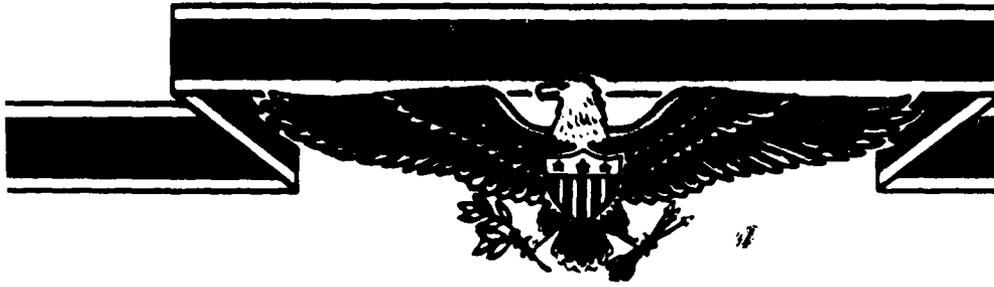


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DEPARTMENT OF CLINICAL INVESTIGATION

**ANNUAL RESEARCH  
PROGRESS REPORT**

**FISCAL YEAR 1988**

**VOLUME 2**

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234



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Detail Summary Sheet

Date: 3 Oct 88	Proj No: A-1-85	Status: Completed
Title: Effects of Secondary Chronic Hypertension on the Hydrodynamics of the Aortic Pulse: A Primate Model.		

Start Date 25 Mar 85	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D. Richard Walsh, M.D. Nico Westerhof, Ph.D.
Key Words: Hypertension	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 18,115.00
Number of Subjects Enrolled During Reporting Period:	n/a
Total Number of Subjects Enrolled to Date:	n/a
Date of Periodic Review	Results

Objective(s): 1) Study the effects of chronic hypertension in a primate population on arterial dynamics compared to age-sex matched controls.

2) Determine specificity and sensitivity of arterial dynamic parameters to assess the resistive and capacitive components of hypertension.

3) Assess the accuracy of in vivo catheterization techniques to predict directly measured central aortic compliance.

4) Evaluate the differences of hydrodynamic variables between in vivo and in vitro states.

Technical Approach: Arterial dynamics in five baboons, hypertensive by kidney clip or wrap (Group II), were compared to five age-sex matched controls (Group I) to investigate whether alterations in systemic hydrodynamics induced by hypertension return to normal with reduction of blood pressure to normotensive levels. Left ventricular pressure, aortic flow velocity, and five simultaneous pressures along the aorta were recorded by multisensor micromanometry. Studies were performed at normotensive, hypotensive (nipride), and hypertensive (phenylephrine) pressure levels. Ventriculography and aortography were performed at each pressure level. Regional pulse wave velocities by foot-foot and apparent phase velocity techniques and reflection coefficients ( ) were determined from area-velocity ratios.

Progress: Results revealed significant changes in compliance in hypertensive animals at all pressures. Data suggests hypertension starts peripherally and works proximal.

Detail Summary Sheet

Date: 3 Oct 88      Proj No: A-1-86      Status: Ongoing  
 Title: Gravitational Effects on Hemodynamics in the Normotensive Primate and Effects of Pressure Suit Inflation

Start Date 26 Mar 86	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D.
Key Words:	Robert Schwartz, MAJ, USAF MC Paul Celio, MAJ, USAF MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 12,425.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

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

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

Technical Approach: As outlined in the study protocol.

Progress: Initial results show total compliance of arterial tree increases when standing but percent in proximal aorta falls. This may be due to lower hydrostatic column in head when upright. There were no change in areas of PWV's.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-4-86                      Status: Terminated  
 Title: Use of Anticoagulated Circuits and Umbilical Vessel Access During Extra-  
 corporeal Membrane Oxygenation of Newborn Baboons.

Start Date 24 Jan 86	Est Comp Date:
Principal Investigator (vice Cornish) Jan Carter, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To show that total heart-lung bypass on an extracorporeal membrane oxygenator circuit can be provided a newborn baboon using the umbilical vein, one umbilical artery, and one external carotid artery for vascular access.

2) To show that a new type of anticoagulant coating, when bound to the plastic of the circuit, will prevent blood from clotting in the circuit but will provide normal clotting characteristics in the animal.

Technical Approach: 2.0 to 3.0 kg baboon infants are submitted to a detailed neurologic exam and then sedated. Cannulae are then placed surgically in the right radial artery (for monitoring blood pressure and blood gases), right femoral artery and right external carotid artery and in the right internal jugular vein. The animal is intubated and placed on a ventilator. Heart-lung bypass is then initiated at 100 ml/kg/min, and the ventilator is changed to CPAP at 8 cm H<sub>2</sub>O with pure nitrogen inflating the lungs. Bypass is continued for 8 hours, then the animal is placed back on conventional ventilator support and taken off ECMO. 44 hours later the animal is sacrificed for histologic studies.

Progress: This study was terminated due to nonavailability of funds for continuation.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-7-86                      Status: Terminated  
 Title: The Meconium Aspiration Syndrome: A Baboon Model of Neonatal Lung Injury

Start Date 6 Aug 86	Est Comp Date:
Principal Investigator J. Devn Cornish, MAJ, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Syndrome, meconium aspiration	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 5188.73
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): Research in the field of Neonatology has focused in large measure on pulmonary injury and recovery during the respiratory distress syndrome and its companion disease bronchopulmonary dysplasia. However, greater understanding of these entities has led to the conclusion that the important research questions to be asked about pulmonary injury and recovery in general are broader than is implied by our concentration on these diseases alone. An animal system which faithfully reproduces the physiologic, biochemical, and histologic consequences of fulminant, reversible neonatal pulmonary disease. Therefore, the objectives of this study are to develop such a model. In doing so, we will: (1) demonstrate that reproducible, severe pulmonary dysfunction can be induced in the neonatal baboon in response to both perinatal asphyxia and meconium aspiration; (2) identify the relative importance of asphyxia and meconium aspiration to the induction of the observed injury; and (3) document the physiologic, biochemical, and histologic nature of the injury and compare these to their human counterparts.

Technical Approach: As outlined in the study protocol.

Progress: Although this study showed great promise, as reported in the FY 87 Annual Research Progress Report, it was terminated due to nonavailability of funds.

Detail Summary Sheet

Date: 4 Oct 88	Proj No: A-9-86	Status: Completed
Title: An Animal Model for Blunt Renal Trauma		

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator Arthur H. Legate, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC John Bauman, MAJ, MC Laurie Gossard, SP4
Key Words: Trauma, renal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To develop a consistently reproducible animal model for blunt renal trauma in the human.

2) To utilize this model to differentiate return of renal function among groups of animals who, after a standardized injury and surgical exploration, undergo different therapeutic surgical procedures.

Technical Approach: A mechanism for the reproducible application of blunt force was designed and constructed. The force required to produce various degrees of trauma to pig kidneys in situ and ex corpus was calibrated. Major unilateral renal lacerations were produced in a series of pigs, half of which were repaired; measures of postoperative recovery were made.

Progress: This study has been completed. The principal investigator has been transferred, and we have been unable to obtain a summary of the results.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-1-87                      Status: Terminated  
 Title: C-Reactive Protein in Irradiated, Bone Marrow Transplanted and Infected Rats

Start Date 19 Nov 86	Est Comp Date:
Principal Investigator Hugh M. Gelston, Jr., MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Sheila Jones, SSG
Key Words: C-reactive protein	Alfonso Clemmings, SP4 Gerald Merrill, DAC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 2240.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the C-reactive protein (an acute phase reactant) levels of lethally irradiated (10 GY - Gamma), bone marrow transplanted (BMT), and BMT and infected rats.

Technical Approach: C-reactive protein (C-RP) will be isolated from rat serum by affinity chromatography using ortho-phosphorylethanolamine-agarose. The C-RP will be purified by HPLC using a size exclusion column. Antiserum to the rat C-RP will be produced by injecting the purified C-RP into New Zealand white rabbits. Each rabbit will receive 3 sets of immunizations and 10.0 ml of blood will be taken from each rabbit 14 days after the final immunization. Anti-C-RP antibodies will be purified by affinity chromatography. These antibodies will be used to quantify the C-RP levels of stored serum samples by radial immunodiffusion. The total protein levels of the same serum samples will be determined using the BCA protein assay. The data obtained will be analyzed using ANOVA to compare the mean values obtained for each point among the various control and experimental groups.

Progress: The rat C-RP has been isolated and purified. The five rabbits were immunized. Sufficient antisera was determined and serum samples were obtained. Assays for C-RP and total program were started; however, the principal investigator PCS'd in July and the study was terminated.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-3-87                      Status: Ongoing  
 Title: Treatment of Chlorine Gas Inhalation Injury with Nebulized Sodium Bicarbonate Using a Sheep Model

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

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

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

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

Progress: Phase II has been completed; data analysis in progress.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: A-4-87	Status: Completed
Title: Renal Preservation Following Severe Ischemia with Prophylactic Calcium Dchannel Blockers		

Start Date 2 Apr 87	Est Comp Date:
Principal Investigator William H. Boykin, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC Marlene Gaines, SGT Laurie Gossard, SP4
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 577.50
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To ascertain if the calcium channel blocker verapamil can prevent renal ischemic damage in the rat model.

Technical Approach: Fifty male Sprague-Dawley rats will be obtained, housed, and fed lab chow and tap water ad lib. Baseline creatinine clearance will be calculated from a 24 hour urine specimen and serum obtained from a tail vein. 48 hours later, the animals will be anesthetized with intraperitoneal pentobarbital. Once adequate anesthesia has been obtained, the animals will be restrained on a rat board and a midline surgical incision made. In accordance with a randomized schedule, each animal will receive inter an intracaval bolus of verapamil or placebo. After 15 minutes to allow drug dispersion, the right renal artery will be encircled and occluded. Next a left nephrectomy will be performed. Occlusion of the right renal artery will be maintained for 60 minutes, observing the kidney for signs of obvious ischemia. Postoperatively the animals will be allowed to resume unrestricted po intake. Creatinine clearances will be recalculated from 24 hour urine specimens and tail vein blood samples as previously described on the 2nd and 14th postoperative days.

Progress: This study has been completed. Verapamil seems to have a quite marginal effect on renal function in the ischemic kidney.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-5-87                      Status: Ongoing  
 Title: The Effect of Dietary Fiber on the Incidence of Adenocarcinoma Following Ureterosigmoidostomy in Rats

Start Date 2 Apr 87	Est Comp Date:
Principal Investigator William H. Boykin, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC Gene B. Hubbard, D.V.M. Marlene Gaines, SGT Laurie Gossard, SP4
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,781.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if alteration in dietary fiber content decreases the incidence of adenocarcinoma following ureterosigmoidostomy in an animal model.

Technical Approach: One hundred twenty male Sprague-Dawley rats will be obtained, housed and fed standard lab chow and tap water ad lib. On the night before the surgical procedure, all animals will be kept NPO. All animals will undergo ureterosigmoidostomy and then randomized into two treatment arms: one group will be recovered/fed lab chow with a higher fiber content, and the other will receive a diet high in protein and carbohydrates but with minimal fiber. The remainder of the study will be conducted as outlined in the study protocol.

Progress: This study was placed on hold for approximately one year. Four animals are long-term survivors with ureterosigmoidostomy at over one year from surgery - the longest reported to date.

Detail Summary Sheet

Date: 3 Oct 88                      Proj No: A-6-87                      Status: Terminated  
 Title: Hemodynamic Effects of the Palmaz Stent in the Aorta and Coronary Arteries of the Adult Dog (Collaborative Study with the University of Texas Health Science Center)

Start Date 13 May 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Richard A. Schatz, M.D. Julio Palmaz, M.D., UTHSC Ares Pasipoularides, M.D., Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To describe and define the global and regional effects of placing a balloon expandable intravascular stent in the canine aorta or a proximal epicardial coronary artery.

Technical Approach: After the animals are sufficiently sedated and anesthetized, a cut-down will be performed on the right femoral artery and the right carotid artery. Through the right carotid artery, a custom-designed high fidelity catheter mounted with two micromanometric transducers and an electromagnetic flow velocity probe with a proximal transducer housing will be advanced into the carotid artery. This catheter will be positioned with fluoroscopic guidance such that the distal tip of the catheter will be in the left ventricular cavity and the proximal sensor will be at the level of the aortic valve. Through the right femoral artery, a multisensor catheter will be introduced and advanced with fluoroscopic guidance to the level such that the tip is at the arch of the aorta. The catheter will be positioned such that the stent is located midway between two of the pressure transducers. The remainder of the study will be conducted as outlined in the protocol.

Progress: This phase of the study has been completed by Dr. Palmaz. The stent is now available for human implantation.

Detail Summary Sheet

Date: 10 Nov 88 Proj No: A-7-87 Status: Ongoing  
 Title: Urodynamic Profile of Three Types of Urinary Reservoirs

Start Date 28 May 87	Est Comp Date:
Principal Investigator William H. Boykin, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators: Ian M. Thompson, MAJ, MC William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To develop an animal model for three basic types of enteral urinary reservoirs.

2) To objectively document with urodynamics the pressure characteristics of the different reservoirs.

Technical Approach: This study will be conducted at the Clinical Investigation Facility, Wilford Hall USAF Medical Center. Fifteen pigs will be randomized into three treatment groups. One group will undergo isoperistaltic/antiperistaltic anastomosis of two segments of ileum, the second group will undergo a similar procedure utilizing large bowel, and the third group will have a reservoir fashioned from a combination of large and small bowel. The technical details will be carried out as outlined in the study protocol.

Progress: This study has not been started due to logistic difficulties of getting the investigators to the Clinical Investigation Facility at Wilford Hall USAF Hospital. Will attempt to start in the near future.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-8-87                      Status: Completed  
 Title: Effect of Hyperbaric Oxygen Therapy on Snake Bit Envenomation of Rabbits

Start Date 15 Jun 87	Est Comp Date:
Principal Investigator Michael R. Stolpe, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Carey D. Chisholm, MAJ, MC Robert N. Norris, CPT, MC Michael F Hartshorne, MAJ, MC William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effect of hyperbaric oxygen therapy in an envenomated animal model as an augmentation to antivenin therapy.

Technical Approach: Twenty-nine medium-sized female New Zealand white rabbits were injected intramuscularly, in the anterior compartment of the right hind leg with a sublethal dose of Crotalus atrox venom. An equal amount of normal saline was injected into the anterior compartment of the left hind leg. The first group (ten rabbits) received one vial of antivenin intravenously. The second group (ten rabbits) received one vial of antivenin intravenously plus three HBO treatments. The three HBO treatments consisted of 90 minute dives in 98% oxygen at 2.4 atmospheres at two hours, eight hours, and twenty-four hours post-injection. The third group (nine rabbits) received no treatments. Forty-eight hours after venom injection, all rabbits received 500 microcuries of Tc99 stannous pyrophosphate intravenously. Three hours later the rabbits were euthanized with an overdose of sodium pentobarbital and were scanned with a standard gamma counter. The vastus lateralis and rectus femoris muscles of both hind legs were harvested, weighed, and stored separately for histologic examination. The lungs were also harvested for histologic examination to assess for possible oxygen toxicity. The ratios of Tc99 pyrophosphate uptake and muscle weight were derived between the control left and venom-injected right muscles for all three treatment groups.

Progress: There was no statistically significant difference between any of the groups in terms of parameters. Histologic examination confirmed this lack of

A-8-87 (continued)

difference between the groups, with all three demonstrating severe muscle necrosis. There was no evidence of oxygen toxicity by histologic examination of the lungs. We conclude that muscle necrosis secondary to Crotalus atrox venom poisoning is not significantly altered either by Antivenin (Crotalidae) Polyvalent in the dose used alone or in combination with intermittent HBO treatments in the rabbit model.

Detail Summary Sheet

Date: 30 Jun 88                      Proj No: A-10-87                      Status: Terminated  
 Title: A Pilot Study on Evaluating the Amount of Structural Changes to Porcine Bone with Drilling

Start Date 29 Jul 87	Est Comp Date:
Principal Investigator Seth M. Silver, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Robert B. Nett Theophilus Peace, COL, VC David L. Danley, MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the effects of stainless steel cobalt chromium, smooth shank, trocar tip and variable fluted drill bits on bone.

