $_{B2\text{-}3}$ and $C_{1\text{-}3}$ 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: This study has been fully analyzed with the intergroup study. The Southwest Oncology Group accrued 165 patients to this study. The results of the study are not available, except that Methyl-CCNU added nothing to 5-FU in any of the any of the arms of the study. Therefore, Methyl-CCNU does not need to be used for future rectal adjuvant studies.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
Key Words: Cancer, Breast, Node Negative	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3
Total Number of Subjects Enrolled to Date: 34
Date of Periodic Review 19 Oct 92 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: This trial is accruing at more than 150 patients per month. More than 2,270 patients have now been registered. The low risk portion of this trial should be ready for closure in the next six months. The high risk portion, which needs 2,600 randomized patients should be closed in the next 12

to 18 months. There have been no toxic deaths. Toxicities are as expected and include nausea, vomiting, and granulocytopenia primarily.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
Key Words: Cancer, Colon, Duke's B/C	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4
Total Number of Subjects Enrolled to Date: 18
Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To independently assess the effectiveness of 5-FU + low-dose Leucovorin, 5-FU + high dose Leucovorin 5-FU + Levamisole and 5-FU + low-dose Leucovorin + Levamisole as surgical adjuvant therapy for resectable colon cancer

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

Progress: This is the intergroup adjuvant study that is currently a four arm clinical trial. The Southwest Oncology Group continues to lead in accruals to this study with approximately 816 patients accrued. The accrual is proceeding nicely with about half the total accrual of 2800 patients currently on study. No significant major toxicities have been in reported with this study.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8900 Status: Completed

Title: A Phase II Pilot of VAD and VAD/Verapamil for Refractory Myeloma.

Start Date FY 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:
Key Words: Myeloma, Refractory	
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 19 Oct 92 Results Completed

Objective(s): 1) To estimate the response rate and response duration with chemotherapy alone (VAD) and chemotherapy plus the chemo-modifier, verapamil (VAD/V), in patients who have failed previous combination chemotherapy. 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: There is no reportable data at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8901 Status: Ongoing

Title: Clinical Trial of the Most Active Drugs Selected by Clonogenic Assay to be Administered by the Intrahepatic Arterial Route for Colorectal Cancer Metastatic to the Liver.

Start Date FY 91	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, 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 19 Oct 92 Results Continue

Objective(s): 1) To assess, in the setting of a phase II clinical trial, the efficacy of the approach of selecting anticancer drugs based on the results of the human tumor clonogenic assay for intrahepatic arterial administration in patients with colorectal cancer metastatic in the liver. 2) To assess the toxicities of anticancer drugs chosen by this approach.

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

Progress: Only two cases have been accrued onto this study. This is a limited institutional pilot study.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8905 Status: Ongoing

Title: Phase II/III Study of Fluorouracil (5FU) and its Modulation in Advanced Colorectal Cancer.

Start Date FY 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:
Key Words: Cancer, Colorectal, Advanced	
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 19 Oct 92 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 accrued approximately 315 patients and therefore has over half its anticipated accrual of 560. No comments could be made about response or survival, but it was commented that there is a delay in getting information to the study coordinators. Approximately 25% of response information is not available to coordinators. The Group was encouraged to get their information on the study to the coordinators as soon as possible. The study will continue to be active.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8906 Status: Completed

Title: Evaluation of Merbarone in Hepatoma, Phase II

Start Date FY 90	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	
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 19 Oct 92 Results Completed

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 are 22 patients on study, and the clinical trial was temporarily closed. There was one Grade 5 toxicity from infection, three Grade 4 granulocytopenias, and one Grade 4 leukopenia on the study. The study is temporarily closed while undergoing evaluation.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8910 Status: Ongoing

Title: Evaluation of Low Dose Continuous 5-Fluorouracil (5-FU) and Weekly Cis-Platinum (CDDP) in Advanced Adenocarcinoma of the Stomach.

Start Date FY 90	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 19 Oct 92 Results Continue

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: Twenty-four patients have been accrued, and the study is undergoing analysis. There were no significant toxicities.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8911 Status: Ongoing

Title: Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II.

Start Date FY 90	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 19 Oct 92 Results Continue

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 92 Proj No: SWOG 8913 Status: Ongoing

Title: Phase II Trial of Merbarone in Disseminated Malignant Melanoma.

Start Date FY 91	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, Disseminated	
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the response rate of disseminated malignant melanoma 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 at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8915 Status: Completed

Title: A Phase II Study of 6-Thioguanine Administered as 120-Hour Continuous Infusion for Refractory or Recurrent Small Cell Carcinoma.

Start Date FY 90	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 19 Oct 92 Results Completed

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: After temporary closure, this study will reopen to accrue approximately four more patients to insure an adequate denominator for response assessments.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8917 Status: Ongoing

Title: 5-Fluorouracil, Leucovorin and Roferon-A in Advanced Colorectal Cancer, Phase II Pilot.

Start Date FY 90	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: 5

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review 19 Oct 92 Results Continue

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: Therapy will follow the schema outlined in the protocol.

Progress: Thirty-two patients have been enrolled in the study, and the study has been temporarily closed since April 1990. Twelve patients are fully evaluable. There have been responses. There has not been significant toxicity noted. The Committee was encouraged to increase submission of data for this study so that it could be fully analyzed. With the presence of responses, it was elected to open this study so that a total of fifty patients can be accrued.

Detail Summary Sheet

Date: 1 Oct 92 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 90	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: 2

Date of Periodic Review 19 Oct 92 Results Continue

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, cisplatinum (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 trial remains open for accrual to the DTIC/Cisplatin/Tamoxifen arm only. The two IL-2 containing arms have completed their accrual goals of 15 patients each, and the response rates for these two arms are being tabulated. As of April 8, 1991, 41 patients out of a target of 50 have been accrued to the DTIC/Cisplatin/Tamoxifen arm. The response rate for the tamoxifen containing combination will be compared to 12% rate obtained in SWOG-8804 for DTIC/Cisplatin alone in order to determine if there is justification for proceeding with a randomized Phase II trial comparing DTIC/Cisplatin to DTIC/Cisplatin/Tamoxifen.

Detail Summary Sheet

Date: 1 Oct 92 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 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:
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 19 Oct 92 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 92 Proj No: SWOG 8929 Status: Ongoing

Title: Evaluation of Merbarone in Patients with Advanced Renal Cell Carcinoma.

Start Date FY 90	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 M. Thompson, MAJ, MC
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: 2

Date of Periodic Review 19 Oct 92 Results Continue

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 92 Proj No: SWOG 8930 Status: Completed

Title: Phase II Trial of Piroxantrone for Advanced or Metastatic Soft-Tissue Sarcomas.

Start Date FY 90	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 19 Oct 92 Results Completed

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: There is no reportable data at this time.

Detail Summary Sheet

Date: 1 Oct 92 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 90	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: 1

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 19 Oct 92 Results Continue

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 92 Proj No: SWOG 8936 Status: Completed

Title: Evaluation of Piroxantrone in Gastric Carcinoma.

Start Date FY 91	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, 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 19 Oct 92 Results Completed

Objective(s): 1) To assess the response rate and response duration gastric carcinoma treated with Piroxantrone. 2) To evaluate the qualitative and quantitative toxicities of Piroxantrone administered in Phase II study.

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

Progress: This study has accrued seven patients and accrual will continue. It is too early to analyze the study for toxicity or response.

Detail Summary Sheet

Date: 1 Oct 92 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 90	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: 1
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 19 Oct 92 Results Continue

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 Phase II study of autologous bone marrow transplant for relapsed non-Hodgkin's lymphomas has accrued nine patients. No changes are planned at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8947 Status: Ongoing

Title: Central Lymphoma Serum Repository Protocol.

Start Date FY 90	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: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 19 Oct 92 Results Continue

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: Thirty-two specimens have been shipped to the Serum Repository. The first study of the Serum Repository will be a study of IL-6 levels in non-Hodgkin's lymphomas.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8949 Status: Ongoing

Title: A Randomized Comparison of Nephrectomy Followed by Intron-A vs Intron-A Alone in Patients with Advanced Renal Cell Carcinoma

Start Date FY 91	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 M. Thompson, MAJ, MC
Key Words: Carcinoma, Advanced Renal 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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate and compare the survival and response rates of patients with metastatic renal cell carcinoma receiving nephrectomy followed by Interferon Alpha-2b (Intron-A) vs. Interferon Alpha-2b (Intron-A) alone. 2) To evaluate morbidity and mortality associated with adjuvant nephrectomy in metastatic renal cell carcinoma.

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

Progress: This is a new study and no reportable data is available at this time.

Detail Summary Sheet

Date: 1 Oct 92 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 90	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: 2

Date of Periodic Review 19 Oct 92 Results Continue

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: The Southwest Oncology Group has registered sixty seven patients on this study which is coordinated by CALGB. Southwest Oncology Group accrual now represents 43% of the study.

Detail Summary Sheet

Date: 1 Oct 92 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 90	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 19 Oct 92 Results Continue

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 has accrued four patients. This is a rare disease and accrual is proceeding slowly, as expected.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8955 Status: Ongoing

Title: Treatment of Stage D, Hormone Refractory Carcinoma of the Prostate with 5 Fluorouracil and Roferon-A, Phase I.

Start Date FY 92	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 M. Thompson MD
Key Words: Refractory 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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with 5-FU and Roferon-A ® in order to assess whether this regimen should be advanced to further studies. 2) To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8956 Status: Ongoing

Title: A Phase II Study of Cisplatin and 5-FU Infusion for Treatment of Advanced and /or Recurrent Metastatic Carcinoma of the Urinary Bladder.