Technical Approach: Pig femurs will be obtained within one hour of sacrifice as a result of other studies. Each femur will be drilled in a standardized fashion using the equipment outlined in the protocol. Five drill holes will be made in each specimen using the jig and different bits at constant speed. The drilled bone will then be fixed sectioned and analyzed as follows: Each hole is divided into eight sections - four from the outer cortex and four from the inner cortex. The pathologist, being unaware of which bit cut each hole, will evaluate the extent of bone destruction using a microscope and stage micrometer.

Progress: All of the necessary equipment was obtained. On 1 Dec 87, five pig femurs were drilled with five holes in each. These were labelled and sent Dr. Nett for decalcification and subsequent sectioning. Subsequently, Dr. Nett was transferred, and we were unable to find someone to complete the work. Therefore, the study was terminated.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-11-87                      Status: Completed  
 Title: Removal of Common Toxins from the Blood by Continuous Arteriovenous Hemofiltration (CAVH)

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator Joseph P. Ducey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery	Associate Investigators: John F. Reilly, Jr., CPT, USAF MC
Key Words: Toxins	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 8,174.25
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To assess the feasibility of CAVH in removing certain drugs/toxins from the circulatory system and from the body.

b) To establish a swine model for drug removal using CAVH.

Technical Approach: Swine were randomized either to receive CAVH (n = 3; Group A) or not to receive CAVH (n = 3, Group b) over a four hour period following an intravenous infusion of 0.5 ml/kg of methanol. Each animal was monitored with an arterial line, EKG and rectal probe. An Amicon Diafilter® - 20 hemofilter was used in the study group.

Progress: Those swine that underwent CAVH demonstrated a significantly greater four hour clearance of methanol compared to their controls (P < .001). 13.5 +/- 3.4% of the administered methanol was cleared after four hours in Group A, compared with 2.5 +/- .5% in Group B (P < .005). Also, in Group A, the greatest part of methanol and formate was cleared in the ultrafiltrate, with renal clearance contributing less than five per cent (P < .001 and P < .05, respectively). CAVH may be an important therapeutic intervention in the early hours following methanol intoxication. This is especially relevant in smaller facilities which do not have dialysis capabilities.

Detail Summary Sheet

Date: 10 Nov 88 Proj No: A-12-87 Status: Ongoing  
 Title: Hemodynamic Effects of Anesthetic Induction with Ketamine or Etomidate in Hypovolemic Swine

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator (vice Knight) Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Hypovolemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1166.73
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

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

Technical Approach: Eighteen swine were anesthetized with halothane in oxygen and intubated. After placement of arterial and pulmonary artery catheters, a midline sternotomy was performed. An umbilical ligature was placed around the inferior vena cava to vary preload during determination of the left ventricular end-systolic pressure-diameter relationship. One pair of internal diameter ultrasonic transducer crystals was implanted at the endocardial surface for measurement of anteroposterior left ventricular diameter and a 20 g catheter was placed transmurally to measure left ventricular pressure. End-systolic elastance (ES) was measured 20 msec prior to peak negative dp/dt. Halothane was continued and 70% nitrous oxide added for analgesia. Muscle relaxation was achieved with vecuronium. Mechanical ventilation maintained the PaCO<sub>2</sub> at 35 ± 10 mmHg and PaO<sub>2</sub> at 129 ± 32 mmHg. Body temperature was maintained at 36.3 ± 0.9°C. When end-tidal halothane was less than 0.1%, baseline measurements were obtained and ketamine or etomidate was given as a bolus. Hemodynamic measurements were then made at 1, 5, 15, and 30 min.

Progress: In these normovolemic swine, acutely instrumented and ventilated with 70% nitrous oxide, both ketamine and etomidate produced significant depression of CO but did so by different mechanisms. Ketamine acted primarily by depressing myocardial contractility and increasing systemic vascular resistance (SVR). Etomidate had no effect on myocardial contractility but increased SVR and

A-12-87 (continued)

pulmonary vascular resistance (PVR) while decreasing HR. MAP was maintained in each group. Maintenance of adequate perfusion pressure to vital organs is of prime importance when anesthetizing the trauma patient. Transient decreases in cardiac output are undesirable in this situation but may be acceptable if cerebral and myocardial perfusion are maintained.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: A-13-87	Status: Ongoing
Title: A Comparison of the Effects of Resuscitation from Hemorrhagic Shock with Normal Saline, Hewtastarch, Whole Blood, and Hypertonic Saline on Intracranial Pressure, Intracranial Compliance and Cerebral Metabolism		
Start Date 28 Sep 87	Est Comp Date:	
Principal Investigator Joseph P. Ducey, MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Surgery	Associate Investigators: David W. Mazingo, CPT, MC Marlene Gaines, SGT Theopolis Peace, COL, VC	
Key Words: Shock, hemorrhagic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1532.00	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review _____		Results _____

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

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

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

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

Solutions of 6% NaCl (HS), 0.9% NaCl (NS), 6% hetastarch (HE), and whole blood (WB) were used to resuscitate swine in severe hemorrhagic shock. The end point of resuscitation was normal oxygen delivery (DO<sub>2</sub>), cardiac index (CI) and pulmonary artery occlusion pressure (PAOP). Measurements of intracranial pressure (ICP), cerebral perfusion pressure (CPP), and intracranial elastance (ICE) were made in the absence and presence of an epidural mass, created by inflating an epidural balloon.

A-13-87 (Continued)

Equal volumes of HS, HE, and WB were required to maintain acceptable hemodynamic parameters. Greater than three times this amount was required when NS was used. HS resulted in a lower ICP, and normalization of CPP throughout resuscitation. HE, WB, and NS infusion raised ICP above baseline and NS decreased CPP by the end of resuscitation. ICP fell markedly in the HS group. This improvement was even more dramatic in the presence of an epidural mass. No significant histopathologic abnormalities were detected in the brains in any group.

In hemorrhagic shock accompanied by severe head injury, full resuscitation with hypertonic saline, while not offering a significant hemodynamic advantage, may offer benefits not afforded by whole blood, normal saline or 6% hetastarch by decreasing ICP and diminishing the effects of an expanding mass on ICP.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-14-87                      Status: Completed  
 Title: The Effect of the Pneumatic Antishock Garment (PASG) on Systemic Acidosis and Lactic Acid Levels in a Primate Model

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator Brenda A. Gowsky, CPT, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Carey D. Chisholm, MAJ, MC James R. Cooper, MAJ, USAF
Key Words: Pneumatic Antishock Garment	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2336.42
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine the effects of the PASG on arterial pH using the hemorrhagic shock and non-shock baboon model.

2) To evaluate lactic acid levels secondary to PASG utilization in the hemorrhagic shock and non-hemorrhagic shock model.

Technical Approach: We utilized 10 adult, male baboons, species papio anubis with a mean weight of 26.1 kg. The study was carried out in two phases separed by a 5 week recovery period to allow equilibration. Each baboon was sedated with ketamine IM and anesthetized with pentobarbital over the study period. Each baboon was intubated and allowed to breath room air. Cenbtral venous and femoral arterial lines were placed, and hemorrhagic shock induced. Blood was sampled for lactate, arterial pH, serum bicarbonate, serum chloride, arterial CO<sub>2</sub>, and arterial O<sub>2</sub>. Blood samples were taken at baseline and post-hypovolemia prior to inflation of the PASG. The PASG was inflated to 100 mmHg pressure at time 0 in Phase 1. This pressure was maintained for 17 minutes and then the PASG was rapidly deflated. A blood sampe was taken at 5 minutes post-deflation and prior to volume expansion. After the experiment, each animal was reinfused with his own stored blood with an equal volume of Ringer's lactae for resuscitation. Phase 2 was accomplished five weeks later in the same manner but without the application of PASG.

Progress: There was a significant increase in central venous lactate levels with the use of the PASG in the baboon hemorrhagic shock model. We also demonstrated statistically significant decreases in serum bicarbonate and serum chloride 5 minutes post-deflation of the PASG. We postulate that this decrease in chloride and bicarbonate is a compensatory mechanism for the metabolic acidosis seen with

significant release of lactate into the central circulation with deflation of the PASG. Because of our sampling times, we were not able to demonstrate this elevation in lactate either prior to our 5 minute sample or in the washout period when the baboons were retransfused and resuscitated with an equal volume of fluid. We did, however, make an interesting observation. We noted that the baboons in Phase 1 of the study took 2 to 3 days to recover from their ordeal compared to baboons in Phase 2 who were back to their normal behavioral patterns, sitting up and feeding in 4 to 6 hours. It is felt that this difference in recovery of the baboons in Phase 1 compared to those in Phase 2 may also be due to accumulation of lactate in the central circulation.

Conclusion: The use of PASG in the hypovolemic non-human primate model resulted in statistically significant increases in central venous lactate levels with decreases in  $p\text{CO}_2$ , chloride, and  $p\text{O}_2$ . Statistically significant increases in serum bicarbonate were also noted. We feel that the sudden decrease in bicarbonate may denote release of lactate into the central circulation, and this warrants further study. This theory is substantiated by the sharp decline in chloride observed upon deflation of the PASG.

Although the clinical significance of these changes remains unclear, the prolonged time period to recovery when the PASG was utilized suggests further studies should be conducted examining a potential relationship between the PASG and clinically significant lactic acidosis in the setting of hemorrhagic shock. More frequent sampling in the immediate post deflation period and during the wash out phase during reperfusion will provide more data on which to base therapeutic interventions.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: A-1-88	Status: Ongoing
Title: The Effect of Lysine on Substance P in Guinea Pigs		

Start Date 2 Dec 88	Est Comp Date:
Principal Investigator Eleanor Ayala	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1170.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

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

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

Progress: Nine animals (four L-lysine treated, two SP treated, one CAP treated, and two untreated) have been used in the study. Only one animal received CAP because the chemical was recalled by Sigma after they discovered it contained 50% pseudo-capsaicin. Although the sites did wheal and flare and dissipate within 30 minutes when the animals were given cutaneous injections of SP or CAP, the animals did not scratch, bite, or rub the injected sites. Approximately 100 sections were cut from each of the 56 DRGs and ten tissue biopsies collected from each animal. For some DRGs, the numbers of SP stained cells per section have

A-1-88 (continued)

varied as little as 100 cells; however, for others, the numbers increase by as much as 300-500 as deeper sections are cut. For this reason, many sections have had to be counted. Similar results have been obtained from the DRGs of lysine treated and the untreated animals. The DRGs of the SP and CAP treated animals have contained few SP stained cells. Preliminary results may indicate that the l-lysine has not affected the concentration of production of SP, but its possible effect on the functional activity of SP has not been ruled out.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-2-88                      Status: Terminated  
 Title: Comparison of the Effects of Propranolol and Labetalol in the Treatment  
 of Cocaine Induced Hypertension in a Canine Model

Start Date 25 Feb 88	Est Comp Date:
Principal Investigator Boris Berejan, CPT, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Carey Chisholm, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the effects of propranolol and labetalol on hypertension caused by injection of cocaine.

Technical Approach: As outlined in the study protocol.

Progress: This study was approved and was to have been done at the Clinical Investigation Facility, Wilford Hall USAF Medical Center. However, approval was obtained too late for the principal investigator to finish prior to completion of his residency training.

Detail Summary Sheet

Date: 10 Nov 88 Proj No: A-3-88 Status: Ongoing  
 Title: Evaluation of Uncemented Canine Hip Prosthesis

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

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

Technical Approach: As outlined in the Company protocol.

Progress: Richards Medical Company is currently making the prostheses for the dogs. They should be ready in the near future.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: A-4-88	Status: Ongoing
Title: A Conscious Baboon ( <u>Papio anubis</u> ) Model to Study Ventricular Pressure-Volume Relations and Ventricular/Vascular Coupling in Altered Gravitational Environments.		

Start Date 14 Apr 88	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: James R. Hickman, COL, USAF MC Carter Alexander, Ph.D. Paul Celio, M.D.
Key Words:	

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

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

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

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

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

Progress: Pressure suits (2), pulsator, driver, and computer have arrived. Awaiting AFOSR funding and animals to be shipped from Wright Patterson AFB, Ohio.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: A-5-88                      Status: Ongoing  
 Title: Use of a Swine Model for Evaluation and Training with the OHMEDA PAC Vaporizer (Draw-over Anesthesia Device)

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

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

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

Technical Approach: Swine are randomized to receive halothane, isoflurane, or ethrane using a PAC vaporizer. Anesthetic is provided in increasing concentration with end tidal oxygen, carbon dioxide, and agent concentration recorded at each level. Pulse oximetry and respiratory volumes are monitored, and arterial blood samples are analyzed.

Progress: Six pigs have been studied. The device appears to function well. No complications have been noted.

Detail Summary Sheet

Date: 30 Sep 88	Proj No: A-6-88	Status: Ongoing
Title: Use of a Swine Model for Evaluation and Training with the PENLON Vaporizer (Draw-over Anesthesia Device)		

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

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

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

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

Progress: None. Awaiting completion of A-5-88.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: A-7-88	Status: Ongoing
Title: Evaluation of Chemexfoliation on Surgical Skin Flaps		

Start Date 9 May 88	Est Comp Date:
Principal Investigator David D. Hayes, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kweon I. Stambaugh, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the effect of simultaneous chemexfoliation on the viability of a broad-based skin flap.

Technical Approach: Each of the guinea pigs has had a broad-based random skin flap created. Half had only the flap and half had both the flap as well as chemexfoliation. The animals were anesthetized and punch biopsies taken at regular intervals.

Progress: Clinical phase of the project has been completed. Data have shown that there was a significant detrimental effect on the pegged flaps. Pathological compilation of data is still pending.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: A-8-88	Status: Ongoing
Title: Magnesium and Calcium Interaction in the Rat Cardiovascular System		

Start Date 1 Sep 88	Est Comp Date:
Principal Investigator John A. Ward, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Linda Koehler, MA, MT Gene V. Hubbard, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effect of the Ca/Mg ratio in magnesium deficiency on the function of vascular smooth muscle, contraction will be studied by measuring tension vs. Ca<sup>++</sup> curves for the abdominal aorta in five groups of rats: 1) magnesium sufficient, 2) magnesium deficient, 3) magnesium deficient, calcium excess, 4) magnesium deficient, calcium deficient, and 5) lab chow.

To determine the effect of Ca/Mg ratio in magnesium deficiency on the hemodynamics of an isolated vascular bed. Hemodynamic alterations will be studied by measuring pressure-flow vs. Ca<sup>++</sup> curves in five groups of rats as above.

Technical Approach: All animal studies will be conducted at Incarnate Word College Division of Nursing and the Sciences. All procedures will be done as outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-4-82                      Status: Ongoing  
 Title: Neonatal Chest Tube Insertion Utilizing Rabbit Model

Start Date 19 May 83	Est Comp Date:
Principal Investigator (vice Parry) Richard T. Takao, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To allow practice in recognition and prompt appropriate response to a neonate with life-threatening pneumothorax.

Technical Approach: Following demonstration of chest tube insertion by the instructor, subsequent practice is carried out by the students. Insertion of appropriate sized chest tubes is carried out after the instructor has discussed methods, sites and complications of chest tube insertion.

A new protocol is being prepared and will be submitted in the near future.

Progress: Training of pediatric residents continues.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: T-5-82	Status: Ongoing
Title: Kitten Intubation Laboratory		

Start Date 23 Jun 82	Est Comp Date:
Principal Investigator (vice Parry) Richard T. Takao, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To allow all persons delivering health care to newborn infants to become familiar with intubation techniques.

Technical Approach: Intubation technique is demonstrated and supervised by the instructor as outlined in the training protocol.

This study is being revised and will be submitted in the near future.

Progress: This continues to be an effective method of teaching intubation techniques.

Detail Summary Sheet

Date: 10 Nov 88      Proj No: T-2-85      Status: Ongoing  
 Title: Utilization of Goats for Training Special Forces Aidman

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator (vice Gregg) Michael D. Matthews, CPT, MC	Facility Special Forces School, Fort Bragg, NC
Dept/Svc Department of	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 8 Feb 88      Results Continue	

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

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

Progress: Training continues.