Start Date FY 91	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 M. Thompson, MAJ, MC
Key Words: Carcinoma, 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 19 Oct 92 Results Continue

Objective(s): 1) To assess efficacy and feasibility of utilizing Cisplatin (CDDP) and 5-Fluorouracil infusion (5-FU) in patients with advanced and/or recurrent carcinoma of the urinary bladder. 2) To evaluate the toxicity of Cisplatin + 5-FU in this group of patients.

Technical Approach: 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 92 Proj No: SWOG 8957 Status: Completed

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 90	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 19 Oct 92 Results Completed

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: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8990 Status: Ongoing

Title: Combined Modality Treatment for Resectable Metastatic Colorectal Carcinoma to the Liver: Surgical Resection of Hepatic Metastases in Combination with Continuous Infusion of Chemotherapy.

Start Date FY 91	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, Colorectal Metastatic to liver	
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 19 Oct 92 Results Continue

Objective(s): 1) To study the incidence of recurrence and time to recurrence in patients with 1-3 hepatic metastases treated with resection alone versus resection and continuous infusion of 5-FU into the systemic venous system and FUDR into the hepatic artery.

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 92 Proj No: SWOG 8991 Status: Ongoing

Title: A phase III Study of Cisplatin plus Etoposide Combined with Standard Fractionation Thoracic Radiotherapy vs Cisplatin Plus Etoposide Combined with Multiple Daily Fractionated Thoracic Radiotherapy for Limited Stage Small Cell Lung Cancer.

Start Date FY 92	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 Stage 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 19 Oct 92 Results Continue

Objective(s): 1) To compare the median and long-term (i.e., > 2 year) survivals of limited stage SCLC patients receiving Cisplatin/Etoposide induction chemotherapy combined with concurrent thoracic radiotherapy given in either a standard, once daily fractionation scheme or a twice daily fractionation scheme. 2) To compare intrathoracic, within radiation portal and distant failure rates of these regiments. 3) To compare the toxicities of standard fraction, concurrent thoracic radiotherapy with the toxicities of small, multiple daily fraction concurrent thoracic radiotherapy. 4) To determine the clinical significance of variant morphology small cell carinoma of the lung.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8993 Status: Ongoing

Title: Phase II Study of High Dose Melphalan with Hemopoietic Stem Cell Support and GM-CSF in Refractory Multiple Myeloma.

Start Date FY 91	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: 0

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To evaluate therapeutic efficacy and toxicity of high dose melphalan (HDM 200mg/M^2) in patients with multiple myeloma (MM) resistant to VAD and alkylating agents followed by autologous hemopoietic stem cell support (marrow and/or blood) and GM-CSF administration. 2) To assess the feasibility of measuring multi-drug resistance in this group of patients. 3) To determine the feasibility of conducting such high dose therapy in a multi-institutional setting such as SWOG as a prelude to future trials for patients earlier in the disease course.

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 92 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 90	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 M. Thompson, MAJ, MC
Key Words: Prostate, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4
Total Number of Subjects Enrolled to Date: 9
Date of Periodic Review 19 Oct 92 Results Continue

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 secondary 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: There is no reportable data at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 8997 Status: Completed

Title: Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide.

Start Date FY 90	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 M. Thompson, 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: 0

Date of Periodic Review 19 Oct 92 Results Completed

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 ECOG intergroup study was activated in 10/1/89. A total of 192 patients have been accrued, 52 of which are from the Southwest Oncology Group. As it continues, the study will complete its accrual by June 1992. No further data is available at this time.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9000 Status: Ongoing

Title: Biomarkers of Colorectal Cancer Prognosis.

Start Date FY 91	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: Colorectal 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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate if aneuploidy in Dukes B or C colon cancers as determined by flow cytometric analysis of DNA content has independent prognostic significance for survival or disease free survival in patients enrolled on SWOG-8591. 2) To evaluate if aneuploidy in colon cancers is predictive of patients who benefitted from adjuvant therapy with levamisole or 5-FU plus levamisole by increased survival or disease free survival in SWOG-8591.

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 92 Proj No: SWOG 9007 Status: Ongoing

Title: Cytogenetic Studies in Leukemia Patients, Ancillary.

Start Date FY 91	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	
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 19 Oct 92 Results Continue

Objective(s): 1) To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. 2) To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. 3) To provide quality control for all Southwest Oncology Group cytogenetic data.

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 92 Proj No: SWOG 9008 Status: Ongoing

Title: Trial of Adjuvant Chemoirradiation After Gastric Resection for Adenocarcinoma.

Start Date FY 91	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, Gastric	
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 19 Oct 92 Results Continue

Objective(s): 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoirradiation after gastric resection.

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 92 Proj No: SWOG 9009 Status: Ongoing

Title: Pilot Study for Analysis of Lymphocyte Subsets and Natural Killer Activity after Treatment with Levamisole.

Start Date FY 91	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	
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 19 Oct 92 Results Continue

Objective(s): 1) Describe the effect of levamisole on lymphocyte subsets in the peripheral blood over time in patients receiving adjuvant levamisole. 2) Describe the effect of levamisole on peripheral blood "natural killer" cytotoxicity over time in patients receiving adjuvant levamisole.

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 92 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 90	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 transplant, hodgkins disease	
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 19 Oct 92 Results Continue

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 Phase II bone marrow transplant study for relapsed Hodgkin's disease has now accrued five patients. No fatal toxicities have been reported.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9012 Status: Completed

Title: Evaluation of Low Dose Alpha-Interferon in Patients with Advanced Renal Cell Carcinoma, Phase II.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncolog	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, Renal 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 19 Oct 92 Results Completed

Objective(s): 1) Evaluate the likelihood of response in order to assess whether low dose alpha-interferon should be advanced to further studies and, 2) Evaluate 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 92 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 90	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: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 19 Oct 92 Results Continue

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: 1 Oct 92 Proj No: SWOG 9015 Status: Ongoing

Title: A Randomized Trial of Pre- and Post- operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-Small Cell Carcinoma of the Lung, Phase III.

Start Date FY 92	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, non-small cell lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To compare the survival experience of patients with clincal stages T2N1. T1N1, T2N0, T3N0, and T3N1 NSCLC (mediastinoscopy negative) (Clinical stages 1b,11, 111a) treated with either surgical resection alone (control) or a regimen of pre- and post-operative chemotherapy (experimental arm). 2) To estimate the response rate to pre-operative chemotherapy. 3) To test the associationbetween response to pre-operative chemotherapy and survival of those patients who receive chemotherapy. 4) To estimate the toxicity, including operative complications, of combined pre- and post-operative chemotherapy.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9016 Status: Ongoing

Title: Study of External Brain Irradiation and Cisplatin/BCNU Followed by BCNU for the Treatment of Primary Malignant Brain Tumors.

Start Date FY 91	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, Brain	
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 19 Oct 92 Results Continue

Objective(s): The objectives of this study are to determine whether this regimen (radiation therapy + BCNU/cisplatin) can be given safely in a cooperative group setting and to demonstrate that adequate accrual can be achieved with this regimen. Other goals are: estimation of response and disease stabilization rates, and estimation of the probability of one year survival.

Technical Approach: The 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 92 Proj No: SWOG 9019 Status: ongoing

Title: A Phase III, Randomized, Prospective Comparison Between Chemotherapy Plus Radiotherapy Together with Surgery for Selected Stage IIIa (Positive Mediastinal Nodes) and Selected Stage IIIb (No Malignant Effusion) Non-Small Cell Lung Cancer.

Start Date FY 92	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:	
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 19 Oct 92 Results Continue

Objective(s): 1) Assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (N2-positive) and selected IIIb non-small cell lung cancer. 2) Evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9021 Status: Ongoing

Title: Post-Operative Radiotherapy for Single Brain Metastases, Phase II.

Start Date FY 91	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: Metastases	
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the effectiveness of whole brain radiation therapy given after complete resection of single brain metastasis from systemic cancer. 2) To compare complete surgical resection plus postoperative whole brain radiation therapy to complete resection alone, with respect to survival, site of recurrence, cause of death, and quality of life. 3) To evaluate the use of Quality of Life Questionnaire specific for CNS malignancies.

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 92 Proj No: SWOG 9019 Status: Ongoing

Title: A Phase III, Randomized, Prospective Comparison Between Chemotherapy Plus Radiotherapy Together with Surgery for Selected Stage IIIa (Positive Mediastinal Nodes) and Selected Stage IIIb (No Malignant Effusion) Non-Small Cell Lung Cancer.

Start Date FY 92	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: 0

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) Assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (N2-positive) and selected IIIb non-small cell lung cancer. 2) Evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG

9024 Status: Ongoing

Title: A Pilot Study of Combined Modality Therapy in T3, 4; No, Mo Adenocarcinoma of the Prostate, Phase II.

Start Date FY 91	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 M. Thompson, MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the likelihood of complete response of T3, T4; N0, M0 prostate cancer to prolonged venous infusion of 5-fluorouracil in combination with external beam radiation therapy. 2) To evaluate the safety and toxicity of pelvic irradiation in combination with prolonged venous infusion of 5-fluorouracil at a dose of 200mg/m2/day.

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 92 Proj No: SWOG 9028 Status: Ongoing

Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD to VAD/Verapamil/Quinine for Induction with Crossover to VAD/Verapamil/Quinine for VAD Induction Failures; (2) Alpha-2B Interferon or Alpha-2B Interferon Plus Prednisone for Remission Maintenance.

Start Date FY 91	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: 1
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To compare the effectiveness of the VAD chemotherapy regimen when administered alone or in combination with chemosensitizers (verapmil/quinine) intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma.