Detail Summary Sheet

Date: 10 Nov 88 Proj No: T-3-86 Status: Ongoing  
 Title: Urologic Microsurgery - A Training Protocol

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator (vice Thompson) Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: John Norbeck, CPT, MC Francisco R. Rodriguez, COL, MC Theopolis Peace, COL, VC Marlene Gaines, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

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

Technical Approach: In the first phase, the trainee will learn basic suturing techniques using the operating microscope and a cut rubber glove to imitate tissue. The second phase will teach the techniques of microscopic reanastomosis of the vas deferens. The third phase will teach the technique of microvascular anastomosis.

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

Detail Summary Sheet

Date: 10 Nov 88      Proj No: 1-7-86      Status: Ongoing  
 Title: Meuse Inoculation Test (MI) - Rabies Diagnosis

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

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

Technical Approach: As outlined in the training protocol.

Progress: Approximately 1,000 mice are utilized annually for the MI test.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-8-86                      Status: Ongoing  
 Title: Production of Positive and Negative Controls for Rabies FA Test

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

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

Technical Approach: As outlined in the training protocol.

Progress: Approximately 50 mice are utilized annually for preparing rabies infected and uninfected mouse brain tissue slide impressions.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-9-86                      Status: Ongoing  
 Title: Orthopaedic Microsurgery - A Training Protocol

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 66.30
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

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 microneurorrhaphy, and the four phase will teach the technique of free tissue transfer using microvascular anastomoses.

Progress: Fifteen residents have been trained in the various phases.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: T-10-86	Status: Ongoing
Title: Supervised Basic Abdominal and Vascular Surgical Experience		

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator (vice Rosenthal) Michael J. Walters, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Robert Solenberger, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 910.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

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

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

Progress: Training of 13 residents is conducted bi-monthly.

Detail Summary Sheet

Date: 11 Nov 88                      Proj No: T-11-86                      Status: Ongoing  
 Title: Microsurgery Training Protocol for Plastic Surgery Staff, Residents and Rotators.

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

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

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

Progress: Training continues on a regularly scheduled basis.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: T-12-86	Status: Ongoing
Title: Urology Surgical Training Protocol		

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Francisco R. Rodriguez, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC Eric S. Zeidman, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,750.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To improve the technical skills of Urology Service residents in performing procedures essential to the specialty of Urology.

Technical Approach: As outlined in the training protocol.

Progress: Training of four urology residents is conducted bi-monthly.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: T-13-86	Status: Ongoing
Title: Swine Model for Technical Procedure Training of Emergency Medicine Residents		

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Carey D. Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 2,450.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

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: Twenty-six residents have received training in frequently used emergency procedures.

Detail Summary Sheet

Date: 10 Nov 88 Proj No: T-14-86 Status: Ongoing  
 Title: Cardiothoracic Surgery Service Porcine Surgery

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator Robert A. Helsel, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Brent A. Grishkin, COL, MC Richard M. Briggs, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 420.00
Number of Subjects Enrolled During Reporting Period:	_____
Total Number of Subjects Enrolled to Date:	_____
Date of Periodic Review _____	Results _____

Objective(s): 1) To provide operative experience for cardiothoracic and rotating general surgery residents in procedures not generally available in clinical settings.

- 2) To provide practical experience prior to initial human clinical experience.
- 3) To provide experience for clinical perfusion trainee.

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

Progress: Three training sessions were conducted during the year.

Detail Summary Sheet

Date: 10 Nov 88		Proj No: T-1-87		Status: Ongoing	
Title: Military Working Dogs utilization in teaching first aid, bandaging, gastric tube passage and subcutaneous injections of medications to kennel masters					
Start Date 19 Nov 86			Est Comp Date:		
Principal Investigator George E. Moore, CPT, VC			Facility Academy of Health Sciences		
Dept/Svc Department of Medicine			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: _____					
Total Number of Subjects Enrolled to Date: _____					
Date of Periodic Review _____				Results _____	

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

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

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

Detail Summary Sheet

Date: 3 Oct 88                      Proj No: T-2-87                      Status: Ongoing  
 Title: Anesthesiology for ANC Officers Course (6F-66F)

Start Date 6 Feb 87	Est Comp Date:
Principal Investigator (vice Keeler) Gary Zarr, MAJ, AN	Facility Academy of Health Sciences
Dept/Svc Department of Nursing	Associate Investigators: John Pennycook, MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

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

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

Progress: Thirty-six students were trained during FY 88.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-3-87                      Status: Ongoing  
 Title: Abdominal Surgical Experience - Gynecology Service

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

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

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

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

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-4-87                      Status: Ongoing  
 Title: Canine Utilization for Rigid Endoscopic Training

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Wittich) Jesse Moss, Jr., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

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

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

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

Technical Approach: Training conducted as outlined in the protocol.

Progress: Eighteen residents attended the course. This course was well received by both the residents and staff. It has immeasurable benefits in that proper training in endoscopy surgery prevents the dreaded possible complication of a ruptured esophagus or bronchus and CO<sub>2</sub> laser complication.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-5-87                      Status: Ongoing  
 Title: Utilization of Goats for Training of DOD Medical Department Officers for  
 the Combat Casualty Care Course (C-4).

Start Date 13 May 87	Est Comp Date:
Principal Investigator Kenneth Pasch, CPT, MS	Facility Academy of Health Sciences
Dept/Svc Training Division, C-4 Task Force	Associate Investigators: John Sheffield, John, SSG Rick Somers, LTC, VC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 20 Mar 87                      Results Replaced by T-5-87	

Objective(s): To provide training in trauma resuscitation.

Technical Approach: Students are trained to do procedures such as cri-  
 cothyroidotomy, tracheotomy, tube thoracostomy, cardiac repair, aortic cross  
 clamping, venous cutdown, peritoneal lavage, etc. as outlined in the training  
 protocol.

Progress: During FY 88, 2,380 officers have completed this course.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-6-87                      Status: Ongoing  
 Title: Utilization of Goats for the Training of Physicians and Physician Assistants in the Advanced Trauma Life Support Instructor Course and Warrant Officer Candidates in the Military Physician Assistant (PA) Course

Start Date 13 May 87	Est Comp Date:
Principal Investigator David W. Robert, COL	Facility Academy of Health Sciences
Dept/Svc Medicine and Surgery Division	Associate Investigators: Richard J. Lowney, CW3
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

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

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

Progress: During FY 88, 39 PA students were trained and 16 ATLS instructors.

Detail Summary Sheet

Date: 10 Nov 88                      Proj No: T-7-87                      Status: Ongoing  
 Title: Utilization of Goats for Training of 91B Medical NCO for the Medical NCO Course

Start Date 13 May 87	Est Comp Date:
Principal Investigator Susan G. Connger, MAJ, AN	Facility Academy of Health Sciences
Dept/Svc Combat Medical Specialist Division	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	_____
Total Number of Subjects Enrolled to Date:	_____
Date of Periodic Review _____	Results _____

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

Technical Approach: Training conducted as outlined in the protocol.

Progress: During FY 88, 1401 NCOs completed the course.

Detail Summary Sheet

Date: 10 Nov 88	Proj No: T-1-88	Status: Ongoing
Title: Oculoplastic Seminar and Laboratory and Wound Closure		

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

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 nine residents by members of the ophthalmology staff was conducted.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 7804      Status: Ongoing  
 Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date FY 78	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 9 Sep 88	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: Eligible patients must have localized lesions at least extending into the submucos and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: 80 patients have been evaluated for toxicity to FAM. One patient had a fatal cardiac toxicity, 3 patients had Grade 3 cardiac toxicities and two patients experienced Grade 4 thrombocytopenia. The miscellaneous toxicities were moderate pulmonary fibrosis and moderate microangiopathic hemolytic anemia.

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 7808 Status: Completed  
 Title: Combined Modality Treatment for Stages III and IV, Hodgkin's Disease  
 MOPP #6.

Start Date FY 79	Est Comp Date:
Principal Investigator: (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Hodgkin's Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review 9 Sep 88	Results Closed

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: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: Results are quite encouraging in the overall 79% of all previously untreated patients achieved a complete response. A new finding is the fact that many patients who were in partial remission at the completion of MOP-BAP chemotherapy could be converted to complete response by their consolidation radiation therapy.

Detail Summary Sheet

Date: 1 Nov 1988	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: 60	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

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

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

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

Progress: The premenopausal trial should reach its necessary accrual by the end of this year. The postmenopausal trial will be closed as soon as the replacement trial has been activated. A publication describing the results of the ER-negative component to the trial will be done in the next year.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8094      Status: Ongoing  
 Title: Radiotherapy With and Without Chemotherapy for Malignant Mesothelioma  
 Localized to One Hemithorax, Phase III.

Start Date 22 May 81	Est Comp Date:
Principal Investigator: (vice Mills) Timothy J. O'Rourke, LIC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To evaluate, in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

2) To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been two lethal and four life-threatening toxicities of those patients evaluated for radiation therapy toxicities. Six complete and 16 partial responses have been observed from radiation therapy. One patient had life-threatening leukopenia on the Adriamycin arm of the study. At the current rate of accrual and ineligibility, this study will need to remain open until November, 1990.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8107      Status: Completed  
 Title: Management of disseminated Melanoma, Master Protocol, Phase II-III.

Start Date 9 Jul 82	Est Comp Date:
Principal Investigator: (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Melanoma	
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 9 Sep 88	Results Closed

Objective(s): To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases.

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases. Patients will be randomized to Arm I (DTIC plus Actinomycin) vs. Arm II (Cisplatinum, Velban, and Bleomycin).

Therapy will follow the schema outlined in the study protocol.

Progress: Out of 90 patients registered to the preinduction phase of this study only 28 patients were evaluable, 5/14 RT patients and 9/14 control patients developed brain metastasis. Survival for the RT patients was 4.0 months and 4.6 months for the controls. This difference was statistically significant (one tailed p=.25). For the chemotherapy portion of the study, there is no significant difference in survival between DTIC and ACT-D patients and those who received platinum, Velban, and Bleomycin.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8208 Status: Completed  
 Title: Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma,  
 Phase II

Start Date 11 Mar 83	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Carcinoma, islet 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 8 September 1988 Results Closed	

Objective(s): 1) To study the response of functioning and non-functioning islet cell carcinoma to chlorozotocin (CTZ) and 5-fluorouracil (5-FU).

2) To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: To be eligible for this study, all patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy, and a minimum life expectancy of greater than six weeks. All patients must have objectively measurable disease or a significant biochemical abnormality secondary to endocrine hyperfunction specific for their islet cell tumors.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entries.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8216/38 Status: Ongoing  
 Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date 30 Aug 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: Richard O. Giudice, 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 9 Sep 88	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: Patients with a histologically confirmed diagnosis of transitional cell carcinoma of the bladder, Stage O(P<sub>a</sub>) and A(P<sub>1</sub>)m with two recurrences within the last twelve months will be eligible as well as all patients with documented carcinoma in situ (PIS) on random biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8221 Status: Completed  
 Title: Treatment of Advanced Bladder Cancer with Preoperative Irradiation and Radical Cystectomy vs. Radical Cystectomy Alone, Phase III.

Start Date 17 Dec 85	Est Comp Date:
Principal Investigator (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Closed

Objective(s): To compare survival and pelvic recurrence rates in patients with transitional cell bladder cancer treated with radical surgery alone versus patients treated with preoperative irradiation with 2,000 rads followed by cystectomy.

Technical Approach: All patients must have a histologically proven diagnosis of transitional cell carcinoma of the bladder and must be judged by the investigator as potentially curable.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has recently been closed and at this time there is no obvious survival difference.

Detail Summary Sheet

Date: 1 Nov 88                      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 10 Dec 82	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
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 9 Sep 88                      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 and Prednisone will increase the remission rate (at least 75% tumor regression).

4) To determine whether sequential half-body radiotherapy along with Vincristine and Prednisone can serve as an effective form of induction therapy for patients who fail to respond to chemotherapy or suffer early relapse.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma are eligible. This is a first-line study and only patients without prior cytotoxic chemotherapy are eligible.

Progress: There are no significant differences in the frequencies of response, toxicity or any difference in survival between the alternating and syncopated arms of the protocol. On SWOG 8230 the remaining patients will receive GM-CSF in a effort to see if this will reduce the hematologic toxicities for those patients randomized to the chemotherapy or to sequential hemibody radiation.



Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8300 Status: Completed  
 Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Radiation plus Chemotherapy (FOMi/CAP), Phase III.

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Non-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 9 Sep 88	Results Coompleted

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

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

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

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

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

Technical Approach: All patients must have a histologic or cytologic diagnosis of non-small cell carcinoma of the lung. Patients must have limited disease. Disease must be confined to a single hemithorax, and/or ipsilateral hilar lymph nodes, and/or the mediastinum, and/or the ipsilateral supraclavicular lymph nodes. In addition, the patient's disease must be encompassable in a single radiation port.

Therapy will follow the schema outlined in the study protocol.

Progress: No unusual or unexpected specific toxicities were seen, but there is at this time a significant survival difference favoring the patients who were randomized not to receive elective whole brain irradiation.

Detail Summary Sheet

Date: 1 Nov 88	Proj No: SWOG 8309	Status: Ongoing
Title: Autologous Marrow Transplantation for the Treatment of Non-Hodgkin's Lymphoma, Phase II.		

Start Date 19 Dec 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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: 3	
Date of Periodic Review 9 Sep 88                      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: Patients with lymphocytic lymphoma, Burkitt's lymphoma, or diffuse undifferentiated lymphoma with central nervous system involvement at presentation who are in first remission or subsequently relapse are eligible. Patients with histiocytic lymphoma with CNS or bone marrow involvement at presentation are in first remission or subsequently relapse are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This study continues to have poor accrual, with a total of 35 patients on study to date. One transplant-related death has been reported within the first two weeks of treatment on this study.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8312                      Status: Ongoing  
 Title: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in  
 Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive  
 Metastatic Breast Cancer, Phase III

Start Date 31 Aug 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: Richard O. Giudice, MAJ, MC
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 9 Sep 88	Results Continue

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

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

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

Technical Approach: Postmenopausal female patients with progressive, measurable metastatic breast carcinoma are eligible. Patients must have received an adequate trial of tamoxifen therapy and achieved at least a partial response in all areas of measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This trial continues to accrue patients at about five per month. There have been several episodes of severe granulocytopenia and one toxic death due to granulocytopenia in patients on aminoglutethimide. It is recommended that patients on these drugs be monitored closely for myelosuppression.

Detail Summary Sheet

Date: 1 Nov 88                      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 31 Aug 84	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facilit, Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Breast carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review 9 Sep 88	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: All patients must have histologically proven breast carcinoma with metastases to one or more axillary nodes to be eligible. Only patients with ER- breast carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This trial has now accrued more than 400 patients and has been opened to ECOG participation. We will probably continue accrual until the end of this year or until a replacement trial has been activated.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8320 Status: Completed  
 Title: Evaluation of Fludarabine Phosphate in Endometrial Cancer, Phase II.

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator (vice Mills) Timothy J O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate in patients with metastatic or recurrent epithelial carcinomas of the endometrium who have failed on higher priority treatment protocols.

2) To determine the nature and toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the endometrium are eligible. Patients must have a life expectancy of six weeks and clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This trial has now accrued more than 400 patients and has been opened to ECOG participation. We will probably continue accrual until the end of this year or until a replacement trial has been activated.

Detail Summary Sheet

Date: 1 Nov 88	Proj No: SWOG 8321	Status: Completed
Title: Evaluation of Carboplatin vs Cisplatinum + Infusion 5-Fluorouracil + Allopurinol in the Treatment of Metastatic or Recurrent Squamous Ca.cinoma of the Uterine Cervix, Phase II.		
Start Date 26 Apr 85	Est Comp Date:	
Principal Investigator (vice Mills Timothy J. O'Rourke, LTC, MC)	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC	
Key Words: Carcinoma, uterine cervix		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review	Results	

Objective(s): 1) To carry out a randomized phase II trial of two treatment regimens, carboplatin and cisplatin/continuous infusion 5-FU + allopurinol in patients with metastatic or recurrent squamous carcinoma of the cervix who have failed treatment protocols of higher priority.

2) To determine and compare the nature and degrees of toxicity of each of these treatment regimens.

Technical Approach: All patients with histologically proven metastatic or recurrent squamous carcinoma of the uterine cervix are potential candidates for this study. Patients must have a life expectancy of at least 6 weeks, a performance status of 0-2, and measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: In patients treated with cisplatin/5-FU plus or minus allopurinol, there have been 9 PRs and 6 CRs for overall objective response rate of 29%. The response rate on the carboplatin arm cannot accurately be assessed at this point.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8323                      Status: Completed  
 Title: Evaluation of Fludarabine Phosphate in Advanced Mycosis Fungoides,  
 Phase II.

Start Date 28 Sep 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: Richard O. Giudice, MAJ, MC
Key Words: Mycosis fungoides	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Sep 88                      Results Completed	

Objective(s): 1) To determine the response-rate and remission duration of treatment with low dose fludarabine phosphate used on an every three-week schedule in advanced mycosis fungoides.

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

Technical Approach: Patients must have advanced mycosis fungoides with at least extensive plaque disease, or skin nodules, gross skin tumor, lymph node involvement or extranodal involvement. All patients must have measurable disease clearly documented prior to initiation of therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: A 25% partial response rate has been observed. This study was closed because accrual goals had been met.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8324 Status: Completed  
 Title: Evaluation of Fludarabine Phosphate in Malignant Melanoma.

Start Date 29 Aug 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: Richard O. Giudice, MAJ, MC
Key Words: Malignant melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To determine the response rate and response duration in patients with malignant melanoma treated with Fludarabine Phosphate.

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

Technical Approach: To be eligible for this study, all patients must have a pathologically verified histologic diagnosis of melanoma. Patients must have measurable disease and must not be receiving concomitant radiation therapy, hormonal therapy or other chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No anti-tumor responses were observed and this drug will not be further pursued in melanoma.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8325                      Status: Ongoing  
 Title: Combination Chemotherapy with Mitotane (O,P'-DDD) and Cis-Platinum  
 in Metastatic Adrenal Carcinoma, Phase II.

Start Date 2 May 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: Richard O. Giudice, MAJ, MC
Key Words: Adrenal 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 9 Sep 88	Results Continue

Objective(s): 1) To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-Platinum (DDP) and Mitotane (O,P'DDD).

2) To study the prognostic features of patients with metastatic and/or unresectable adrenal carcinoma receiving chemotherapy.

3) To document the toxicity of chemotherapy in this group of patients.

Technical Approach: Patients with metastatic or residual adrenocortical carcinoma in whom further surgical removal of disease is not possible will be eligible. Prior treatment with O,P'-DDD or radiotherapy is allowed. Prior chemotherapy with agents other than cis-platinum is also acceptable.

Progress: This rare tumor study has accrued 34 patients. No inordinate problems have been reported.

Detail Summary Sheet

Date: 1 Nov 88 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 30 Aug 85	Est Comp Date:
Principal Investigator Timothy J. G'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Leukemia, adult acute Leukemia, chronic granulocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Sep 88	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: All patients with the following types of leukemia in relapse (including CNS involvement) are eligible: 1) Acute non-lymphocytic leukemia including newly diagnosed secondary leukemia, and ANLL with failure of induction from standard chemotherapy; 2) Chronic granulocytic leukemia during accelerated phase or blastic phase.

Therapy will follow the schema outlined in the study protocol.

Progress: Evaluation of toxicities resulted in the closing of arm II induction and arm V consolidation regimens due to a significantly higher number of toxicities.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8369                      Status: Ongoing  
 Title: Combination Chemotherapy with Mitoxantrone, Cis-Platinum and MGBG for Refractory Lymphoma, Phase II.

Start Date <u>20 Aug 85</u>	Est Comp Date:
Principal Investigator <u>Timothy J. O'Rourke, LTC, MC</u>	Facility <u>Brooke Army Medical Center</u>
Dept/Svc <u>Department of Medicine/Oncology</u>	Associate Investigators: <u>Richard O. Giudice, MAJ, MC</u>
Key Words: <u>Lymphoma</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: <u>0</u>	
Total Number of Subjects Enrolled to Date: <u>1</u>	
Date of Periodic Review <u>9 Sep 88</u> Results <u>Continue</u>	

Objective(s): 1) To determine if the combination of Mitoxantrone, Cis-Platinum and Methyl-Glyoxal Bis-Guanylhydrazone (MGBG) has reasonable activity (response rate >30%) in patients with refractory unfavorable histology non-Hodgkin's lymphoma. Response duration will also be assessed.

2) To determine the toxicities of this combination of drugs.

Technical Approach: Patients must have histologically confirmed unfavorable histology non-Hodgkin's lymphomas refractory to standard chemotherapy. Patients must have received no more than one prior chemotherapy regimen and must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have had complete remission, and three patients have had partial remissions. The overall response rate is 29%.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8390                      Status: Completed  
 Title: Chemotherapy of Gastric Cancer with 5-Fluorouracil (5-FU) and Folinic Acid, Phase II

Start Date 9 Nov 86	Est Comp Date:
Principal Investigator (vice Zaloznik) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To determine the toxicity of 5-Fluorouracil (5-FU) and folinic acid in patients with metastatic gastric carcinoma.

2) To determine the response-rate in previously untreated patients receiving 5-FU and folinic acid.

Technical Approach: To be eligible for this study, patients must have biopsy-prove adenocarcinoma arising from the stomach. Patients must have clinically measurable disease to qualify for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 90 patients accrued to this study. The responses are yet to be evaluated; however, toxicity has been determined to be roughly equal between the two groups.



Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8406 Status: Completed  
 Title: Evaluation of Esorubicin (4'Deoxydoxorubicin) in Malignant Lymphoma, Phase II.

Start Date 4 Dec 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: Richard O. Giudice, MAJ, MC
Key Words: Lymphoma, malignant	
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 9 Sep 88 Results Completed	

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: All patients must have a pathologically verified histologic diagnosis of malignant lymphoma. Patients must have a life expectancy of more than 8 weeks and must have evaluable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This regimen has caused no fatal toxicity and, in fact, shows no minimal toxicity. The major complaint is fatigue. There is a 64% partial response rate in patients with Hodgkin's disease.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8407 Status: Completed  
 Title: Evaluation of CBDCA in Advanced Endometrial Carcinoma, Phase II

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Endometrial 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 9 Sep 88	Results Completed

Objective(s): 1) To determine the response rate, duration of response, and survival of patients with advanced endometrial carcinoma treated with CBDCA [1,1-cyclobutane-dicarboxylato-(2)-0,0']-(SP-4-2) platinum, NSC-241240).

2) To assess the toxicity of CBDCA in patients who have received no prior chemotherapy.

Technical Approach: Patients with histologically proven measurable metastatic or locally recurrent endometrial carcinoma are eligible for entry. Patients must have relapsed following primary treatment with surgery or radiotherapy plus surgery or have obvious metastatic disease at the time of diagnosis. All patients must have a performance status of 0-2 and an expected survival of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Of 22 patients that are fully evaluable for response, at this point, there has been complete responder (5%) and six partial responders (27%). It is obvious that carboplatin is a highly active drug in the treatment of advanced, recurrent endometrial cancer.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8408 Status: Completed  
 Title: Evaluation of Esorubicin in Gynecological Malignancies, Phase II

Start Date 30 Jan 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Esorubicin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To determine the antitumor activity of esorubicin in patients with advanced, endometrial carcinoma.

2) To assess the nature and degree of toxicity of esorubicin in patients who have received no prior chemotherapy.

Technical Approach: Patients with histologically proven measurable metastatic or locally recurrent endometrial carcinoma are eligible for this study. Patients must have a life expectancy of >8 weeks and must have relapsed following primary treatment with surgery or radiotherapy plus surgery or have obvious metastatic disease at the time of diagnosis.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been no drug related fatalities, and only one case of life-threatening granulocytopenia. Thus far, there appears to be only one partial responder.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8409 Status: Completed  
 Title: Evaluation of Fludarabine Phosphate in Refractory Multiple Myeloma, Phase II.

Start Date 4 Jan 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: Richard O. Giudice, MAJ, MC
Key Words: Multiple myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To determine the response rate and response duration to Fludarabine Phosphate in patients with refractory multiple myeloma when treated on a daily times five, every three week schedule.

2) To define the qualitative and quantitative toxicity of Fludarabine Phosphate in a Phase II setting.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Fludarabine phosphate is intended for therapy of patients with multiple myeloma who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have measurable disease and must not have received either radiation therapy or chemotherapy for at least three weeks prior to beginning therapy with fludarabine phosphate.

Therapy will follow the schema outlined in the study protocol.

Progress: There has been Grade 3 hematologic toxicity at the 18mg/m<sup>2</sup>dose level but there are no significant objective responses at this level or at the lower two dosage levels.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8411 Status: Completed  
 Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II.

Start Date 26 Oct 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: Richard O. Giudice, MAJ, MC
Key Words: Carcinoid, metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To determine the effectiveness of dimethyl triazeno imidazole carboxamide (DTIC) in the treatment of metastatic carcinoid.

2) To determine the survival of patients with metastatic carcinoid receiving DTIC.

Technical Approach: All patients must have biopsy-prove carcinoid not amenable to further surgery. Patients must have a minimum life expectancy of 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Partial responses for this study are 15% for the good risk group and 16% for the poor risk group. Furthermore, the survival curves reveal median survival for the good risk patients of 19.5 months and for the poor risk patients 16.3 months.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8415                      Status: Completed  
 Title: Evaluation of Tamoxifen in Unresectable and Refractory Meningiomas,  
 Phase II.

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Meningioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To determine the antitumor activity of Tamoxifen in meningiomas not amenable to surgery or radiotherapy.

2) To estimate the response rate and response duration experienced by these patients.

Technical Approach: All patients must have a biopsy-proven diagnosis of benign meningioma and measurable disease by CT scan or NMR scan. Patients must have documented recurrence not amenable to radiation therapy or documented growth after definitive radiation therapy. Patient's tumor must be unresectable for medical or technical reasons, or have measurable residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: It has been concluded that tamoxifen is an inactive agent in the treatment of meningiomas.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8417/19 Status: Ongoing  
 Title: Evaluation of Two Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III

Start Date 27 Sep 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: Richard O. Giudice, MAJ, MC
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: 4	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: All patients must have a diagnosis of acute lymphoblastic leukemia. Patients must have no evidence of serious liver or renal dysfunction defined as a bilirubin and creatinine greater than the institutional normals.

Therapy will follow the schema outlined in the study protocol.

Progress: Accrual to this study has been excellent. The regimen appears to be very well tolerated and leukemic cell samples are being appropriately received by the central reference laboratory at the University of Texas at San Antonio.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8500 Status: Ongoing  
 Title: Second-Line Treatment of Advanced Measurable Ovarian Cancer with CHIP, Phase II

Start Date 7 Nov 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: Patients must have a histologically confirmed diagnosis of incurable, advanced, metastatic or recurrent epithelial carcinoma of the ovary who progress on or who fail to achieve a complete response on first-line therapy. Patients must have bidimensionally measurable disease and a life expectancy of >6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study remains open only to patients who have progressed on carboplatin therapy.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8507 Status: Ongoing  
 Title: Maintenance versus no Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phse III

Start Date 28 Mar 86	Est Comp Date:
Principal Investigator (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard G. Giudice, MAJ, MC
Key Words: Bladder cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 9 Sep 88	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.

3) To assess the association of intermediate strength PPD skin test reactivity with disease-free status in patients treated with BCG immunotherapy.

Technical Approach: All patients must have a histologically confirmed diagnosis of Stage 0 (T<sub>a</sub>,P<sub>a</sub>) or Stage A (T<sub>1</sub>,P<sub>1</sub>) transitional cell carcinoma of the bladder. All patients must be available for long-term follow-up.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been over 500 patients entered with one probable BCG related death and with one death related to traumatic catheterization.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8509 Status: Ongoing  
 Title: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II

Start Date 3 Jan 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: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, prostate	
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 9 Sep 88 Results Continue	

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

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

Technical Approach: Eligible patients must have a histologically proven diagnosis of adenocarcinoma of the prostate and must have evaluable or measurable disease. They must have a life expectancy of at least six weeks and a performance status of 3 or better.

Therapy will follow the schema outlined in the study protocol.

Progress: This protocol is near closure in terms of accrual needs. Since last reported no new inordinate toxicities are recorded.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8510                      Status: Ongoing  
 Title: Intra-Arterial Cis-Platinum and Radiation Therapy in Primary Brain  
 Tumors: A Phase Randomized Study Comparing Sequential and Combined Treatments

Start Date 30 Jul 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: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCARE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To assess the toxicity and response to therapy of intra-arterial Cis-platinum administered in two schedules, sequential and concomitant with radiation therapy in the treatment of patients with primary malignant gliomas.

2) To determine the time to progression and overall survival in patients with malignant gliomas treated with intr.-arterial Cis-platinum in addition to radiation therapy.

Technical Approach: All patients must have a histologically confirmed diagnosis of primary malignant glioma. Patients who have had surgery with histologic diagnosis within four weeks prior to entry on this study will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: 27 patients have been registered on this study. There have been some severe neurologic toxicities related to air/embolus and/or thrombosis, and drug effect on the central nervous system. This study will be closed when a replacement study is opened.

Detail Summary Sheet

Date: 1 Nov 88		Proj No: SWOG 8514		Status: Ongoing	
Title: Randomized Comparison of Cisplatin + 5-Fluorouracil vs CBDCA + 5-Fluorouracil vs Methotrexate in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase III					
Start Date 28 Mar 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: Richard O. Giudice, MAJ, MC		
Key Words: Carcinoma, squamous 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 9 Sep 88 Results Continue					

Objective(s): 1) To determine and compare the response rate (complete and partial), duration of response and survival time of patients treated with two combination chemotherapy regimens: (Arm I) Cisplatin + 5-fluorouracil, (Arm II) CBDCA + 5-fluorouracil with (Arm III) single agent methotrexate.

2) To determine the toxicities associated with each of the three treatments.

Technical Approach: Patients must have a histologically proven advanced (M<sub>1</sub>) or recurrent squamous cell carcinoma of the head and neck region which is not curable by other forms of therapy. Patients must have objectively measurable disease and a life expectancy of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There has been a high accession rate with only one life-threatening toxicity sepsis reported in the CBDCA group. At this time it is estimated that this study will close in one more year.

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8515 Status: Ongoing  
 Title: Evaluation of Menogaril in Non-Hodgkins Lymphoma, Phase II.

Start Date 13 May 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Non-Hodgkins, Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	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  $\geq 250$  mg/m<sup>2</sup> 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: There have been five patients registered to this study so far. It is too early to evaluate toxicity or response.

Detail Summary Sheet

Date: 1 Nov 88                      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 30 May 86	Est Comp Date:
Principal Investigator (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 9 Sep 88	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 regimens: CHOP, m-BACOD, ProMACE-CytaBOM, or MACOP-B.

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

Technical Approach: All patients must have biopsy proven, measurable "bulky Stage II", Stage III or Stage IV non-Hodgkin's lymphoma.

Therapy will follow the schema outlined in the study protocol.

Progress: This study is accruing extremely well, with 268 patients entered to date. The accrual rate is approximately 15 patients per month. ECOG has joined this study and is entering patients also. The accrual goal will remain at 750 patients.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8518 Status: Ongoing  
 Title: Study of Combined Modality Treatment for Inoperable Squamous Cell Carcinoma of the Esophagus, Phase I-II

Start Date 31 Jul 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, squamous 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 9 Sep 88	Results Continue

Objective(s): 1) To determine the efficacy and toxicity of 5-Fluorouracil (5-FU) and Cis-Platinum combined with concurrent radiotherapy in patients with Stage III epidermoid carcinoma of the esophagus.

2) To determine the feasibility and toxicity of "up-front" palliative laser therapy with this regiment

3) To estimate the response rate and duration of response by clinical and computed tomography staging.

4) To determine the survival of patients treated by these modalities.

Technical Approach: Previously untreated patients with biopsy proven epidermoid esophageal carcinoma are eligible. All patients must have measurable disease either by roentgenogram, CT or endoscopy.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been only 4 patients accrued on this study in the last 2 years. It was recommended that it be closed. However it has been planned to develop a working group on laser therapy within the GI Committee to help develop laser initiatives.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8519 Status: Ongoing  
 Title: Phase II Evaluation of Methyl-Glyoxal Bis-Guanylhydrazone (MGBG)  
 Patients with Advanced Bladder Cancer.