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 92 Proj No: SWOG 9030 Status: Ongoing

Title: Phase II Study of High Dose Ara-C/Mitoxanthrone For the Treatment of Relapsed/Refractory Acute Lymphocytic Leukemia.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Lymphocytic Leukemia
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 19 Oct 92 Results Continue

Objective(s): 1) To assess the complete response rate achieved in adult patients with relapsed or refractory ALL using the combination of high-dose Ara-C with mitoxantrone. 2) To evaluate the toxicities associated with this induction regimen.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9031 Status: Ongoing

Title: A Double Blind Placebo Controlled Trial of Daunomycin and Cytosine Arabinoside With or Without rhG-CSF in Elderly Patients With Acute Myeloid Leukemia, Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Acute myeloid Leukemia
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 19 Oct 92 Results Continue

Objective(s): 1) To compare the complete response rates and durations of survival in patients aged 56 or older with acute myeloid leukemia (AML) when treated with standard doses of Cytosine Arabinoside (Ara-C) and Daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). 2) To assess the frequency and severity of toxicities of the two treatment regimens. 3) To compare the duration of neutropenia and thrombocytopenia; the total of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). 4) To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9032 Status: Ongoing

Title: A Controlled Trial of Cyclosporine As a Chemotherapy-Resistance Modifier In Blast Phase-Chronic Myelogenous Leukemia, Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: cyclosporine, Chemotherapy-Modifier
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 19 Oct 92 Results Continue

Objective(s): 1) To compare the duration of survival in patients with chronic myelogenous leukemia (CML) in blast phase, when treated with either chemotherpay (Ara-c/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA). 2) To estimate the frequency of P-glycoprotein expression and its association with blast lineage and prognosis. 3) To compare the frequency and severity of toxicity of the two treatment regimens.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9035 Status: Ongoing

Title: Randomized Trial of Adjuvant Immunotherapy with an Allogenic Melanoma Vaccine for Patients with Intermediate Thickness Node, Negative Malignant Melanoma (T3N0M0) Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Allogenic Melanoma Vaccine
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 19 Oct 92 Results Continue

Objective(s): 1) To compare disease-free survival and overall survival between patients with T3N0M0 malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. 2) To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3N0M0 malignant melanoma.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9037 Status: Ongoing

Title: Prediction of Recurrence and Survival in Node Negative Breast Cancer Patients using a Panel of Prognostic Factors: A Companion Protocol to SWOG 8897.

Start Date FY 91	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 19 Oct 92 Results Continue

Objective(s): 1) To measure the following, histologic and nuclear grade; Estrogen and progesterone receptors; HER-2 oncogene; Cathepsin D; EGF receptor; PS2; hsp27, 70 and 90, in paraffin-embedded histopathological specimens from lymph node-negative breast cancer patients. 2) To correlate the above factors with biological and clinical features including recurrence and survival in patients entered on SWOG protocol SWOG-8897, "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."

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 92 Proj No: SWOG 9038 Status: Ongoing

Title: Extended Administration of Oral Etoposide and Cyclophosphamide for the Treatment of Advanced Non-Small Cell Lung Cancer Phase II Pilot.

Start Date FY 91	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, Lung Non-Small Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To estimate the response rate of extended oral administration of etoposide and cyclophosphamide in advanced non-small cell lung cancer. 2) To evaluate the qualitative toxicities of this regimen 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 92 Proj No: SWOG 9039 Status: Ongoing

Title: Evaluation of Quality of Life in Patients with Stage D2 Cancer of the Prostate Enrolled on SWOG-8894.

Start Date FY 91	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 M. Thompson, MAJ, MC
Key Words: Cancer, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 11

Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): The Cancer Control intervention study measures quality of life in patients with advanced carcinoma of the prostate. Specifically, it is a companion protocol for SWOG-8894. Treatment of Stage D2 Carcinoma of the Prostate Comparing Orchiectomy +/- Flutimide.

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 92 Proj No: SWOG 9040 Status: Ongoing

Title: Intergroup Rectal Adjuvant Protocol, A Phase III Study.

Start Date FY 91	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 19 Oct 92 Results Continue

Objective(s): The objective of the proposed study is to determine the relative efficacy of: 5-FU, 5-FU and leucovorin, 5-FU and levamisole and 5-FU, leucovorin and levamisole when combined with pelvic radiation therapy in the treatment of Stages B-2 and C rectal cancer.

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 92 Proj No: SWOG 9045 Status: Ongoing

Title: Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG-8905.

Start Date FY 91	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 19 Oct 92 Results Continue

Objective(s): This Cancer Control intervention study measures quality of life in patients with advanced colorectal cancer. Specifically, it is a companion protocol for SWOG-8905 Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG-8905.

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 92 Proj No: SWOG 9046 Status: Completed

Title: Evaluation of 10-EdAM in Patients with Squamous Cell Carcinoma of the Head and Neck, Phase II.

Start Date FY 91	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 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 19 Oct 92 Results Completed

Objective(s): 1) To evaluate the likelihood of response in order to assess whether 10-EdAM should be advanced to further studies. 2) To evaluate 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 92 Proj No: SWOG 9054 Status: Ongoing

Title: Ancillary Bone Mineral Density Study in Premenopausal Women on SWOG 8851, EST 5188 (Intergroup 0101)

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Bone Mineral Density
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 19 Oct 92 Results Continue

Objective(s): 1) To determine whether tamoxifen (10 mg BID) protects against loss of bone mineral density in the lumbar spine and in the femur in premenopausal women with breast cancer following their being made postmenopausal by cytotoxic and ovarian function-suppressing hormonal therapy. 2) To determine the effects Zoladex therapy has on bone mineral density in the lumbar spine and femur in premenopausal women with breast cancer following treatment with 6 cycles of cytotoxic chemotherapy. 3) To determine the rates, pattern of rates and pattern of bone loss in the lumbar spine and femur occurring in premenopausal women treated with a standard course of 6 cycles of cytoxic chemotherapy. 4) The fourth objective of this study is to investigate the serum marker of bone mineral metabolism, serum osteocalcin, in a population of women undergoing significant changes in their bone density.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9058 Status: Ongoing

Title: A Phase II Trial of Intravenous Vinorelbine (Navlebine) in Previously Untreated Extensive Small Cell Lung Carcinoma.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Vinorelbine, Lung Carcinoma
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 19 Oct 92 Results Continue

Objective(s): 1) To assess whether vinorelbine (Navelbine) given as a weekly intravenous infusion produces objective clinical responses in patients with previously untreated extensive small cell lung cancer. 2) To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous vinorelbine (Navelbine).

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9060 Status: Ongoing

Title: A Pilot Study Evaluation of Multimodality Treatment of Local regional Esophageal Carcinoma, Phase II.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Esophageal Carcinoma
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the feasibility and toxicity of combined radiotherapy-chemotherapy with continuous infusion 5-fluorouracil plus cisplatin in epidermal carcinoma or adenocarcinoma of the middle and distal esophagus. 2) To estimate the disease-free survival and survival duration associated with this combined modality regimen.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9061 Status: Ongoing

Title: A Phase III Study of Conventional Adjuvant Chemotherapy Versus High Dose Chemotherapy and Autologous Bone Marrow Transplantation Versus Adjuvant Intensification Therapy Following Conventional Adjuvant Chemotherapy in patients with Stage II and III Breast Cancer at High Risk of Recurrence.

Start Date FY 92	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 19 Oct 92 Results Continue

Objective(s): 1) To compare the sites and rates of recurrence, disease-free survival and overall survival, and toxicity of adjuvant chemotherapy (CAF) with adjuvant chemotherapy plus high-dose therapy with cyclophosphamide and ThioTEPA with autologous marrow infusion in patients with breast cancer with 10 or more positive lymph nodes. 2) To compare the efficacy and toxicity of 3 different infusion schedules of GM-CSF. 3) To prospectively evaluate the incidence and degree of occult marrow contamination due to breast cancer cells at the time of study entry and following CAF chemotherapy by analyzing samples of marrow using a panel of monoclonal antibodies specific for breast cancer. 4) To document the changes in psychosocial function that occur during treatment on the two regimens and to compare post-treatment recovery of psychosocial function.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9062 Status: Ongoing

Title: Evaluation of 96 Hour Infusion of 5-FU & Alpha Interferon in Patients with Recurrent/Metastic Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Metastic Squamous cell Carcinoma
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the complete response rate in order to assess whether this regimen should be advanced to further studies and, 2) To evaluate the qualitative and quantitive toxicities associated with this regimen and, 3) To assess the feasibility of this regimen.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9108 Status: Ongoing

Title: A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate + Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia.

Start Date FY 91	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: 0
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 19 Oct 92 Results Continue

Objective(s): 1) To compare in previously untreated CLL patients the response rates and progression free survival. 2) To determine whether the quality of life is superior using any of the three regimens. 3) To determine whether Fludarabine Phosphate and chlorambucil are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they were initially randomized.

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 92 Proj No: SWOG 9110 Status: Ongoing

Title: A Phase II Evaluation of Didemnin B In Central Nervous System Tumors.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Central Nervous Tumors, Didemnin B
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 19 Oct 92 Results Continue

Objective(s): 1) evaluate the likelihood of response in order to assess whether didemnin B should be advanced to further studies and, 2) evaluate the qualitative and quantitive toxicities of didemnin B.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9111 Status: Ongoing

Title: Phase III Study of Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma.

Start Date FY 91	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, 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 19 Oct 92 Results Continue

Objective(s): 1) To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alfa-2b as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. 2) To evaluate the efficacy and tolerance of long-term Interferon alfa-2b at 3 MU/d (SC TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

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 92 Proj No: SWOG 9115 Status: Ongoing

Title: Randomized Study of Standard Chemotherapy vs STAMP V with ABMT in Stage IV poor Prognosis Breast Carcinoma, Phase III.

Start Date FY 92	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 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 19 Oct 92 Results Continue

Objective(s): 1) To compare the overall survival as well as the time to treatment failure of a high dose program with autologous stem cell infusion as consolidation treatment for patients with poor prognosis, Stage IV breast cancer at the completion of induction chemotherapy to further standard treatment (continuation of outpatient chemotherapy).