Start Date 28 Mar 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: Richard O. Giudice, 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: 0	
Date of Periodic Review 9 Sep 87 Results Continue	

Objective(s): 1) To determine response rate and remission duration with weekly intravenous therapy using MGBG in patients with metastatic bladder carcinoma who have failed on higher priority protocols.

2) To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: All patients must have a histologically confirmed diagnosis of metastatic transitional cell carcinoma of the urothelium. All patients must have at least one bidimensional objectively measurable site of disease and a performance status of 3 or better.

Therapy will follow the schema outlined in the study protocol.

Progress: There has been one responder in the 20 patients entered to date. This study remains open and no inordinate toxicities were reported.

Detail Summary Sheet

Date: 1 Nov 88 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 7 Nov 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: Richard O. Giudice, 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 9 Sep 88	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: Patients must have biopsy proven epidermoid carcinoma of the penis, Stage III or IV, refractory to surgery and radiotherapy. Patients must have a life expectancy greater than six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been only four patients entered on this study to date.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8522 Status: Ongoing  
 Title: Treatment of Acute Non-lymphocytic Leukemia Patients Over 50 Years,  
 Phase II Pilot.

Start Date 30 Jan 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Leukemia, nonlymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To determine the complete remission rate and toxicity of a chemotherapy regimen in patients over 50 years of age with acute non-lymphocytic leukemia (ANLL).

2) To identify and document prognostic variables in patients over 50 with ANLL by measuring karyotype, FAB classification, presence of prior hematologic disease, and parameters affecting determination of physiologic age from an aging evaluation form.

3) To determine the cause of treatment failure by a method devised by Preisler.

Technical Approach: This protocol is intended for those adult patients with ANLL who are over 50 years and who have received no prior therapy. The diagnosis of ANLL will be made by bone marrow smear, clot section or biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8526 Status: Completed  
 Title: The Clinical Antitumor Activity of Recombinant Beta Interferon in Diffuse Mesothelioma.

Start Date 29 Aug 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: Richard O. Giudice, MAJ, MC
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 9 Sep 88	Results Completed

Objective(s): 1) To evaluate the clinical response of a 5 day per week intramuscular dose of recombinant Beta interferon in diffuse malignant mesothelioma.  
 2) To evaluate the safety and adverse effects resulting from this schedule and duration of administration of recombinant Beta interferon.

Technical Approach: Patients must have a histologically verified diagnosis of diffuse malignant mesothelioma. The mesothelioma may arise either in the thorax or abdomen, but must be of the diffuse malignant type. Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases. Patients must have a performance status of 2 or better and have an expected survival of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been no responses seen in the evaluable patients and the toxicity was primarily flu-like symptoms.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8530      Status: Ongoing  
 Title: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Glucocorticoid Receptors, Phase II.

Start Date 7 Nov 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: Accrual goals for this study should be met in 1988 and a preliminary analysis of the relationship between receptor number and response to treatment should then prove feasible.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8568 Status: Ongoing  
 Title: Combined Modality Therapy for Advanced Stage III Breast Cancer (T3b any N, T3aN2-3, or any T4)

Start Date 28 May 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88 Results Continue	

Objective(s): 1) To evaluate by serial biopsy and flow cytometry whether or not an increase of the percentage of cells in S+G<sub>2</sub>+M can be induced in patients with locally advanced breast cancer by synchronization with a high physiologic dose of estradiol before chemotherapy is applied.

2) To obtain information by flow cytometry and serial biopsy when this increase in S+G<sub>2</sub>+M occurs.

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

Technical Approach: Patients must have clinically or pathologically locally advanced Stage III breast cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Sixteen patients have now been entered onto this trial. Most of the patients have had an increase in the S-phase fraction in response to estrogen priming. The trial will remain open.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8573 Status: Completed  
 Title: Treatment of Limited Small Cell Cancer with Concurrent Chemotherapy  
 Radiotherapy and Intensification with High Dose Cyclophosphamide.

Start Date 30 May 86	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, small cell	
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 9 Sep 88	Results Completed

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: All patients must have histologically proven small cell carcinoma of the lung and evaluable or measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This protocol has met its initial accrual objectives and was permanently closed May 1 1988.

Detail Summary Sheet

Date: 1 Nov 88	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 28 Jun 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: Richard O. Giudice, MAJ, MC	
Key Words: Squamous cell carcinoma of head and neck		
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 9 Sep 88		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: Eligible patients must have histologically confirmed squamous cell carcinoma. The patient's medical condition must be such that surgery and subsequent treatment with chemotherapy and radiation are not contraindicated.

Therapy will follow the schema outlined in the study protocol.

Progress: This protocol is accruing patients at a faster rate than projected. However, the high incidence of positive surgical margins and the low compliance rate have increased the demands for accrual and will prolong the time until enough patients have been registered.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8591 Status: Completed  
 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 28 Jun 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: Richard O. Giudice, MAJ, MC
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 9 Sep 88	Results Completed

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: Eligible patients must have histologic proof of adenocarcinoma taking origin in the colon. A potentially curative resection must have been performed with neither gross nor microscopic evidence of residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Over 1200 patients have been entered onto this Intergroup study, with SWOG placing 175 patients per year on study. It will be several years before this study has publishable results.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8592 Status: Completed  
 Title: Evaluation of Low-Dose Ara-C versus Supportive Therapy Alone in the Treatment of Myelodysplastic Syndromes.

Start Date 25 Oct 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: Richard O. Giudice, MAJ, MC
Key Words: Syndrome, myelodysplastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To compare, in a randomized controlled trial, the benefit of low-dose Ara-C therapy versus supportive care in patients with myelodysplastic syndromes.

2) To determine the frequency, extent, and duration of response to low-dose Ara-C therapy in patients with myelodysplastic syndromes.

3) To assess the toxicity of a 21 day course of low-dose Ara-C.

4) To correlate patient response with presenting clinical characteristics and marrow cytogenetic and morphological features.

Technical Approach: Patients must have documented morphologic proof of a myelodysplastic syndrome of one of the following types: (1) refractory anemia (RA), (2) RA with ringed sideroblasts, (3) RA with excess of blasts (RAEB), (4) Chronic myelomonocytic leukemia (CMML), or (5) RAEB in transformation. Patients must have a projected survival of greater than 2 months.

Therapy will follow the schema outlined in the study protocol.

Progress: This study is in the process of being summarized by the coordinators for submission as an abstract.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8594                      Status: Ongoing  
 Title: A Phase III Trial of Cis-Platin Alone or in Combination with  
 Doxorubicin, Vinblastine, and Methotrexate in Advanced Bladder Cancer.

Start Date 27 Jun 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: Richard O. Giudice, 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 9 Sep 88                      Results Continue	

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

Technical Approach: Patients must have histologically proven advanced bladder carcinoma, not curable by surgery or radiation therapy. They must have bidimensionally measurable and evaluable metastases, not previously radiated and a Karnofsky performance status of 60% or higher. Patients must have a life expectancy of 3 months or longer.

Therapy will follow the schema outlined in the study protocol.

Progress: It was reported the the accrual was a little slower than what was hoped for. At the present time it looks as though at least two more years of accrual will be necessary.

Detail Summary Sheet

Date: 1 Nov 88	Proj No: SWOG 8596	Status: Completed
Title: A Randomized Phase III Intergroup Study of Radiation Therapy versus Cisplatin plus Etoposide plus Bleomycin for Advanced Stage II Seminoma.		
Start Date 27 Jun 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: Richard O. Giudice, MAJ, MC	
Key Words: Seminoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review 9 Sep 88	Results	Completed

Objective(s): 1) To examine the response rate and duration of remission for definitive radiotherapy versus cisplatin plus etoposide plus bleomycin (BEP) in advanced stage II seminoma.

2) To examine the relative toxicity of definitive radiotherapy and cisplatin combination chemotherapy.

3) To evaluate the complete response rate and duration of remission of BEP in advanced stage II seminoma patients who relapse subsequent to definitive radiotherapy.

Technical Approach: All male patients with a histologic diagnosis of stage IIB classic or anaplastic testicular seminoma with or without elevation of BHCG (but not alpha feta protein).

Therapy will follow the schema outlined in the study protocol.

Progress: There is some question as to whether or not this study will remain open because of extraordinarily slow accrual.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8597                      Status: Completed  
 Title: Randomized Phase III Intergroup Study of Supradiaphragmatic Irradiation  
 in Stage II-A Seminoma.

Start Date 27 Jun 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: Richard O. Giudice, MAJ, MC
Key Words: Seminoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Completed

Objective(s): 1) To compare the recurrence rates and the patterns of stage II-A seminomas treated with either infradiaphragmatic irradiation only or infradiaphragmatic irradiation followed by supradiaphragmatic irradiation.

2) To assess the tolerance to chemotherapy and the salvage rate in relapsing patients.

3) To examine the effect of the treatment on gonadal function.

Technical Approach: Patients with histologically pure seminoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 88 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 30 Jan 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	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: To be eligible for this study, the patient must have biopsy proven squamous cell carcinoma of the thoracic esophagus. There must be no evidence of disseminated cancer by physical examination.

Therapy will follow the schema outlined in the study protocol.

Progress: There are approximately 50 patients accrued to this trial. There is no reportable data.

Detail Summary Sheet

Date: 1 Nov 88		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 30 Jan 87			Est Comp Date:		
Principal Investigator Timothy J. O'Rourke, LTC, MC			Facility Brooke Army Medical Center		
Dept/Svc Department of Medicine/Oncology			Associate Investigators: Richard O. Giudice, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: 0					
Total Number of Subjects Enrolled to Date: 1					
Date of Periodic Review 9 Sep 88			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: All patients less than 65 years of age, with the diagnosis of acute non-lymphocytic leukemia who have not received prior therapy for leukemia will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Overall toxicity appears to be comparable between the two induction regimens. There are four of 44 eligible patients, however, who had neurologic toxicity on the high dose ara-C regimen which is obviously different from the standard induction regimen.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8604 Status: Completed  
 Title: Evaluation of 6-Thioguanine (6-TG) in Refractory and Relapsing Myeloma

Start Date 30 Jan 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88 Results Completed	

Objective(s): 1) To determine the antitumor activity of 6-Thioguanine (6-TG) in patients with refractory and relapsing multiple myeloma by determination of the response rate and the remission duration.

2) To define the qualitative and quantitative toxicities of 6-TG administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma.

Therapy will follow the schema outlined in the study protocol.

Progress: This agent shows at best minimal activity in myeloma.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8608                      Status: Ongoing  
 Title: Mitoxantrone Plus Cis-Platinum in Patients with Advanced Breast Cancer,  
 Phase I-II

Start Date 24 Apr 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Breast cancer	
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 9 Sep 88	Results Continue

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

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

Technical Approach: To be eligible for this study, patients must have histologic proof of advanced, metastatic breast cancer and must have measurable disease. Patients must have had only one previous chemotherapy regimen for metastatic disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This trial has 26 patients entered and is temporarily closed pending an evaluation of the currently evaluable patients.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8611 Status: Ongoing  
 Title: A Randomized Trial of Two Schedules of Trimetrexate Versus 5-Fluorouracil in Colorectal Carcinoma, Phase II-III

Start Date 27 Feb 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, colorectal	
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 9 Sep 88	Results Continue

Objective(s): 1) To determine and compare the response rates, response durations and toxicities of trimetrexate given on two different schedules to patients with advanced colorectal cancer.

2) To compare patient survival on trimetrexate with those on 5-FU alone.

Technical Approach: Patients with biopsy proven adenocarcinoma arising from the colon or rectum and who have measurable disease are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been four toxic death rates reported in the Trimetrexate arm. Response rates are not available.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8616 Status: Ongoing  
 Title: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine with and without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma

Start Date 31 Jul 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	Results Continue

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

Technical Approach: Patients with histologically documented metastatic or unresectable sarcoma are eligible for this study. Patients with metastatic osteogenic, Ewings, and Rhabdomyosarcoma will be assigned to arm II.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 117 patients registered on this study. 2 patients on the Adriamycin/DTIC and four on the Adriamycin/DTIC/IFF have had life-threatening hematologic toxicity.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8621      Status: Ongoing  
 Title: Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept./Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	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: To early for any reportable data.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8622 Status: Completed  
 Title: Evaluation of Echinomycin in Advanced Colorectal Cancer, Phase II

Start Date 30 Jan 87	Est Comp Date:
Principal Investigator (vice Zaloznik) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	Results Completed

Objective(s): 1) To determine the antitumor activity of echinomycin in patients with colorectal carcinoma by determination of the response rate and remission duration.

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

Technical Approach: Patients with biopsy proven adenocarcinoma arising from the colon or rectum are eligible for this study. Patients may not have received prior chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: There are 18 evaluable patients with no responses.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8623 Status: Completed  
 Title: A Phase II Trial of Trimetrexate in Untreated Advanced Gastric Carcinoma.

Start Date 10 Nov 87	Est Comp Date:
Principal Investigator (vice Zalosnik) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, 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 8 September 1988	Results Closed

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 gastric carcinoma.

Technical Approach: Patients must have biopsy proven adenocarcinoma arising from the stomach. They must have measurable disease and must not be eligible for higher priority protocols.

Therapy will follow th schema outlined in the study protocol.

Progress: This study was closed 8 September 1988. No data are available.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8624                      Status: Ongoing  
 Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Multiple Myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: Patients must have objective evidence of, or be symptomatic from complications due to myeloma and must not have receive prior chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: 130 patients have been registered to the induction arm of this study.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8625      Status: Completed  
 Title: Weekly Cis-Platinum Based Induction for Extensive Non-Small Cell Lung Cancer, with Cis-Platinum + VP-16 Consolidation, Phase II.

Start Date 13 Nov 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: Richard O. Giudice, MAJ, MC
Key Words: Cancer, 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 9 Sep 88	Results Closed

Objective(s): 1) To estimate the response rate and toxicity of a combination of weekly cisplatin, mitomycin, vinblastine and 5-fluorouracil, given in an alternating fashion.

2) To measure time to disease progression and survival in patients so treated.

Technical Approach: Patients with biopsy proven non-small cell lung cancer who have extensive and/or locally recurrent disease after treatment with primary radiation therapy or surgery alone will be eligible for this study. Adequate renal function is required and patients must have had no prior chemotherapy, no congestive heart failure and no other active malignant disease.

therapy will follow the schema outlined in the study protocol.

Progress: This study accrued 82 patients in just over 4 months. 55 patients have been evaluated for toxicity, with one case of life-threatening nephrotoxicity. 25 patients have been evaluated for response, with 1 complete response and 6 partial responses to date. The study is now undergoing final evaluation.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8626 Status: Ongoing  
 Title: Study of Recombinant DNA Gamma Interferon in Advanced Cancer of the Pancreas, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Pancreatic cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: Patients with pathologically verified diagnosis of pancreatic adenocarcinoma will be eligible. They must have bidimensionally measurable recurrent or disseminated disease to qualify for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The bolus arm has been closed in this study because of the unavailability of the drug. The continuous infusion arm has accrued 20 patients. These patients are being evaluated. Toxicity is not inordinate.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8629 Status: Ongoing  
 Title: Adjuvant Therapy with Adriamycin Plus Cisplatin for Endometrial Sarcomas at High Risk of Recurrence, Phase II

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Sarcoma, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To examine the effect of adjuvant systemic chemotherapy on survival and pattern of recurrence in patients with limited endometrial sarcoma.

2) To determine the toxicities of the adjuvant systemic chemotherapy in patients with limited endometrial sarcoma.

Technical Approach: Patients with biopsy-proven sarcoma of the endometrium or mixed carcinosarcoma of the endometrium are eligible. Patients must undergo complete surgical staging including resection of the uterus, cervix, tubes and ovaries, and a very thorough exploration of the entire peritoneal cavity.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been amended to allow entry of patients who have deep myometrial invasion with or without evidence of pathologically proven pubic or paraaortic lymph node involvement with sarcoma.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: 8702 8630 Status: Ongoing  
 Title: Phase II Study of Recombinant DNA Gamma Interferon in Advanced Colorectal Cancer

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Timothy J. O'Kourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Colorectal cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To determine the clinical response rate of recombinant gamma interferon in colorectal cancer.

2) To define the qualitative and quantitative toxicities of recombinant gamma interferon in colorectal cancer.

Technical Approach: Patients with biopsy proven adenocarcinoma arising from the colon or rectum will be eligible. Patients must have bidimensionally measurable recurrent or disseminated disease to qualify for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: There are 22 patients on the bolus arm and 24 patients on the continuous infusion arm. The toxicity was as expected with fever and flu-like activities and some episodes of hypotension have been noted.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8632      Status: Ongoing  
 Title: Evaluation of Echinomycin in Central Nervous System Tumors, Phase II.

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Central nervous system tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To assess the efficacy of Echinomycin given once every seven days X four weeks followed by a two week rest in recurrent or residual central nervous system tumors by evaluation of response--rate, duration and survival.

2) To assess the qualitative and quantitative toxicities of Echinomycin given by this schedule in a Phase II setting.

Technical Approach: Patients must have a histologically confirmed diagnosis of astrocytoma, anaplastic astrocytoma, ependyoblastoma, glioblastoma, medulloblastoma, or anaplastic oligodendroglioma. Patients must have failed primary surgical and/or radiation therapies and must not be eligible for higher priority protocols.

Therapy will follow the schema outlined in the study protocol.

Progress: The toxicity observed in this study has been predominately nausea and vomiting, with seven of ten patients having mild to moderate symptoms. Myelosuppression has been minimal. The plan is to continue accessions on this trial until a minimum of 15 to 20 patients have been entered with no prior chemotherapy. Accrual goals for this study should be met in 1988 and a preliminary analysis of the relationship between receptor number and response to treatment should then prove feasible.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8640      Status: Ongoing  
 Title: Evaluation of Didemnin B or Trimetrexate in the Treatment of  
 Metastatic or Recurrent Squamous Carcinoma of the Uterine Cervix.

Start Date 15 Dec 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): To evaluate tumor response to didemnin-B or trimetrexate in patients with metastatic or recurrent squamous carcinoma of the uterine cervix who have failed treatment protocols of higher priority.

Technical Approach: This study is open to patients who have histologically proven metastatic or recurrent squamous carcinoma of the uterine cervix. The patients must have bidimensionally measurable disease. The patients may have no detectable ascites or pleural fluid. There may be no prior systemic chemotherapy and any prior radiotherapy must have been to less than 25% of the bone marrow.

Therapy will follow the schema outlined in the study protocol.

Progress: 20 patients have been registered to this study. However, it is too early for any reportable data.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8642 Status: Ongoing  
 Title: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma After Surgical Excision of the Primary Lesion.

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Malignant melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: St I and II melanoma who have undergone complete resection of all known disease but are at high risk for recurrent disease are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 56 patients registered to this study. There is no further reportable data available at this time.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8691 Status: Ongoing  
 Title: A Randomized Comparison of Deoxycoformycin versus Alpha-Interferon in Previously Untreated Patients with Hairy Cell Leukemia

Start Date 27 Feb 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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: 1	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

Technical Approach: Patients with histologically documented hair cell leukemia demonstrated by bone marrow biopsy will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Accrual to this study is proceeding exceptionally well. The quality of the data being received on all patients is excellent. The Pathology review is now being conducted.

Detail Summary Sheet

Date: 1 Nov 1988	Proj No: SWOG 8692	Status: Ongoing
Title: Therapy in Premenopausal Women with advanced, ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs. the LH-RH Analog, Zoladex: Phase III, Intergroup.		
Start Date 14 Oct 88	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC	
Key Words: Cancer, Breast		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period:	0	
Total Number of Subjects Enrolled to Date:	0	
Date of Periodic Review 9 Sep 88	Results Continue	

Objective(s): 1) To compare the time to treatment failure and survival of medical castration using Zoladex with surgical castration in premenopausal women with advanced, ER + or PgR + breast cancer.  
 2) To compare the response rate of the two treatments.  
 3) To assess the response rate to surgical castration in patients failing to respond to or relapsing on Zoladex, and the response rate to Zoladex in patients failing to respond to or relapsing on surgical castration.  
 4) To compare toxicities of medical castration and surgical castration.  
 5) To assess the value of post-treatment hormone levels (LH, FSH and estradiol) in predicting response to medical castration.  
 6) To assess the effect of long-term Zoladex treatment on hormone levels (LH, FSH and estradiol) in responding patients.

Technical Approach: Patients must have metastatic breast cancer. They must be premenopausal, have a performance status of 0-2 and be ER or PgR positive. No prior hormone therapy or chemotherapy for advanced disease is allowed. Prior adjuvant chemotherapy is allowed. Adjuvant tamoxifen is allowed provided relapse occurred  $\geq$  6 months after completion of therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: 16 patients have been entered on this study, the study chairman is in the process of record reviews.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8693 Status: Ongoing  
 Title: Adjuvant Therapy of Primary Osteosarcoma: A Phase III Randomized  
 Intergroup Study

Start Date 29 May 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: Patients with biopsy proven osteosarcoma of the upper or lower extremity are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No toxicities were reported on the patients registered on this study, but a report of significant mucositis with persistently elevated methotrexate level was reported on a patient treated according to protocol but not registered on it.

Detail Summary Sheet

Date: 1 Nov 88                      Proj No: SWOG 8694                      Status: Ongoing  
 Title: A Comparison of Pentostatin and Alpha-Interferon in Splenectomized Patients with Active Hairy Cell Leukemia

Start Date 29 May 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	Results    Continue

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

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

Technical Approach: Patients must have histologically documented hairy cell leukemia and be at least 3 months post-splenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: Difficulty in accrual to this study may reflect an overall different approach to patients with hairy cell leukemia at the time of diagnosis. With the newer developments in chemotherapy for this disease, fewer patients are apparently undergoing splenectomy.

Detail Summary Sheet

Date: 1 Nov 1988                      Proj No: SWOG 8695                      Status: Ongoing  
 Title: (GOG 85) A Randomized Comparison of Hydroxyurea versus 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes.

Start Date 13 July 87	Est Comp Date:
Principal Investigator:(vice Burke) Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Charles R. Harrison, MAJ. MC Kenneth Hancock, MAJ. MC
Key Words: Carcinoma, Cervix	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 272 patients registered to this study thus far. There is no further reportable data.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8696      Status: Ongoing  
 Title: Prediction of Recurrence and Therapy Response in the Node Negative Breast Cancer Patient by DNA Flow Cytometry.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, 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 9 Sep 88	Results Continue

Objective(s): 1) To correlate the proliferative activity, ploidy, and HER-2/new gene expression with clinical features including the response to therapy and survival in patients entered on SWOG 8294.

Technical Approach: Previously obtained tissue specimens from patients enrolled on SWOG 8294 are sent for flow cytometry analysis.

There is no therapy involved in this study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988	Proj No: SWOG 8697	Status: Ongoing
Title: Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P)TH or CMFH Intergroup.		
Start Date 22 Jan 88	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC	
Key Words: 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 9 Sep 88	Results Continue	

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8700      Status: Ongoing  
 Title: Consolidation Therapy with High-Dose Cyclophosphamide and Total Body Irradiation, Followed by Autologous Marrow Infusion in Metastatic Breast Cancer, Phase II.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To assess the effect of high-dose cyclophosphamide and total body irradiation with autologous bone marrow support on the response quality after "standard" chemotherapy.

2) To assess the survival after consolidation with high-dose cyclophosphamide and total body irradiation with autologous bone marrow support.

Technical Approach: Patients must have metastatic breast carcinoma in partial or complete remission after no more the six cycles of an combination chemotherapy. Partial and complete responses must have been maintained for at least four weeks. ER + patients are eligible only if they have failed hormonal therapy of have liver or lymphangitic pulmonary disease.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8703 Status: Ongoing  
 Title: Evaluation of Vinblastine and High-dose Cis-Platinum in the Treatment of Advanced Non-Small Cell Lung Carcinoma, Phase II.

Start Date <u>13 Nov 87</u>	Est Comp Date:
Principal Investigator: <u>Timothy J. O'Rourke, LTC, MC</u>	Facility: <u>Brooke Army Medical Center</u>
Dept/Svc: <u>Department of Medicine/Oncology</u>	Associate Investigators: <u>Richard O. Giudice, MAJ, MC</u>
Key Words: <u>Carcinoma, Lung</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: <u>2</u>	
Total Number of Subjects Enrolled to Date: <u>2</u>	
Date of Periodic Review <u>9 Sep 88</u>	Results <u>Continue</u>

Objective(s): 1) To obtain an estimate of the activity of combination chemotherapy with vinblastine and high dose cisplatin in the treatment of advanced non-small cell lung carcinoma.

2) To assess the toxicity of combination chemotherapy with vinblastine and high dose cisplatin in patients with advanced non-small cell lung carcinoma.

Technical Approach: Patients with extensive non-small cell carcinoma of the lung who have recurrent or metastatic disease post surgery or radiation are eligible for this study. Patients must have adequate renal function, no prior chemotherapy and no history of brain metastasis.

Therapy will follow the schema outlined in the study protocol.

Progress: Eleven patients have been evaluated for toxicity this far. One patient had severe leukopenia, and one had severe nausea and vomiting. The protocol goal of 50 patients should be reached by the end of 1988.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8707      Status: Completed  
 Title: Evaluation of Recombinant Gamma Interferon in Renal Cell Carcinoma.

Start Date 11 Dec 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	Results Closed

Objective(s): 1) To estimate the probability of remission and remission duration in patients with advanced renal cell carcinoma when treated with recombinant gamma interferon.

2) To asses the qualitative and quantitative toxicities

Technical Approach: All patients must have a histologically proven diagnosis of metastatic renal cell carcinoma with clearly measurable disease. There must have been no prior treatment with chemotherapy, hormone (Megace), or biologics, although prior surgery or prior RT to less than 25% of the bone marrow is allowed.

Therapy will follow the schema outlined in the study protocol.

Progress: Accrual to this study was met in seven months at an accrual rate of 3.9 patients per month for a total accrual of 27 patients. The study is now permanently closed because gamma interferon is no longer available from the pharmaceutical company.

Detail Summary Sheet

Date: 1 Nov 1988      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 9 Oct 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 Thompson, MAJ, MC
Key Words: Cystectomy, 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 9 Sep 88	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<sub>2</sub>-T<sub>4a</sub>, N<sub>0</sub>, M<sub>0</sub> 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: Twelve patients have been accrued to this study between August 28, 1987 and June 30, 1988, for an accrual rate of 1.4 patients per month. There were two registrations from ECOG. This is far below the projected accrual rate of 6.2 patients per month.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWDG 8711      Status: Ongoing  
 Title: A Study of Reproductive Function in Patients with Testicular Cancer.

Start Date 15 JUL 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, 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 9 Sep 88	Results Continue

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

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: There have been no registrations to this study.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8712 Status: Ongoing  
 Title: A Phase II Trial of Trimetrexate in the Treatment of Hepatoma

Start Date <u>25 Sep 87</u>	Est Comp Date:
Principal Investigator <u>Timothy J. O'Rourke, LTC, MC</u>	Facility <u>Brooke Army Medical Center</u>
Dept/Svc <u>Department of Medicine/Oncology</u>	Associate Investigators: <u>Richard O. Giudice, MAJ, MC</u>
Key Words: <u>Hepatoma</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: <u>0</u>	
Total Number of Subjects Enrolled to Date: <u>0</u>	
Date of Periodic Review <u>9 Sep 88</u>	Results <u>Continue</u>

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: To be eligible for this study, patients must have measurable disease and a biopsy proven hepatocellular carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-one patients have been accrued. Six patients are too early for evaluation.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8714      Status: Ongoing  
 Title: Evaluation of Amonafide in Colorectal Carcinoma, Phase II.

Start Date 8 Apr 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8715      Status: Ongoing  
 Title: Evaluation of Amonafide in Advanced Sarcomas.

<u>Start Date</u> <u>13 May 88</u>	<u>Est Comp Date:</u>
<u>Principal Investigator:</u> Timothy J. O'Rourke, LTC, MC	<u>Facility:</u> Brooke Army Medical Center
<u>Dept/Svc:</u> Department of Medicine/Oncology	<u>Associate Investigators:</u> Richard O. Giudice, MAJ, MC
<u>Key Words:</u> Sarcomas, Advanced	
<u>Accumulative MEDCASE Cost:</u>	<u>Est Accumulative OMA Cost:</u>
<u>Number of Subjects Enrolled During Reporting Period:</u> <u>1</u>	
<u>Total Number of Subjects Enrolled to Date:</u> <u>1</u>	
<u>Date of Periodic Review</u> <u>9 Sep 88</u>	<u>Results</u> <u>Continue</u>

**Objective(s):** 1) To evaluate the response rate of advanced sarcomas treated with amonafide.

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

**Technical Approach:** Patients must have measurable, pathologically verified, advanced soft tissue sarcoma. Patients may not have mesothelioma, Kaposi's sarcoma or osteogenic sarcoma. Prior treatment is allowed if no more than one prior chemotherapeutic regimen for metastatic disease has been given.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8717 Status: Ongoing  
 Title: Evaluation of Amonafide and Didemnin-B in the Treatment of Ovarian Cancer.

Start Date 15 July 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Charles R. Harrison, MAJ, MC Kenneth Hancock, MAJ, MC
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 9 Sep 88	Results Continue

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8720 Status: Ongoing  
 Title: Evaluation of Amonafide in Pancreatic Adenocarcinoma

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8721      Status: Ongoing  
 Title: A Phase II Trial of Trimetrexate in the Treatment of Esophageal Cancer.

Start Date 13 Nov 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Esophageal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8723 Status: Ongoing  
 Title: Evaluation of Amonafide in Disseminated Malignant Melanoma Phase II.

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8726      Status: Ongoing  
 Title: Evaluation of Amonafide in Refractory and Relapsing Multiple Myeloma.

Start Date 15 July 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8728 Status: Ongoing  
 Title: Evaluation of Didemnin-B in Metastatic Adenocarcinoma of the Kidney, Phase II.

Start Date 22 Jan 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Kidney, Adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-seven patients were accrued to this study in four months for an accrual rate of 6.7 patients per month. The study is now closed for evaluation of response and toxicity.

To date, there are no ineligible patients. Three patients have eligibility pending clarification of the eligibility criteria.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWDG 8729      Status: Ongoing  
 Title: A Phase II Trial of Low Dose Pala and High Dose 5-FU as a Short Term  
 Infusion in the Treatment of Adenocarcinoma of the Pancreas.

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

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: Nineteen patients have been registered to this study between April 20, 1988 and June 30, 1988 for an accrual rate of 9.5 patients per month. This study was temporarily closed to patient accrual on June 15, 1988 for evaluation of response. If three or more responses are seen, the study will be reopened to allow 15 more patients to be accrued.

As of this writing, there are no ineligible patients and all patients are too early for evaluation of response or toxicity.

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8731 Status: Ongoing  
 Title: Ifosfamide and Mesna in Malignant Mesothelioma, Phase II.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Malignant 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 9 Sep 88 Results Continue	

Objective(s): 1) To assess the activity of Ifosfamide and the uroprotector 2-mercaptoethane sodium sulphionate (Mesna) in patients with unresectable malignant mesothelioma.

2) To further evaluate the toxicity pattern of continuous infusion Ifosfamide/Mesna.

Technical Approach: All patients must have a pathologically verified diagnosis of unresectable malignant mesothelioma of the pleura, peritoneum, pericardium, or paratesticular area. All patients must have bidimensionally objectively measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Seven patients have been registered since the study opened in March 1988. Most are too early for response or toxicity evaluation. Two of the three patients evaluable for toxicity have had Grade 4 leukopenia and granulocytopenia.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8732      Status: Ongoing  
 Title: Evaluation of Amonafide in Endometrial Carcinoma.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Charles R. Harrison, MAJ, MC Kenneth Hancock, MAJ, MC
Key Words: Carcinoma, Endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Technical Approach: Patients must have histologically proven incurable advanced metastatic or recurrent endometrial carcinoma. Disease must be bidimensionally measurable.