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9119 Status: Ongoing

Title: Primary Chemotherapy of Poor Prognosis Soft Tissue Sarcomas Phase II, Pilot.

Start Date FY 92	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 Sarcomas	
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the efficacy of primary chemotherapy, wide surgical resection, adjuvant chemotherapy and radiotherapy on local control, metastasis free survival and overall survival. 2) To evaluate the utility of tumor response to primary chemotherapy as an indicator of local and systemic disease control in high grade soft tissue sarcoma. 3) To evaluate the toxicity of primary chemotherapy, surgery, adjuvant chemotherapy and radiation therapy in this patient population.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9124 Status: Ongoing

Title: Evaluation of Edatrexate in Patients with Relapsed or Refractory Germ Cell Tumors.

Start Date FY 92	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 M. Thompson MD
Key Words: Refractory, Germ Cell 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 19 Oct 92 Results Continue

Objective(s): 1) To assess the rate and duration of response to Edatrexate. 2) Evaluate patterns of toxicity (qualitative and quantitative) in patients treated with Edatrexate.Therapy will follow the schema outlined in the protocol.

Technical Approach: This is a new study there is no reportable data available.

Progress:

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9125 Status: Ongoing

Title: A Phase II Trial of CVAD/Verapamil/Quinine for the Treatment of Non-Hodgkin's Lymphoma.

Start Date FY 91	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 19 Oct 92 Results Continue

Objective(s): To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) when administered in combination with chemosensitizers (verapamil and quinine) which are intended to block the emergence of multidrug resistance in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. To assess the toxicities and side effects associated with the CVAD regimen when combined with verapamil and quinine.

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 92 Proj No: SWOG 9127 Status: Completed

Title: A Phase II Evaluation of Cisplatin, Carboplatin, and Etoposide in Selected Stage IV Non-Small Cell Lung Carcinoma.

Start Date FY 91	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, Non-Small Cell Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 19 Oct 92 Results Completed

Objective(s): 1) To assess the survival of patients with non-small cell carcinoma of the lung treated with cisplatin, carboplatin, and etoposide in an every four week schedule. 2) To assess the response rate of this combination in these patients. 3) To investigate the qualitative and quantitative toxicities of this drug combination 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 92 Proj No: SWOG 9134 Status: Ongoing

Title: A Phase II Trial of Taxol and Granulocyte-Colony Stimulating Factor (G-CSF) in Patients with Advanced Soft Tissue Sarcoma

Start Date FY 92	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, Soft Tissue, 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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the clinical response rate of taxol administered with G-CSF in advanced soft tissue sarcomas. 2) To define the qualitative and quantitative toxicities of taxol administered with G-CSF in this patient population.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9135 Status: Ongoing

Title: A Phase II Trial of Taxol and Granulocyte-Colony Stimulating Factor (G-CSF) in Patients with Pancreatic Adenocarcinoma.

Start Date FY 92	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, Pancreatic	
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the clinical response rate of taxol administered with G-CSF in pancreatic adenocarcinoma. 2) To define the qualitative and quantitative toxicities of taxol administered with G-CSF in this patient population.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9139 Status: Ongoing

Title: Adjuvant Therapy of Primary Osteogenic Sarcomas, Phase II.

Start Date FY 92	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, Osteogenic	
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 19 Oct 92 Results Continue

Objective(s): To estimate the time to treatment failure and survival rate of the three drug combination Adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. 2) To evaluate histopathologic tumor necrosis following preoperative Adriamycin, cisplatin, and ifosfamide. 3) To assess the feasibility of determining histopathologic tumor necrosis in a cooperative group setting. 4) To assess the influence of clinical prognostic variables on disease outcome. 5) To assess the toxicity of this regimen.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9150 Status: Ongoing

Title: Evaluation of Topotecan in Gastric Cancer, Phase II

Start Date FY 92	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, Gastric	
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 19 Oct 92 Results Continue

Objective(s): 1) To evaluate the response rate of gastric carcinoma treated with topotecan. 2) To evaluate the qualitative and quantitive toxicities of topotecan administered in a Phase II study.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9151 Status: Ongoing

Title: Evaluation of Topotecan in Hepatoma, Phase II.

Start Date FY 92	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	
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 19 Oct 92 Results Continue

Objective(s):

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 1 Oct 92 Proj No: SWOG 9152 Status: Ongoing

Title: Predicition of Recurrence and Therapy Response in Advanced Germ Cell Tumors by DNA Flow Cytometry.

Start Date FY 92	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:	
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 19 Oct 92 Results Continue

Objective(s): 1) To determine the proliferative activity and presence of aneuploidy within paraffin-embedded histopathologic specimens from patients with advanced disseminated (poor prognosis) GCT. 2) To correlate proliferative activity and aneuploidy with clinical features including response to therapy, relapse-free survival, and overall survival in patients entered on ECOG protocol EST 3887/SWOG 8997/CALGB 8991; Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin plus Etoposide with either Bleomycin or Ifosfamide.

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

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 7799 Status: Ongoing

Title: Rare Tumor Registry for Childhood Sold Tumor Malignancies.

Start date: 25 Sep 81	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allen R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 1
Periodic review date: 9 Jul 90 Review 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: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8104 Status: Completed

Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start date: 27 Jan 83	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allen R. Potter, LTC, MC
Key Words: Neuroblastoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 8
Periodic review date: 9 Jul 90 Review 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 fol
low the schema outlined in the study protocol.

Progress: Three patients remain on the study. Study remains open for followup.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8340 Status: Completed

Title: Allogenic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study.

Start date: 12 Aug 85	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center
Department/Service: Department of Pediatrics	Associate Investigator(s): Walter H. Harvey, MAJ, MC John J. Posch Barbara Reeb
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
Total number of subjects enrolled to date: 22
Periodic review date: 9 Jul 90 Review results: Closed to new entries

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. Disease free survival remains at 30%.

Study replaced by POG 8844. Study remains open for follow-up only.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8398 Status: Terminated

Title: Up-front alternating chemotherapy for Acute Lymphocytic Leukemia in Childhood.

Start date: 12 Jun 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Study has been closed.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: POG 8451	Status: Completed

Title: Intergroup Rhabdomyosarcoma Study III.

Start date: 1 Feb 85	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Study closed to patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8600/01/02 Status: Completed

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: Closed 1990
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Leukemia, Lymphoid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
Total number of subjects enrolled to date: 10
Periodic review date: 9 Apr 93 Review results: Open only for followup

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: This study remains open for followup only.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8616 Status: Completed

Title: Intensive Chemotherapies for Stage III Diffuse Undifferentiated Lymphoma (DU NHL, Burkitt and Non-Burkitt).

Start date: 19 Dec 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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 Cytoxan, 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: Feb 93 Protocol Number: POG 8617 Status: Completed

Title: Therapy of B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas.

Start date: 19 Dec 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 1
Periodic review date: 9 Jul 90 Review 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: Study closed. No followup necessary.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8625/26 Status: Completed

Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA, Hodgkin's Disease in Pediatric Patients.

Start date: 30 Jul 86	Est Comp date: 01 Sep 92
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Hodgkin's	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 3
Periodic review date: 9 Jul 90 Review 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: Study closed except for followup.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: 4 Feb 93 Protocol Number: POG 8650 Status: Ongoing

Title: National Wilms Tumor Study - 4: Stage I/Favorable or Anaplastic Histology.

Start date: 19 Dec 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Wilms tumor	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 3
Periodic review date: 9 Jul 90 Review results: Continue

Objective(s): To gain a better understanding of the Wilms's 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: Study remains open.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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.
5

Start date: 27 Mar 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: 4 Feb 93 Protocol Number: POG 8653/54 Status: Ongoing

Title: A Study of Soft Tissue Sarcomas Other Than Rhabdomyosarcoma and Its Variants.

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Protocol POG 8653 closed. POG 8654 remains open. No new patients entered.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8691 Status: Ongoing

Title: T-Cell #3 Pilot Study.

Start date: 30 Jul 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 3
Periodic review date: 9 Jul 90 Review 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 state T-cell lymphoma.

2) To determine the feasibility of using this chemotherapy regimen as the backbone of a randomized groupwide T-cell study evaluating intensive L-asparaginase therapy.

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

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8704 Status: Completed

Title: T-Cell #3 Protocol - A POG Phase III Study.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review results: _____

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: Study closed. However, two patients are currently being followed.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8710 Status: Completed

Title: Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia (SIMAL #5).

Start date: 29 Jul 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: 9 Jul 90 Review 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 protocol.

Progress: This study has been closed. No new patients entered.

Trial Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8719 Status: Completed

Title: Trial of shortened Therapy without Maintenance for the Treatment of Localized Non-Hodgkin's Lymphoma.

Start date: 25 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Lymphoma, Non-Hodgkin's	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review results: _____

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: Study closed to patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8725 Status: Completed

Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) +/- Low Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIA$_2$, IIIB, and IV Hodgkin's Disease in Pediatric Patients.

Start date: 29 Jul 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 2
Periodic review date: 9 Jul 90 Review results: _____

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: Study closed. Two patients entered on study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8731 Status: Completed

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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review results: 0

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 associated with the use of this agent given in this manner.

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

Progress: Study closed. 0 patients entered.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
Total number of subjects enrolled to date: 2
Periodic review date: 9 Jul 90 Review 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: Study remains open for follow-up.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8743 Status: Ongoing

Title: Treatment in 'Better Risk' Neuroblastoma: POG Stage B (All Ages) and POG Stage C, D, and DS (VS) <365 Days.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, C L, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allan R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: 9 Jul 90 Review 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 being followed with no evidence of disease. Although the study has been closed to new entries, it remains open for follow-up.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8751 Status: Completed

Title: Low Dose Methotrexate in the Treatment of Rhabdomyosarcoma, Phase II.