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 Nov 1988      Proj No: SWOG 8733      Status: Ongoing  
 Title: Evaluation of Operable Bladder Cancer Patients with Pre-Operative Irradiation + 5FU Alone, Phase II, a Pilot Study for Patients Ineligible for SWOG-8710.

Start Date	15 Jul 88	Est Comp Date:	
Principal Investigator:	Timothy J. O'Rourke, LTC, MC	Facility:	Brooke Army Medical Center
Dept/Svc:	Department of Medicine/Oncology	Associate Investigators:	Ian Thompson, MAJ, MC
Key Words:	Cancer, Bladder		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period:			0
Total Number of Subjects Enrolled to Date:			0
Date of Periodic Review	9 Sep 88	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 peivis and no evidence of spread beyond the regional lymph nodes at or below the level of the bifurcation of the iliac vessels. Patients must not have any prior pelvic irradiation, or prior malignancies which are active, or synchronous non-bladder malignancies other than basal or squamous cell carcinoma of the skin or any other carcinoma in situ. Patients with prior inactive malignancies are eligible.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8734      Status: Ongoing  
 Title: A Phase II Trial of Low Dose Pala and High Dose 5-FU as a Short Term  
 Infusion in the Treatment of Adenocarcinoma of the Stomach.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Stomach	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 Sep 88	Results Continue

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

Technical Approach: Patients must have verified advanced gastric adenocarcinoma that is objectively measurable. A central venous access placement is necessary prior to starting the therapy.

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 Nov 1988 Proj No: SWOG 8736 Status: Ongoing  
 Title: Treatment of Localized Non-Hodgkin's Lymphoma: comparison of  
 Chemotherapy (CHOP) to Chemotherapy plus Radiation Therapy.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	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: There is no reportable data available at this time.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8738      Status: Ongoing  
 Title: Treatment of Extensive Non-Small Cell Lung Cancer: Standard Dose  
 Cisplatin Versus High-Dose Cisplatin in Hypertonic Saline Alone Versus High-  
 Dose Cisplatin/Mitomycin-C.

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8742 Status: Ongoing  
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Metastatic Sarcoma.

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

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

2) To assess the tolerance and toxicity of rTNF.

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988	Proj No: SWOG 8743	Status: Ongoing
Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Metastatic Colorectal Adenocarcinoma.		

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Sep 88	Results Continue

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

2) To assess the tolerance and toxicity of rTNF.

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8755      Status: Ongoing  
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in  
 Patients with Pancreatic Adenocarcinoma.

Start Date	12 Aug 88	Est Comp Date:	
Principal Investigator:	Timothy J. O'Rourke, LTC, MC	Facility:	Brooke Army Medical Center
Dept/Svc:	Department of Medicine/Oncology	Associate Investigators:	Richard O. Giudice, MAJ, MC
Key Words:	Adenocarcinoma, 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	9 Sep 88	Results	Continue

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

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have histologically confirmed diagnosis of pancreatic adenocarcinoma. Patients must have bidimensionally measurable disease. Prior surgery and/or radiation therapy is acceptable. Patients must not have had prior chemotherapy.

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 Nov 1988 Proj No: SWOG 8760 Status: Ongoing  
 Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Gastric Adenocarcinoma.

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Gastric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

2) To assess the tolerance and toxicity of rTNF.

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8788      Status: Ongoing  
 Title: Phase III Evaluation of "High Dose" versus "Standard Dose" Cisplatin  
 Combined with Bleomycin and VP-16 for Advanced Metastatic Testicular Cancer.

Start Date 11 Mar 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988	Proj No: SWOG 8790	Status: Ongoing
Title: A Randomized Trial of Adjuvant Intraperitoneal Recombinant Interferon Alpha-2 in Stage III Ovarian Carcinoma in Patients who have no Evidence of Disease after Surgery and Chemotherapy.		

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	Results Continue

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 88 Proj No: SWOG 8792 Status: Ongoing  
 Title: Phase III Study of Alfa-n1 (Wellferon®) as Advanced Treatment for Resectable Renal Cell Carcinoma

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	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: Patients must have histologic proof of adenocarcinoma of the kidney in whom complete resection of the primary tumor has been performed with neither gross nor microscopic evidence of residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is an ECOG study with a combined total of 11 patients entered. No inordinate toxicities reported.

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8793      Status: Ongoing  
 Title: Randomized Phase III Evaluation of Hormonal Therapy versus Observation  
 in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic  
 Lymphadenectomy and Radical Prostatectomy.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988      Proj No: SWOG 8794      Status: Ongoing  
 Title: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy.

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988	Proj No: SWOG 8796	Status: Ongoing
Title: Combination Chemotherapy for Advanced Hodgkin's Disease, Phase III Intergroup.		

Start Date 22 Jan 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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: 1	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time

Detail Summary Sheet

Date: 1 Nov 1988 Proj No: SWOG 8804 Status: Ongoing  
 Title: Evaluation of Cis-Platinum and DTIC in Inoperable Stage III and Stage IV Melanoma, Phase II.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Melanoma, Inoperable	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Sep 88	Results Continue

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

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

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 1 Nov 1988 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 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: 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 9 Sep 88	Results Continue

Objective(s): 1) Evaluate, following three and six courses of treatment the likelihood of increased numbers of patients achieving complete response rates when given three additional courses of the same regimen.

2) Evaluate the qualitative and quantitative toxicities of 5-fluorouracil and cisplatin following three and six courses of treatment.

3) Evaluate by serial biopsy and flow cytometry the correlation of the cellular DNA parameters of degree of aneuploidy (DNA index) and proliferative activity (SPF) with patient clinical characteristics, tumor morphology, cytotoxic response, disease free interval and survival.

Technical Approach: Patients must have a histologically confirmed diagnosis of advanced unresectable squamous cell carcinoma of the head and neck Stages T4, N0-3, M0 or T2-3, N2-3, M0. Each patient will be examined by a multi-modality team prior to entry on study. Patients must be staged as having measurable disease within one week prior to entry on study.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG-26A      **Status:** TErminated

**Title:** Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

<b>Start Date:</b> FY 78	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Malignancy, pelvic	
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**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. There are 11 treatment arms still open on this study. They are 26C, 26D, 26N, 26O, 26Q, 26R, 26S, 26T, 26U, 26V, 26W.

**Progress:** This study remains open for the study of new Phase II drugs. No patients have been entered.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88		<b>Proj No:</b> GOG-34		<b>Status:</b> Terminated	
<b>Title:</b> A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II.					
<b>Start Date:</b> FY 78			<b>Est Comp Date:</b>		
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC			<b>Facility:</b> Brooke Army Medical Center		
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology			<b>Associate Investigators:</b>		
<b>Key Words:</b> Carcinoma, endometrial					
<b>Accumulative MEDCASE Cost:</b>			<b>Est Accumulative OMA Cost:</b>		
<b>Number of Subjects Enrolled During Reporting Period:</b>				0	
<b>Total Number of Subjects Enrolled to Date:</b>				2	
<b>Date of Periodic Review:</b> 8 May 1987				<b>Results:</b> Continue	

**Objective(s):** To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.

**Technical Approach:** All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I and Stage II occult, all grades, with one or more of the following high risk criteria are eligible: (1) all lesions equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Two patients remain on the study and are responding well.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG-40      **Status:** Terminated  
**Title:** A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas.

<b>Start Date:</b> FY 79	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Sarcoma, uterine	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

**Technical Approach:** All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Groupwide: The distribution by cell type shows dominance of mixed mesodermal tumors as found in earlier sarcoma protocols. There is a trend toward tumor size being a significant factor. No significant serious adverse effects have been encountered.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG-54      **Status:** Terminated

**Title:** Treatment of Women with Malignant Tumors of the Ovarian Stroma with Combination VCR, Dactinomycin and CTX (Phase III)

<b>Start Date:</b> FY85	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Ovarian Stroma	
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** 1) To evaluate the effectiveness of combined Vincristine, Dactinomycin, and Cyclophosphamide (VAC) in treatment of malignant tumors of the ovarian stroma in patients with residual, recurrent or advanced disease.

2) To confirm completeness of response to VAC treatment with restaging laparotomy.

3) To evaluate the endometrium histologically to learn more about the relationship between stromal tumors and endometrial cancer.

4) To learn more about hormonal effects in patients with stromal tumors.

**Technical Approach:** All patients with histologically confirmed malignant tumors of the ovarian stroma not amenable to cure by further surgery or radiation therapy 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:** 1 Oct 88      **Proj No:** GOG 55      **Status:** Terminated

**Title:** Hormonal Contraception and Trophoblastic Sequelae after Hydatidiform Mole (Phase III)

<b>Start Date:</b> FY85	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b>  Trophoblastic Sequelae	
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** To determine whether the administration of estrogen-progesterone oral contraceptives following the evacuation of a hydatidiform mole, and prior to the HCG titer reaching undetectable levels, affects the incidence of Trophoblastic sequelae requiring chemotherapy.

**Technical Approach:** All patients with a histologically verified diagnosis of hydatidiform mole evacuated by suction evacuation 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:** 1 Oct 88      **Proj No:** GOG 57      **Status:** Terminated

**Title:** A Study of Multiple Agent Chemotherapy with Methotrexate, Dactinomycin and Chlorambucil in the Treatment of "Poor Prognosis" Metastatic Gestational Trophoblastic Disease Phase II

<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Trophoblastic Disease	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 11 Sept 87	<b>Results:</b> Continue

**Objective(s):** To evaluate the effectiveness and toxicity of the standard triple agent chemotherapy with methotrexate, dactinomycin and chlorambucil (MAC) in patients with "poor prognosis" metastatic gestational trophoblastic disease (MGTD).

**Technical Approach:** Patients who have a diagnosis of metastatic gestational trophoblastic disease and an elevated HCG titer, who are considered "oor prognosis".

**Progress:** No patients have been entered on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88		<b>Proj No:</b> GOG 63		<b>Status:</b> Terminated	
<b>Title:</b> A Clinical-Pathological study of Stages IIB, III and IVA Carcinoma of the Cervix					
<b>Start Date:</b> FY 85			<b>Est Comp Date:</b>		
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC			<b>Facility:</b> Brooke Army Medical Center		
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology			<b>Associate Investigators:</b>		
<b>Key Words:</b> Carcinoma, Cervix					
<b>Accumulative MRDCASE Cost:</b>			<b>Est Accumulative OMA Cost:</b>		
<b>Number of Subjects Enrolled During Reporting Period:</b> 1					
<b>Total Number of Subjects Enrolled to Date:</b> 1					
<b>Date of Periodic Review:</b> 8 May 1987 <b>Results:</b> Continue					

**Objective(s):** 1) To evaluate the sensitivity and specificity of non-invasive procedures such as sonography, CT scan, and Lymphangiography in detection of metastases.

2) To better understand the significance of various surgical and pathological factors involved in staging and therapy for "advanced" cervical cancer. The accumulated clinical/surgical/pathological data may then play a role in modification or design of future protocols.

**Technical Approach:** All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the uterine cervix, clinical stages IIB through IVA, all cell types, will be eligible for this study.

**Progress:** One patient has been entered on this study.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG 66      **Status:** Terminated

**Title:** Ultrastructural, Staging, and Therapeutic Considerations in Small Cell Carcinoma of the Cervix (Phase II)

<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC:</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Small Cell Carcinoma, Cervix	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** 1) To determine the incidence of neuroendocrine carcinoma of the cervix in cases which are histologically classified as small cell carcinoma.

2) To determine the response rate to combination chemotherapy in patients with Stage IVB small cell carcinoma of the cervix and in patients with progressive local disease after radiation therapy.

**Technical Approach:** Patients with histologic diagnosis of small cell carcinoma of the cervix. A patient who has small cell carcinoma mixed with large cell keratinizing carcinoma or adenocarcinoma is eligible, providing that the small cell elements comprise 50% of the tumor.

**Progress:** No patients have been entered on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 71	<b>Status:</b> Terminated
<b>Title:</b> Treatment of Patients with Sub-Optimal ("Bulky") Stage IB Carcinoma of the Cervix: A Randomized Comparison of Radiation Therapy Versus Radiation Therapy plus Adjuvant Extradascial Hysterectomy Phase III.		
<b>Start Date:</b> FY 85	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Carcinoma, Cervix		
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	1	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b>	Continue

**Objective(s):** 1) Evaluation of the role of adjunctive extradascial hysterectomy in the treatment of suboptimal Stage IB carcinoma of the cervix with negative paraaortic and high common iliac nodes. 2) Evaluation of survival and patterns of failure in suboptimal IB cervical cancer. 3) The study of toxicity of a combined radiation and surgical therapeutic program. 4) Evaluation of the prognostic value of various surgical/pathological characteristics in suboptimal Stage IB carcinoma of the cervix. 5) To estimate the prevalence of various disease characteristics (e.g., positive para-aortic nodes) in suboptimal Stage IB carcinoma of the cervix.

**Technical Approach:** Patients with primary, untreated, histologically confirmed invasive carcinoma of the uterine cervix, suboptimal or bulky, FIGO stage IB, as confirmed by cervical cone biopsy and endometrial sampling are eligible for this study.

Therapy will follow the schema outlined in the study

**Progress:** One patient was entered on this study she died of disease on 2 Oct 86.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 72	<b>Status:</b> Terminated
<b>Title:</b> Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin		
<b>Start Date:</b> FY 85	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC:</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Cancer, Ovary		
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b> 1		
<b>Total Number of Subjects Enrolled to Date:</b> 1		
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue	

- 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. Patients must have undergone adequate surgical staging and any stage of disease from I-IV inclusive.

**Progress:** One patient has been registered on this study.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG 73      **Status:** Terminated

**Title:** A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy

<b>Start Date:</b> FY85	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Melanoma, Vulva	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** 1) To determine the relationship of histopathologic parameters (including microstaging of primary malignant melanoma of the vulva) to FIGO staging, nodal status and ultimate prognosis. 2) To ultimately recommend appropriate therapy for malignant melanomas of the vulva based on histopathologic and microstaging data.

**Technical Approach:** All patients receiving primary therapy for malignant melanoma of the vulva, including all histopathologic types and differentiation, and all FIGO stages. All patients must have at least a modified radical hemivulvectomy, as well as entered within 8 weeks of initiation of primary therapy

**Progress:** No patients have been registered on this study

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:**GOG 74      **Status:**Terminated

**Title:** Early Stage I Vulvar Carcinoma Treated with Ipsilateral Superficial Inguinal Lymphadenectomy and Modified Radical Hemivulvectomy (Phase II)

<b>Start Date:</b> FY 85	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Carcinoma, Vulvar	
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** 1) To document the rates and patterns of recurrence of patients with early Stage I vulvar carcinoma treated with ipsilateral superficial inguinal lymphadenectomy and modified radical hemivulvectomy.

2) To document the survival and recurrence-free interval in the same group of patients.

**Technical Approach:** All patients with primary, untreated, histologically confirmed squamous cell carcinoma of the vulva, Stage I, will be eligible for surgical treatment as "early superficially invasive carcinoma of the vulva" if: 1) a wide local excision with normal skin margins greater than 2 cm be performed. 2) There is only a single malignant lesion which measures 2 cm or less by largest diameter in vivo.

Therapy will follow the schema outlined in the study

**Progress:** No patients have been registered on this study.

Detail Summary Sheet

**Date:** 1 Oct 88                      **Proj No:**GOG 75                      **Status:** Terminated

**Title:** Postoperative Pelvic Radiation in Stage I and II Mixed Mesodermal Tumors of the Uterus (Phase III)

<b>Start Date:</b> FY 85	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Mesodermal Tumors, Uterus	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** To determine whether pelvic postoperative radiation therapy will decrease local and regional recurrence rates and improve median progression-free interval in patients with Stage I and II mixed mesodermal sarcomas of the uterus.

**Technical Approach:** Patients with primary clinical Stage I and II mixed mesodermal sarcomas of the uterus who have been entered on Protocol 40 and found to have disease confined to the pelvis which has been grossly resected.