Start date: 25 Sep 87	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Study closed.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8761 Status: Completed

Title: A Phase II Study of Homoharringtonine for the Treatment of Children with Refractory Non-Lymphoblastic Leukemia.

Start date: 25 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review results: Continue

Objective(s): 1) To evaluate the efficacy of homoharringtoine for the therapy of refractory acute nonlymphoblastic leukemia (ANLL) in children.

2) To assess the toxicity of homoharringtonine in children.

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: Study has been closed to new entries.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8788 Status: Completed

Title: Intergroup Rhabdomyosarcoma Study IV Study for Clinical Group III Disease.

Start date: 13 May 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review results: Continue

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: 4 Feb 93 Protocol Number: POG 8820 Status: Completed

Title: VP-16, AMSA+/l 5 Azacytidine in Refractory ANLL, Phase II/III.

Start date: 13 Mar 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 2
Periodic review date: 9 Jul 90 Review 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 < 21 years of age at the time initial diagnosis who have either failed to respond to induction therapy or who are in first relapse are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients were entered on this study and both died of progressive disease.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8821 Status: Completed

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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
Total number of subjects enrolled to date: 9
Periodic review date: 9 Jul 90 Review 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/Cytoxan 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: Study closed to new patients but will remain open for followup of nine patients previously enrolled.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8823 Status: Ongoing

Title: Recombinant Alpha-Interferon in Childhood Myelogenous Leukemia, Phase II.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed 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 < 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: 4 Feb 93 Protocol Number: POG 8827 Status: Completed

Title: Treatment of Children with Hodgkin's Disease in Relapse, Phase II.

Start date: 17 Oct 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 9 Jul 90 Review results: Continue

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: Study closed to patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8828 Status: Ongoing

Title: Late Effects of Treatment of Hodgkin's Disease, Non-therapeutic Study.

Start date: 12 Jun 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: 9 Jul 90 Review 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 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: 4 Feb 93 Protocol Number: POG 8829 Status: Ongoing

Title: A Case Control Study of Hodgkin's Disease in Childhood - A Nontherapeutic Study.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90 Review results: Continue

Objective(s): To conduct 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: Study remains open for patient entry.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8844 Status: Closed

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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 3
Periodic review date: 9 Jul 90 Review 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 (ABET) 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. All three patients died.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 1
Periodic review date: 9 Jul 90 Review 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 and 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: Study remains open. One patient continues to do well.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ 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 response and toxicities with plasma levels of adenosine deaminase (ADA), adenosine (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.

Technical 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: 4 Feb 93 Protocol Number: POG 8865 Status: Completed

Title: Recombinant Alpha-Interferon in Relapsed T-Cell Disease, Phase II.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review results: Continue

Objective(s): 1) to determine the response rate to α-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: Study closed due to lack of patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8866 Status: Completed

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	Estimated completion date:
Principal Investigator: Terry E. Pick, COl, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: 4 Feb 93 Protocol Number: POG 8889 Status: Completed

Title: Intergroup Rhabdomyosarcoma Study-IV Pilot Study of Clinical Group IV Disease.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Study closed due to lack of patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8930 Status: Ongoing

Title: A Comprehensive Genetic Analysis of Brain Tumors.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry A. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Study remains open for patient entry.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: POG 8935	Status: Ongoing

Title: A Study of the Biological Behavior of Optic Pathway Tumors, Phase II.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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: Study remains open for patient entry.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: 9 Jul 90 Review 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 an if there is evidence of progressive disease. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient entry.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 8945 Status: Completed

Title: An Intergroup Protocol for the Treatment of Childhood Hepatoblastoma and Hepatocellular Carcinoma.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allan R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: _____ 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: No patients have been entered on this study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9000 Status: Ongoing

Title: ALinC 15 Laboratory Classification Protocol for Acute Lymphoblastic Leukemia.

Start date: 17 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allan R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To determine the specific subtype of leukemia in order to plan treatment.

Technical Approach: All eligible patients will undergo bone marrow aspiration followed by specific blood studies as outlined in the study protocol.

Progress: Protocol remains open for classification study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9005 Status: Ongoing

Title: ALinC 15: Dose Intensification of Methotrexate and 6-Mercaptopurine for ALL in Childhood.

Start date: 18 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
Total number of subjects enrolled to date: 3
Periodic review date: _____ Review results: _____

Objective(s): To determine, in a randomized trial, whether intensification with intermediate-dose methotrexate (ID MTX), and intravenous 6-mercaptopurine (IV 6-MP) is superior or inferior to repeated low-dose, oral methotrexate (LDMTX) and IV 6-MP for prevention of relapse in children with ALL in first remission and at lower risk for relapse.

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

Progress: Three patients enrolled on study and doing well.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9006 Status: Ongoing

Title: ALinC 15: Up-Front 6-MP/MTX vs Up-Front Alternating chemotherapy for Acute Lymphocytic Leukemia in Childhood.

Start date: 18 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Terry E. Pick, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Objective(s): To compare, in a randomized trail of children with ALL at higher risk for relapse, the efficacy and toxicity of A: 12 early intensive courses of IV methotrexate (TMX) plus IV 6-mercaptopurine (6-MP) vs B: 12 early intensive courses of alternating intensive chemotherapy combinations (6-MP/MTX), VM-26/Ara-C, vincristine/prednisone/PEG-L-asparaginase/daunomycin/Ara-C.

Technical Approach: Randomization and therapy will follow the schema outlined in the study protocol.

Progress: Patient is doing well.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9031 Status: Ongoing

Title: Treatment of Children with High-Stage Medulloblastoma: Cisplatin/VP-16 Pre- vs Post-Irradiation.

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: _____ 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 (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: One patient on study and doing well.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9046 Status: Ongoing

Title: Molecular Genetic Study of Wilms' Tumor and Nephrogenic Rests.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ 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: No patients have been entered into this study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9047 Status: Ongoing

Title: Neuroblastoma Biology Protocol.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allen R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 1
Periodic review date: _____ 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: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9048 Status: Ongoing

Title: Treatment of Children with Localized Malignant Germ Cell Tumors: A Phase II Study.

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: _____ Review results: _____

Objective(s): 1) To determine whether > 85% of patients with immature teratomas or Stage I malignant testicular germ cell tumors will have long-term event-free survival when treated with surgery alone, and to estimate a time after which disease recurrence for these patients is very unlikely.
2) To determine whether a long-term event-free survival of > 85% can be achieved for children with stage II malignant testicular germ cell tumors and Stage I a 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: Study remains open. No patients enrolled to date.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9049 Status: Ongoing

Title: Study of High-Risk Malignant Germ Cell Tumors in Children.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting eriod: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ 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: No patients have been entered on this study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9060 Status: Ongoing

Title: Intensive QOD Ifosfamide for the Treatment of Recurrent or Progressive CNS Tumors.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 MR or CT documentation of progressive or recurrent disease after therapy of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9061 Status: Ongoing

Title: The Treatment of Isolated Central Nervous System Leukemia.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ 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 parameters 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: No patients have been entered into this study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9072 Status: Ongoing

Title: Ifosfamide, Carboplatin, Etoposide (ICE) Treatment of Recurrent/Resistant Malignant Solid Tumors of Childhood.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the antitumor activity and toxicity of ifosfamide (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 administration of ICE.

Technical Approach: All patients must be < 21 years of age with documented measurable disease, confirmed with appropriate histologic examination, are eligible. 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: Study remains open with 1 patient enrolled.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9107 Status: Ongoing

Title: Infant Leukemia Protocol.

Start date: 18 Mar 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the toxicity associated with one year of intensive post-induction chemotherapy consisting of rotating courses of high-dose Ara-C/DNR, IV 6-MP/MTX, VP-16/Ara-C, vincristine/prednisone/Cytoxan/Ara-C given to patients < 12 months of age with acute lymphatic leukemia in remission.

2) To determine the incidence, severity, and duration of neutropenia, thrombocytopenia, and anemia associated with each of the above courses.

3) To determine other systemic toxicities (infections, nutritional, etc.) associated with this intensive one-year post-induction chemotherapy.

4) To determine the feasibility of using this regimen in a groupwide phase III protocol for patients < 12 months of age with acute lymphatic leukemia.

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

Progress: Study remains open. No patients enrolled to date.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9110 Status: Ongoing

Title: SIMAL #6: Rotational Drug Therapy After 1st Marrow Relapse on Non-T, Non-B Acute Lymphoblastic Leukemia (ALL).

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the feasibility and toxicity of administering continuous infusion doxorubicin when given as a single agent in an "Investigational Window" to patients with ALL in first marrow relapse.

2) To assess the feasibility and toxicity of a rotating weekly parenteral drug regimen for continuing remission of non-T, non-B ALL in children after first histologic relapse.

3) A secondary goal is estimating the leukemic cell kill in patients receiving continuous infusion doxorubicin in an "Investigational Window".

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

Progress: 1 patient entered into study. Study remains open for followup.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9136 Status: Ongoing

Title: Phase I/II Dose Escalating Trail of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood.

Start date: 19 Aug 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the feasibility of using limited volume hyperfractionated radiation therapy to treat children with localized supratentorial malignant gliomas (Group A).

2) To determine the feasibility of using hyperfractionated craniospinal irradiation to treat children with poorly-differentiated supratentorial embryonal tumors (PFETs) or supratentorial malignant gliomas associated with neuraxis dissemination (Group B).

Additional objectives as outlined in the study protocol.

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

Progress: Study remains open. 0 patients entered into study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9139 Status: Ongoing

Title: A Dose-Escalating Study of Cisplatin Used Concomitantly with Hyperfractionated Irradiation in the Treatment of Children with Newly Diagnosed Brain Stem Gliomas.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Terry E. Pick, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the acute and subacute toxicities associated wit the administration of cisplatin by continuous infusion, to be used as a radio-sensitizer given simultaneously with a previously tested hyperfractionated irradiation regimen in children with newly-diagnosed brain stem glioma (BSG).

2) To establish the dose level of infusional cisplatin that results in maximum tolerated toxicity when combined with hyperfractionated radiotherapy to the brain stem.

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

Progress: None. One patient entered into study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9140 Status: Ongoing

Title: Therapy for Recurrent or Refractory Neuroblastoma.

Start date: 25 Feb 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the response rate and toxicity of three different regimens used to treat patients with resistant or recurrent neuroblastoma: a) Treatment 1 - High-dose cisplatin (HDP) with sodium thiosulfate (STS) plus high-dose VP-16 (HDVP); b) Treatment 2 - high-dose cisplatin (HD-CBDCA) with VP-16 (VP); and c) Treatment 3 - ifosfamide (IFOS) and MESNA with carboplatin (CBDCA).

2) To evaluate the efficacy of 13-cis retinoic acid (RA) in prolonging time to progression of disease for patients with resistant or recurrent neuroblastoma who achieve a response following induction chemotherapy.

3) To measure plasma levels of RA attained during therapy and to determine the correlation of these levels with response to treatment and clinical toxicity.

4) To measure retinoic acid nuclear receptors (RARs) in tumor tissue and to determine their significance in predicting response to therapy.

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

Progress: Study remains open. No new patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9170 Status: Ongoing

Title: Ifosfamide, Etoposide and G-CSF in Treatment of Recurrent/Resistant Malignant Sarcomas of Childhood, including Osteosarcoma, Rhabdomyosarcoma, .

Start date: 25 Feb 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To establish the qualitative and quantitative toxicity of Etoposide (VP-16), ifosfamide (IFOS), and G-CSF administered to children whose cancer is refractory to standard therapy. 2) To establish a dose level of Ifosfamide with VP-16 and G-CSF that results in maximum-tolerable toxicity, which is predictable and reversible (MTD). 3) To establish the acute and chronic dose-limiting toxicities (DLT) of the combinations of VP-16, IFOS, and G-CSF with increasing doses of IFOS in children. 4) To determine if there is cumulative toxicity in children after administration of 3 cycles of therapy.

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

Progress: Study ongoing. No new patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9079 Status: Ongoing

Title: Pilot Study, High-Dose Melphalan and Cyclophosphamide with ABM Rescue for Recurrent/Progressive Malignant Brain Tumors

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the acute and delayed toxicities of melphalan and cyclophosphamide followed by ABM rescue in patients with recurrent/progressive brain tumors. 2) To establish the dose level of cyclophosphamide that results in maximum tolerated non-hematologic toxicity, when combined with melphalan. 3) To determine duration of maximum toxicity and time to recovery. 4) To estimate response to therapy, and time to tumor progression.

Technical Approach: Bone marrow harvesting will be carried out as outlined in the study protocol.

Progress: Study continues to remain open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9082 Status: Ongoing

Title: Protocol for the Development of Intervention Strategies to Reduce the Time Between Symptom Onset and Diagnosis of Childhood Cancer

Start date: 16 Dec 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To describe the constellation of signs and symptoms which occur prior to the definitive diagnosis of childhood cancer. 2) To evaluate factors which may be associated with the length of time between the onset of symptoms and diagnosis. 3) To determine if the pattern of symptoms and the length of time between symptom onset and diagnosis influence prognosis independent of treatment and the stage of disease at diagnosis. 4) To provide information which may be used to develop intervention strategies aimed at reducing the interval between onset of symptoms and diagnosis.

Technical Approach: Eligible patients will receive therapy as outlined in the study protocol.

Progress: Study remains open to patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9130 Status: Ongoing

Title: Treatment of Newly-Diagnosed Low Grade Astrocytomas, A Phase III Study

Start date: 27 Jan 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the beneficial effects of irradiation in newly diagnosed low-grade astrocytomas of the brain in childhood. 2) To define the role of surgical resection in newly diagnosed low-grade astrocytomas of the brain in childhood. 3) To determine if adjuvant radiation therapy improves progression-free survival following incomplete surgical resection in children 5-21 years old with newly diagnosed low-grade astrocytomas of the brain. To document the natural history of newly diagnosed low-grade astrocytomas of the brain in patients receiving radical surgical resection as the sole treatment modality. 5) To determine and compare the late effects and neuropsychological sequelae of the various treatments in a large group of children with slow growing brain tumors likely to have long-term progression-free survival or cure.

Technical Approach: All eligible patient will receive treatment as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9193 Status: Ongoing

Title: Autologous Bone Marrow Transplantation for Recurrent/Refractory Non-Hodgkin's Lymphoma

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the therapeutic feasibility and acute toxicity of treatment in patients with recurrent non-Hodgkin's lymphoma receiving high-dose chemotherapy or chemoradiotherapy and rescued with autologous bone marrow transplantation (ABMT). 2) To estimate the survival of patients with recurrent HBL using chemotherapy or chemoradiotherapy followed by ABMT.

Technical Approach: All eligible patients will receive treatment as outlined in the study protocol.

Progress: Study remains open for patient accrual.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9190 Status: Ongoing

Title: Intensive Chemotherapy for Stage III Diffuse Undifferentiated Non-Hodgkin's Lymphoma (Burkitt's and Non-Burkitt's

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: ___ _____ Review results: _____

Objective(s): 1) To evaluate the toxicity of high-dose Ara-C infusion following high-dose methotrexate, in combination with vincristine and fractionated cyclophosphamide. 2) To correlate Ara-C levels in serum and CSF with toxicity observed.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9222 Status: Ongoing

Title: Mitoxantrone, Etoposide and Cyclosporine (MEC) Therapy in Pediatric Patients with Acute Myeloid Leukemia

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the remission rate and toxicity to mitoxantrone, etoposide and cyclosporine. 2) To measure mdr1 and topoisomerase II messenger RNA levels by PCR in myeloid leukemia cells prior to starting therapy. 3) To detect mdr1 p-glycoprotein and function in leukemic blasts.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: POG 9243	Status: Ongoing

Title: Treatment for Children with Intermediate-Risk Neuroblastoma: POG Stage B (All Ages) and Stages C, D, and DS (<365 Days at Diagnosis)

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine and compare the acute and long-term toxicities experienced by patients treated on Arm A with patients who previously received the same treatment without G-CSF on POG #8743. 2) To determine the acute and long-term toxicities asociated with treatment on Arm B. 3) To assess the relationship of specific biological features of neuroblastoma, as determined on POG #9047, to clinical presentation, response to therapy, and survival. 4) To use G-CSF to ameliorate myelosuppression and its associated morbidity, and thus potentially to reduce the cost of therapy. 5) To determine if G-CSF can improve the dose interval, and therafore the dose intensity on Arm A, compared to that achieved on POG #8743. 6) To determine the short and long-term toxicities associated with the use of G-CSF in infants.

Technical Approach: All eligible patients will be enrolled for therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9132 Status: Ongoing

Title: Hyperfractionated Irradiation for Posterior Fossa Ependymoma, A Phase II/III Study

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the feasibility of using hyperfractionated irradiation to the posterior fossa and upper cervical canal to treat newly-diagnosed patients with posterior fossa ependymoma, and to determine the toxicity of this treatment. 2) To evaluate the response of children with incompletely-resected posterior fossa ependymoma to hyperfractionated irradiation. 3) To estimate the disease control interval and pattern of failure of children with posterior fossa ependymoma following treatment with surgery and hyperfractionated irradiation.

Technical Approach: All eligible patients will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9259 Status: Ongoing

Title: Carboplatin in the Treatment of Newly-Diagnosed Metastatic Osteosarcoma or Unresected Osteosarcoma

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To estimate the response rate to carboplatin in patients presenting with newly-diagnosed metastatic or unresectable osteosarcoma prior to treatment with other chemotherapeutic agents.

Technical Approach: All eligible patients with metastatic disease or unresectable osteosarcoma will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: POG 9264 Status: Ongoing

Title: Chemotherapy Regimen for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phae II Study

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To estimate the complete remission rate for initial induction failures in childhood ALL based on an induction regimen of methotrexate and 6-mercapatopurine. 2) To estimate the one-year disease-free survival for initial induction failures in childhood ALL, based on a new regimen. 3) To try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

Technical Approach: All patients less than 21 years of age at time of initial diagnosis with acute lymphoblastic (T or B cell lineage) leukemia will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: POG 9280	Status: Ongoing

Title: Neuroblastoma Epidemiology Protocol

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To evaluate the relationship between environmental exposures and the occurence of neuroblastoma. 2) To evaluate the relative importance of risk factors for neuroblastoma reported in previous epidemiologic studies. 3) To collect information on additional potential risk factors that can be used to develop new hypotheses such as parental smoking, parental radiation exposure, family history of cancer, gestational and delivery history. 4) To determine the relationship between environmental factors and host factors by evaluating subgroups of cases defined by biologic factors and clinical characteristics.

Technical Approach: Study will include majority of cases newly diagnosed in the US and Canada each year who are registered by the two clinical trials groups. Controls will be identified by using random digit dialing procedure. Case and control parents will be interviewed by telephone. Clinical and biologic data will be collected as part of the cooperative group biological and therapeutic protols will be used to define subgroups of patients.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: POG 9225	Status: Ongoing

Title: 1) To evaluate the activity of a new combined modality therapy in advanced-stage Hodgkin's disease (APE/OPPA with integrated "ping pong" low-dose radiotherapy). 2) To decrease late toxicity while maintaining therapeutic efficacy in the treatment of advanced-stage Hodgkin's disease.

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To evaluate the activity of a new combined modality therapy in advanced-stage Hodgkin's disease (APE/OPPA with integrated "ping pong" low dose-radiotherapy. 2) To decrease late toxicity while maintaining therapeutic efficacy in the treatment of advanced-stage Hodgkin's disease.

Technical Approach: Patients less than 21 years of age with histologic proof of Hodgkin's disease will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 20 Status: Completed

Title: A Randomized Comparison of Adriamycin Versus no Further Therapy in Patients with Uterine Sarcoma, Stage I and II.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: David L. Doering, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 3
Periodic review date: _____ Review results: _____

Status: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 25 Status: Completed

Title: A Randomized Comparison of Melphalan vs. Melphalan Therapy Plus Immunotherapy in the Treatment of Women with Stage III Epithelial Carcinoma of the Ovary.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: David L. Doering, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Status: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 26 Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

Start date: Reopened Feb 91	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1 (26 LL)
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Objective(s): This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol.

Progress: This study remains open.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 26-A Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Allan A. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): To evaluate a succession of new agents (cytoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

Technical Approach: The intent of this protocol is to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. Study design will be primarily based on prior GOG experience in the specific disease entities. This will insure consistency in evaluation of response. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: Study remains open for data accrual

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 26-LL Status: Ongoing

Title: A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Advanced Pelvic Malignancies

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): To evaluate a succession of new agents (cytoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

Technical Approach: The intent of this protocol is to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. Study design will be primarily based on prior GOG experience in the specific disease entities. This will insure consistency in evaluation of response. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 41 Status: Completed

Title: Surgical Staging of Ovarian Carcinoma.

Start date: FY 79	Estimated completion date:
Principal Investigator: David R. Doering, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 1
Periodic review date: _____ 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: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 45 Status: Completed

Title: Evaluation of Vinblastine, Bleomycin and Cis-Platinum in Stage III and IV Recurrent Malignant Germ Cell Tumors of the Ovary, Phase II.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetric/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Status: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 52 Status: Completed

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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 1
Periodic review date: _____ Review results: _____

Status: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93	Protocol Number: GOG 72	Status: Completed

Title: Ovarian Tumors in 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	Estimated completion date:
Principal Investigator: David L. Doering, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 undergoing adequate surgical staging no later than 8 weeks following the initial surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed 1992.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 73 Status: Completed

Title: A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 1
Periodic review date: _____ 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.

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: Study closed 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 81F Status: Ongoing

Title: A Phase II Trial of Tamoxifen Citrate in Patients with Advanced or Recurrent Carcinoma Responsive to Progestins

Start date: 16 Dec 91	Estimated completion date:
Principal Investigator:	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine whether patients with endometrial carcinoma who have responded to medroxyprogesterone acetate and then progressed will respond to a second hormonal manipulation in the form of tamoxifen citrate. 2) To evaluate the level of efficacy (response rate) of tamoxifen in patients with advanced or recurrent endometrial carcinoma not previously exposed to hormonal therapy for their malignancy.

Technical Approach: Patients will receive tamoxifen 20 mg p.o. BID and treatment will be continued until there is evidence of disease progression. Patients will be seen at least once monthly for 3 months after initiation of therapy. If disease process is at least stable, subsequent visits may be less frequent but must occur at least every 3 months.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 85 Status: Completed

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	Estimated completion date:
Principal Investigator: Allan F. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 primary, 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: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 87 Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in the Treatment of Recurrent or Advanced Uterine Sarcomas.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): To identify new agents and agent combinations for the treatment of patients with recurrent or advanced metastatic sarcoma.

Technical Approach: Therapy for each phase II drug study will follow the schedule outlined in the study protocol. In addition to the master protocol, the study has been approved for 87F - Doxorubicin and Ifosfamide with Mesna.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To evaluate the role of intraperitoneal chromic phosphate suspension (intraperitoneal ^{32}P) 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: No patients have been entered on this study.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 94 Status: Completed

Title: A Phase II Study of Whole Abdominal Radiation in Stage I and II Papillary Serous Carcinoma.

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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.

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: No patients have been entered on this study.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: 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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
Total number of subjects enrolled to date: 4
Periodic review date: _____ 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: Four patients have been entered into this study.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 102 Status: Ongoing

Title: Master Protocol for Phase II Intraperitoneal Drug Studies in Treatment of Minimal Residual Ovarian Malignancies Documented at Second-Look Surgery.

Start date: 15 Apr 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the activity of various drugs or BRMs alone or in combination when used by the intraperitoneal route in patients who have persistent minimal residual disease epithelial ovarian malignancies after standard therapy.

2) To evaluate further the toxicity, systemic and local, of drugs and BRMs or combinations used in this study.

Technical Approach: Therapy for the following arms will follow the schema outlined in the study protocol: 102F - Alpha Recombinant Interferon (aIFN); 102G - Cisplatin and Thiotepa; and 102H - Interleukin-2; and 102N - Intraperitoneal Recombinant Alpha-2-Interferon.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 104 Status: Completed

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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ 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: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 107 Status: Completed

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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93	Protocol Number: GOG 108	Status: Ongoing

Title: Ifosfamide (NSC#109724) and the Uroprotector Mesna (NSC#113891) With or Without Cisplatin (NSC#119875) in Patients with Advanced, Persistent or Recurrent Mixed Mesodermal Tumors of the Uterus (Phase III)

Start date: 21 Sep 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To confirm reported high response rates of advanced or recurrent mixed mesodermal tumors of the uterus to ifosfamide/Mesna. 2) To determine whether the additiona of Cisplatin to Ifosfamide/Mesna improves response rates or survival in patients with these tumors. 3) To determine the toxicity of Ifosfamide/Mesna with Cisplatin in patients with these tumors.

Technical Approach: Patient will be hydrated prior to institution of therapy with 1000 cc of normal or one-half normal saline at a rate to maintain urine output at greater than 100 cc/hour. Patients randomized to Ifosfamide without platinum therapy will be instituted with bolus of Mesna 120 mgm/m^2 15 minutes prior to the Ifosfamide. Ifosfamide will be administered. After completing the Ifosfamide, the Mesna will be administered by continuous infusion over five days uninterrupted except on subsequent days when Ifosfamide is administered. For patients receiving Cisplatin, platinum administration will precede the Ifosfamide therapy and should be reconstituted to concentration of approximately 1 mgm/cc and infused at a rate of 1 mgm/min.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 17 Mar 93	Protocol Number: GOG 109	Status: Ongoing

Title: A Randomized Comparison of 5-fU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy, Versus Radiation Therapy Alone in Selected Patients with Stages I-A2, I-B, and II-A Carcinoma of the Cervix Following RAdical Hysterectomy and Node Dissection

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine whether the combination of 5-fluorouracil (5-FU) and cisplatin used as an adjunct to radiation therapy will improve survival rate or progression-free survival and decrease extra pelvic failure compared to radiation therapy alone in patients with positive pelvic lymph nodes, positive parametrial involvement or positive surgical margins following radical hysterectomy and lymph node dissection for Stages I-A2, 1-B and II-A carcinoma of the cervix. 2) To determine the increase in toxicities due to 5-FU and cisplatin as an adjunct to radiation therapy versus radiation therapy alone.

Technical Approach: All eligible patients will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 110 Status: Ongoing

Title: A Randomized Comparison of Cisplatin Versus Cisplatin Plus Dibromodulcitol (NSC#104800) Versus Cisplatin Plus Ifosfamide and Mesna in Advanced Carcinoma of the Cervix

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine if mitolactol plus cisplatin or ifosfamide plus cisplatin improves response rate, response duration, progression-free interval and/or survival in advanced squamous cervical cancer compared to cisplatin alone. 2) To compare the toxicity of these three regimens in advanced cervical cancer.

Technical Approach: Patients will be stratified according to whether or not they have had prior cisplatin as a radiation sensitizer and by performance status. Under Regimen I, cisplatin 50 mg/m^2 with hydration will be repeated every three weeks and treatment will continue until disease progresses or until toxicity prohibits further therapy or for a maximum of six courses. Regimen II will include cisplatin plus dibromodulcitol (mitolactoll), DBD) and treatment will continue until toxicity prohibits further or for a maximum of six courses. Regimen III will include cisplatin plus ifosfamide (plus mesna). Cisplatin 50 mg/m^2 with hydration per GOG guideliens plus ifosfamide 5.0 grams/m^2 in 1 liter of dextrose and saline over 24 hrs plus mesna 6 grams/m^2 will be given concurrently with ifosfamide and for 12 hrs after every 3 weeks. Mesna should be given as 2 gm/m^2 in 1 liter of dextrose/saline or normal saline every 12 hours as a separate infusion which can be "piggy-backed" into the intravenous line for the ifosfamide.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 111 Status: Completed

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	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5
Total number of subjects enrolled to date: 5
Periodic review date: _____ 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: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 112 Status: Ongoing

Title: A Randomized Comparison of Chemoprophylaxis Using Methotrexate Versus Routine Surveillance in the Management of the High Risk Molar Pregnancy.

Start date: 15 Apr 91	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
Total number of subjects enrolled to date: 5
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the incidence of post molar trophoblastic disease after evacuation of the high risk molar pregnancy in those patients receiving chemoprophylaxis versus those randomized to usual post evacuation surveillance.

2) To evaluate the toxicity associated with chemoprophylaxis.

3) To develop a clinical pathologic scoring system for risk of postmolar trophoblastic disease which highly correlates with the serum free beta HCG assay.

Technical Approach: As outlined in the study protocol.

Progress: A total of five patients have been enrolled in this study. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 114 Status: Ongoing

Title: A Phase II Randomized Study of Intravenous Cisplatin and Cyclophosphamide Versus Intravenous Cisplatin and Taxol Versus High Dose Intravenous Carboplatin Followed by Intravenous Taxol and Intraperitoneal Cisplatin in Patients with Optimal Stage III Epithelial Ovarian Carcinoma

Start date: Jun 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To compare recurrence-free interval, complete pathologic response, and survival between the standard regimen: intravenous cisplatin/cyclophosfamide and the two experimental regimens: Intravenous cisplatin/taxol and intravenous carboplatin followed by intravenous taxol and intraperitoneal cisplatin in aptients with optimal (< 1 cm residual) stage III epithelial ovarian carcinoma. 2) To compare the toxicities and complications of the three treatment regimens. 3) To correlate serial serum CA-125 levels with negative second look and recurrence-free interval.

Technical Approach: Therapy will be administered as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 115 Status: Completed

Title: Bleomycin, Etoposide and Cisplatin as First Line Therapy of Malignant Tumors of the Ovarian Stroma (Granulosa Cell, Sertoli-Leydig Tumor, and Unclassified Sec Cord Stromal Tumor).

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To assess the efficacy of bleomycin, etoposide (VP-16), and cisplatin (BEP) chemotherapy in patients with malignant tumors of the ovarian stroma of the ovary as a first-line regimen.

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

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 116 Status: Completed

Title: Evaluation of Adjuvant VP-16 and Carboplatin Therapy in Totally Resected Ovarian Dysgerminoma.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To evaluate the effect of adjuvant VP-16 and carboplatin chemotherapy in patients with completely resected ovarian dysgerminoma.

2) To evaluate the acute and chronic toxicity of this chemotherapy on gonadal and reproductive function.

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

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 117 Status: Ongoing

Title: Adjuvant Ilfosfamide and Mesna with Cisplatin in Patients with Completely Resected Stage I or II Mixed Mesodermal Tumors of the Uterus.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine whether cisplatin and ilfosfamide/mesna can determine the recurrence rate in patients with completely resected stage I or II mixed mesodermal tumors of the uterus.

2) To determine whether postoperative chemotherapy is more effective than surgery alone in local (pelvic) control of these tumors.

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

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 118 Status: Ongoing

Title: Evaluation of the Predicted Value of antineoplastic Drug Resistance Determined by in vitro Assay.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): To evaluate the correlation between response to chemotherapy and in vitro drug resistance assessed by two laboratory endpoints (cytostatic and cytocidal) in untreated epithelial ovarian carcinoma.

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

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 119 Status: Ongoing

Title: A Study of the Use of Provera and Nolvadex for the Treatment of Advanced, Recurrent, or Metastatic Endometrial Cancer.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the efficacy of tamoxifen citrate plus intermittent administration of Provera® (Medroxyprogesterone Acetate) in patients with recurrent or metastatic endometrial carcinoma.

2) To determine the side effects of such treatment in patients with this disease.

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

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 12 Mar 93 | Protocol Number: GOG 120 | Status: Ongoing

Title: A Randomized Comparison of Hydroxyurea Versus Hydroxyurea, 5-FU Infusion and Bolus Cisplatin Versus Weekly Cisplatin as Adjunct to Radiation Therapy in Patients with Stages II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes

Start date: 20 Apr 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine whether hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly displatin is superior as a potentiator of radiation therapy in locally advanced cervical carcinoma. 2) To determine the relative toxicities of hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin given concurrently with radiation therapy.

Technical Approach: Patients with untreated cervical carcinoma Stages II-B, III-A, III-B and IV-A, who have fulfilled the eligibility requirements according to Section 3.0 will receive pelvic radiotherapy as outlined and will be randomized according to regimens outlined in study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 121 Status: Ongoing

Title: A Phase II Trial of High Dose Megestron Acetate (Megace) in Advanced or Recurrent Endometrial Carcinoma

Start date: 21 Oct 91	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the response rate and progression-free interval in patients receiving high dose megestrol acetate (Megace) for advanced or recurrent endometrial carcinoma. 2) To determine the toxicity of high dose megestrol acetate in such patients. 3) To determine if estrogen/progesterone receptor status is predictive of response.

Technical Approach: Patients will take orally two tablets at breakfast, two tablets at lunch and one tablet at dinner for a total daily dose of 800 mg. Therapy will continue as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 122 Status: Ongoing

Title: Whole Abdominal Radiotherapy Versus Circadian-Timed Combination Doxorubicin-Cisplatin Chemotherapy in Advanced Endometrial Carcinoma

Start date: 19 Nov 91	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To compare treatment outcomes (survival and progression-free interval) and failure patterns in patients with stages II-IV endometrial carcinoma (< 2 cm residual disease) treated with whole abdominal irradiation versus combination doxorubicin-cisplatin chemotherapy. 2) To determine and compare the incidence and type of acute and late adverse events observed with the two treatment regimens.

Technical Approach: Therapy will be administered as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 123 Status: Ongoing

Title: A Randomized Comparison of Radiation Therapy and Adjuvant Hysterectomy in Patients with Bulky Stage IB Carcinoma of the Cervix, Phase III

Start date: 19 Nov 91	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine if weekly cisplatin infusion improves local regional control and survival when added to radiation therapy plus extrafascial hysterectomy. 2) To determine the relative toxicities of these two treatment arms.

Technical Approach: In this study, we plan to compare the addition of weekly cisplatin infusion with current apparent better arm of Protocol #71; radiation therapy plus adjuvant hysterectomy in patients with bulky Stage IB carcinoma of the cervix.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93	Protocol Number: GOG 125	Status: Ongoing

Title: Extended Field Radiation Therapy with Concomitant 5-FU Infusion and Cisplatin Chemotherapy in Patients with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes, Phase II

Start date: 27 Jan 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): Patients with uterine cervical carcinoma who have biopsy confirmed para-aortic lymph node metastases will receive combination chemotherapy consisting of displatin and 5-FU intravenous infusion concomitantly with pelvic and para-aortic extended field radiation therapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the uterine cervix (squamous, adenosquamous and adenocarcinoma and all clinical stages (except clinical Stage 111A and IVB), with metastasis to para-aortic lymph nodes proven by cytologic or histologic means will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93	Protocol Number: GOG 132	Status: Ongoing

Title: A Phase III Trial of Taxol at Three Dose Levels and G-CSF at Two Dose Levels in Platinum-Resistant Ovarian Carcinoma

Start date: 18 May 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the relative efficacy of regimens consisting of taxol versus cisplatin versus a combination of the two drugs in patients with suboptimally debulked stage III & IV epithelial ovarian cancer. 2) To determine which of the three regimens contribute most favorably to progression-free interval and survival. 3) To compare the incidence of audiologic sequelae and other toxicities arising from any of the three regimens.

Technical Approach: Once patient eligibility is determined, therapy will continue as outlined in study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 134 Status: Ongoing

Title: Evaluation of Drug Sensitivity and Resistance with the ATP-Cell Viability Assay (ATP-CVA)

Start date: 18 May 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine if the dose of taxol affects response rate, progression-free interval or survival in patients with platinum-resistant ovarian cancer. 2) To compare the toxicities of the three regimens. 3) To compare the efficacy and toxicity of two dose levels of G-CSF (5 ug/kg/day versus 10 ug/kg/day) in patients who receive the highest taxol dose (250 mg/m^2). 4) To determine the relationship between peak taxol plasma concentration and toxicity/response.

Technical Approach: Patients with platinum-resistant ovarian epithelial cancer stage III and stage IV will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 135 Status: Ongoing

Title: Evaluation of Drug Sensitivity and Resistance with the ATP-Cell Viability Assay (ATP-CVA)

Start date: 18 May 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To evaluate the correlation between the ATP-cell viability assay (ATP-CVA) and patient response to chemotherapy in untreated primary epithelial ovarian carcinoma. 2) To correlate laboratory results with the achievement of Pathologic CR at time of 2nd look surgery. 3) To correlate laboratory results with progression-free survival. 4) To correlate single agent and combined agent in vitro studies with clinical outcome.

Technical Approach: Patients with primary ovarian epithelial carcinoma who are eligible will receive therapy as outlined in study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 136 Status: Ongoing

Title: Acquisition of Human Ovarian and Other Tissue Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer

Start date: 22 Jun 92	Estimated completion date:
Principal Investigator: LTC Allana R. Meyer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): 1) To accomplish the collection of human ovarian tissue specimens and serum within GOG participating institutions. 2) To provide a repository for long-term storage of ovarian tumor, tissue and serum. 3) To make available through the Cooperative Human Tissue Network (CHTN), tumor tissue and serum for proposed projects conducted by GOG Investigators (internal bank) and by researchers nationally (external bank).

Technical Approach: All eligible patients who have had ovarian tumor tissue removed including all epithelial tumors, germ cell, sex cord stromal and other primary ovarian malignancies will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 138 Status: Ongoing

Title: A Phase II Trial of Cisplatin and Cyclophosphamide in the Treatment of Extraovarian Peritoneal Serous Papillary Carcinoma

Start date: 21 Sep 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: _____ Review results: _____

Objective(s): To determine the response rate, and response duration in patients with extraovarian peritoneal serous papillary carcinoma treated with a combination of cisplatin and cyclophosphamide.

Technical Approach: Once patient has been determined eligible, treatment will initiated as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 8803 Status: Completed

Title: Flow Cytometrically Determined Tumor DNA Content in Advance Epithelial Ovarian Cancer.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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: Study closed March 1993.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 8809 Status: Ongoing

Title: Flow Cytometrically Determined Tumor DNA Content in Ovarian Tumors of Low Malignant Potential.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: David L. Doering, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 2
Periodic review date: _____ 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 study remains open for data accrual.

Detail Summary Sheet

Date: 12 Mar 93 Protocol Number: GOG 8810 Status: Completed

Title: Flow Cytometrically Determined Tumor DNA Content in Endometrial Carcinoma.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ 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 resistant 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 cm^2 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: Study closed March 1993.