Therapy will follow the schema outlined in the study

**Progress:** No patients have been registered on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> G0G 77	<b>Status:</b> Terminated
<b>Title:</b> A Randomized Study of Carboplatin Versus CHIP in Advanced Carcinoma of the Cervix		
<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Carcinoma, Cervix		
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b> 0		
<b>Total Number of Subjects Enrolled to Date:</b> 0		
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue	

**Objective(s):** 1) to determine the objective response rate of squamous cell carcinoma of the cervix to Carboplatin and to CHIP. 2) To determine in a randomized study whether Carboplatin or CHIP has a superior (statistically significant) objective response rate in cervical carcinoma. 3) To assess and compare toxicity (gastrointestinal and renal) of Carboplatin and CHIP.

**Technical Approach:** Patients who have histologically confirmed, locally advanced, recurrent, persistent or metastatic squamous cell carcinoma of the cervix, which is resistant to curative treatment with surgery or radiotherapy. Eligible patients must have lesions which are measurable or evaluable by physical examination. Measurement by CT scan will be accepted if the lesion is greater than 1 cm and is sharply defined.

Therapy will follow the schema outlined in the study

**Progress:** No patients have been registered on this study

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 78	<b>Status:</b> Terminated
<b>Title:</b> Evaluation of Adjuvant Vinblastine, Bleomycin, and Cisplatin Therapy in Totally Resected Choriocarcinoma, Endodermal Sinus Tumor, or Embryonal Carcinoma of the Ovary		
<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Carcinoma, ovary		
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue	

- Objective(s):**
- 1) To evaluate the effect of adjuvant vinblastine, bleomycin, and cisplatin (VBP) chemotherapy in patients with endodermal sinus tumor and choriocarcinoma of the ovary (pure and mixed) after removal of all gross tumor.
  - 2) To evaluate the role of serum markers, especially alpha fetoprotein (AFP) and human chorionic gonadotropin (HCG) when these are present initially in predicting recurrence.
  - 3) To evaluate the role of reassessment laparotomy in determining response, detecting early relapse and planning further therapy.
  - 4) To compare the biologic behavior of pure endodermal sinus tumors with mixed germ cell tumors containing endodermal sinus elements.

**Technical Approach:** Patients with histologically confirmed Stage I choriocarcinoma, endodermal sinus tumor or embryonal carcinoma of the ovary, pure or mixed with other elements, if totally resected are eligible. Patients with Stage II and Stage III disease are also eligible if all gross tumor has been resected. The serum AFP and Beta-HCG levels should be normal or falling at a

**Progress:** No patients have been registered on this study.

Detail Summary Sheet

**Date:** 1 Oct '88      **Proj No:** GOG 79      **Status:** Terminated  
**Title:** Single Agent Weekly Methotrexate Therapy in the Treatment of Nonmetastatic Gestational Trophoblastic Disease

<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Gestational Trophoblastic Disease, nonmetastatic	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** 1) To determine the efficacy of weekly methotrexate therapy for nonmetastatic gestational trophoblastic disease. 2) To ascertain the toxicity of this regimen. 3) To demonstrate the cost effectiveness of this regimen.

**Technical Approach:** Patients with nonmetastatic gestational trophoblastic disease with antecedent molar pregnancy of post-abortal status who meet the criteria outlined in Section 3.11 of the Study protocol.

**Progress:** No patients have been registered on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 81-A	<b>Status:</b> Terminated
<b>Title:</b> Master Protocol for Hormonal Treatment of Advanced or Recurrent Carcinoma of the Endometrium		
<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Carcinoma, Endometrium		
<b>Accumulative MEDCARE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue	

**Objective(s):** 1) To determine the relative efficacy of two dose schedules of oral MPA in the management of advanced or recurrent endometrial carcinoma.

2) To examine the relationship between the levels of estrogen and progesterone receptors in the neoplasm and subsequent response to progestin therapy.

3) To determine whether patients who respond to therapy with progestins will respond to therapy with anti-estrogens when they relapse on progestins.

**Technical Approach:** Patients must have histologically confirmed advanced, persistent or recurrent endometrial carcinoma with documented disease progression after local therapy.

There are five treatment arms open for this study they are: 81-B, 81-C, 81-D, 81-E, and 81-F.

Therapy will follow the schema outlined in the study protocol.

**Progress:** No patients have been registered on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 82	<b>Status:</b> Terminated
<b>Title:</b> A Phase III Trial Comparing Combination Chemotherapy (CAP) with Whole Abdominal Radiation Therapy for Stage III Optimal Epithelial Ovarian Cancer with no Gross Residual Disease or Gross Residual Disease Equal to or Less than 1 cm.		
<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Cancer, ovary		
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue	

**Objective(s):** 1) To compare survival and progression-free interval of patients with epithelial ovarian cancer, treated either with adjuvant whole abdominal and pelvic irradiation or combination chemotherapy.

2) To determine the influence of grade, histology and treatment in patterns of failures.

3) To compare the acute and late sequelae of adjuvant radiation therapy and chemotherapy.

**Technical Approach:** Patients with previously untreated Stage III ovarian carcinoma with gross residual disease equal to or less than 1 cm greatest diameter or no gross residual disease after initial surgery. Histologic types include all epithelial cancer (serous, mucinous, endometrioid, clear cell, Brenner and undifferentiated).

Therapy will follow the schema outlined in the study

**Progress:** No patients have been enrolled on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88		<b>Proj No:</b> GOG 83		<b>Status:</b> Terminated	
<b>Title:</b> a Clinico-Pathologic Study of Simultaneous Endodermal and Ovarian Carcinomas					
<b>Start Date:</b> FY 86			<b>Est Comp Date:</b>		
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC			<b>Facility:</b> Brooke Army Medical Center		
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology			<b>Associate Investigators:</b>		
<b>Key Words:</b> Cancer, endometrial & ovarian simulataneous					
<b>Accumulative MEDCASE Cost:</b>			<b>Est Accumulative OMA Cost:</b>		
<b>Number of Subjects Enrolled During Reporting Period:</b>				0	
<b>Total Number of Subjects Enrolled to Date:</b>				0	
<b>Date of Periodic Review:</b> 8 May 1987				<b>Results:</b> Continue	

**Objective(s):** 1) To determine the natural history of patients with synchronous adenocarcinoma presenting in both the endometrium and the ovary; to obtain estimates of mortality at five years.

2) To determine whether histologic criteria or pattern of spread can be used to distinguish subsets of patients with differing prognosis.

3) To determine whether these criteria would be appropriate to direct therapy in different patients to that appropriate for Stage III endometrial carcinoma, Stage I or II ovarian carcinoma with endometrial metastases, or stage I or II endometrial metastases, or stage I or II endometrial and ovarian carcinoma.

**Technical Approach:** Patients must have had surgical-pathological identification of the carcinomas in the uterine corpus and ovary within a period of no more than eight weeks, and must be entered no later than four weeks after the last surgical procedure required to complete the identification.

Therapy will follow the schema outlined in the study

**Progress:** No patients have been enrolled on this study.

Detail Summary Sheet

**Date:** 1 Oct 88                      **Proj No:**GOG 84                      **Status:** Terminated

**Title:** Evaluation of a Shortened course of Vincristine, Dactinomycin and Cyclophosphamide (VAC) as Adjuvant therapy for Immature Teratoma of the Ovary Stage I, Grade 2, Completely Resected Phase II

<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Immature Teratoma, Ovary	
<b>Accumulative MEDCASH Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b>	<b>Results:</b>

**Objective(s):** To evaluate vincristine, dactinomycin, and cyclophosphamide (VAC) given in a shortened course as adjuvant chemotherapy for Stage I Grade 2 immature teratomas of the ovary following removal of all gross tumor.

**Technical Approach:** Patients with histologically confirmed immature teratoma of the ovary, Stage I, Grade 2 if they been completely resected and are previously untreated are eligible.

**Progress:** No patients have been entered on this study.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG 86-A      **Status:** Terminated

**Title:** Master Protocol for Phase II Drug Studies in Treatment of Advanced or Recurrent Carcinoma of the Endometrium

<b>Start Date:</b> FY 86	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Advanced, Recurrent Carcinoma, Endometrium	
<b>Accumulative MRCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b> 8 May 1987	<b>Results:</b> Continue

**Objective(s):** 1) This study seeks to identify additional active agents by studying single new drugs in patients with advanced or recurrent endometrial carcinoma not previously exposed to chemotherapy.

**Technical Approach:** This is a study of multiple chemotherapeutic agents

Therapy will follow the schema outlined in the study

There is three treatment arms open on this study 86-B, 86-D, 86-E

**Progress:** No patients have been enrolled on this study.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 87A	<b>Status:</b> Terminated
<b>Title:</b> Master Protocol for Phase II Drug Studies in the Treatment of Recurrent or Advanced Uterine Sarcomas		
<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Uterine, Sarcomas		
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	0	
<b>Date of Periodic Review:</b>	<b>Results:</b>	

**Objective(s):** To allow the best possible chance for a new cytotoxic agent to demonstrate activity, this study constitutes a Phase II design in a population of patients who have had no prior drug therapy.

**Technical Approach:** There is one treatment arm open 87-B

**Progress:** No patients have been entered on this protocol.

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 88	<b>Status:</b> Terminated
<b>Title:</b> A Randomized Study of Radical Vulvectomy and Bilateral Groin Dissection versus Radical Vulvectomy and Bilateral Groin Radiation		
<b>Start Date:</b> FY 88	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Cancer, Vulva		
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	0	
<b>Date of Periodic Review:</b>	<b>Results:</b>	

**Objective(s):** To evaluate the comparative efficacy and morbidity of groin radiation therapy in lieu of groin dissection for selected patients with invasive squamous cell carcinoma of the vulva.

To monitor patterns of recurrence and survival of patients treated with groin radiation therapy in lieu of groin dissection. Dissection Versus Radical Vulvectomy and Bilateral Groin Radiation (Phase III)

**Technical Approach:** Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma of the vulva clinically determined to be Stage I through III that radical vulvectomy would suffice to remove all of the primary lesion. Patients whose histological cell type is invasive squamous cell carcinoma of the vulva.

**Progress:** No patients have been registered on this study

Detail Summary Sheet

<b>Date:</b> 1 Oct 88	<b>Proj No:</b> GOG 90	<b>Status:</b> Terminated
<b>Title:</b> Evaluation of Cisplatin, Etoposide and Bleomycin (BEP) Induction followed by Vincristine Dactinomycin and Cyclophosphamide (VAC) Consolidation in Advanced Ovarian Germ Cell Tumors		
<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>	
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center	
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>	
<b>Key Words:</b> Germ Cell Tumor, Ovary		
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>	
<b>Number of Subjects Enrolled During Reporting Period:</b>	0	
<b>Total Number of Subjects Enrolled to Date:</b>	0	
<b>Date of Periodic Review:</b>	<b>Results:</b>	

**Objective(s):** To evaluate the effect of induction chemotherapy with cisplatin plus etoposide plus bleomycin (BEP) followed by consolidation with vincristine plus dactinomycin plus cyclophosphamide (VAC) in previously untreated patients with advanced ovarian germ cell tumors.

To evaluate the effect of BEP chemotherapy in patients with recurrent or progressive disease during or after previous non-cisplatin containing chemotherapy.

**Technical Approach:** Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage II-IV) disease incompletely resected, including patients with dysgerminoma. Patients with incompletely resected Stage II disease.

**Progress:** No patients have been entered on this study.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:**GOG 93      **Status:** Terminated

**Title:** Evaluation of Intraperitoneal Chromic Phosphate Suspension Therapy following Negative Second-look Laparotomy for Epithelial Ovarian Carcinoma

<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Carcinoma, Ovary	
<b>Accumulative MRDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b>	<b>Results:</b>

**Objective(s):** the purpose of this protocol is to evaluate the role of intraperitoneal chromic phosphate suspension 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 who are in complete clinical remission.

**Progress:** No patients have been entered on this protocol.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG 94      **Status:** Terminated

**Title:** A Phase II Study of the Treatment of Stage III and IV Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serous Carcinoma and Clear Cell Carcinoma of the Endometrium with Total Abdominal Radiation Therapy.

<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Carcinoma, Endometrial	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b>	<b>Results:</b>

**Objective(s):** To determine the survival and progression-free interval of patients with maximally debulked advanced endometrial carcinoma treated with abdominal radiation therapy.

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:** All patients with primary endometrial carcinoma, all histologic types, all clinical and surgical Stage III and IV disease

**Progress:** No patients have been entered on this study.

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:**GOG 99      **Status:** Terminated

**Title:** A Phase III Randomized Study of Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma

<b>Start Date:</b> FY 87	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> adenocarcinoma, Endometrial	
<b>Accumulative MEDCARE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 0	
<b>Date of Periodic Review:</b>	<b>Results:</b>

**Objective(s):** To determine if patients with intermediate risk endometrial adenocarcinoma who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy. To evaluate how the addition of pelvic radiotherpay will alter the site and rate of cancer recurrence in these intermediate risk patients.

**Technical Approach:** Patients with primary histologically confirmed Grades 2 and 3 endometrial adenocarcinoma (endometrioid, villoglandular, mucinous and adenosquamous).

**Progress:** No patients have been entered on this protocol

Detail Summary Sheet

**Date:** 1 Oct 88      **Proj No:** GOG 7602      **Status:** Terminated

**Title:** Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer.

<b>Start Date:</b> FY 80	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Thomas W. Burke, M.D., MAJ, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/SVC</b> GYN-ONC SVC Department of Obstetrics-Gynecology	<b>Associate Investigators:</b>
<b>Key Words:</b> Cancer, ovary	
<b>Accumulative MEDCASE Cost:</b>	<b>Est Accumulative OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 1	
<b>Date of Periodic Review:</b>	<b>Results:</b>

**Objective(s):** 1) To define the natural history (relapse rate, relapse sites, relapse free survival, regression rate, duration of regression of patients treated by surgery plus either chemotherapy or chemotherapy plus radiation therapy.

2) To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

**Technical Approach:** All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous or one of the types identified in Appendix I of the study protocol. After a definitive staging procedure, if the patient is Stage II-A, II-B, II-C, I-Aii, I-Bii, or IAi or IBi with poorly differentiated tumors, she is eligible for the study. The patient must have had no previous treatment except surgical therapy.

Therapy will follow the schema outlined in the study

**Progress:** One patient has been enrolled on this study and continues to do well. This study has been closed to new patient accrual.

Detail Summary Sheet

Date: 22 Nov 88                      Proj No: POG 7799                      Status: Ongoing  
 Title: Rare Tumor Registry for Childhood Solid Tumor Malignancies.

Start Date 25 Sep 81 Principal Investigator Paul J. Thomas, M.D., COL, MC Dept/Svc Department of Pediatrics Key Words: Solid tumor malignancies	Est Comp Date: Facility Brooke Army Medical Center Associate Investigators: Allen R. Potter, LTC, MC
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 12 Feb 88                      Results Continue	

Objective(s): 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: One patient remains on this study. No reportable data are available.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8104                      Status: Ongoing  
 Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start Date 27 Jan 83	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 12 February 1988	Results Continue

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

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

Progress: Two patients remain on the study. Three have been transferred to other areas. One patient transferred here on this study relapsed.

Detail Summary Sheet

Date: 18 Nov 88                      Proj No: POG 8303                      Status: Completed  
 Title: Combination Chemotherapy for First Bone Marrow and/or Testicular  
 Relapse of Childhood Acute Lymphoblastic Leukemia (ALL) During or Shortly  
 Following Initial Continuation Therapy, Phase III.

Start Date 27 Dec 83	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 February 1988                      Results Closed	

Objective(s): 1) To determine if intensive early therapy with a 4-drug rein-  
 duction regimen immediately followed by consolidation therapy is more effective  
 than reinduction regimens used in the past for patients with ALL or lympho-  
 blastic lymphoma who relapse on or shortly following termination of initial  
 continuation therapy.

2) To assess the efficacy and toxicity of continuous and alternating main-  
 tenance therapy during second remission with 2 drug pairs not used during first  
 remission: VM-26 plus Ara-C and vincristine plus cyclophosphamide.

3) To determine the effectiveness and toxicity of periodic 4 drug reinduction  
 therapy (reinforcement) throughout second remission.

Technical Approach: Patients less than 21 years of age who develop their first  
 marrow relapse or overt clinical testicular relapse during initial continuation  
 chemotherapy are eligible. Children with CNS relapse accompanying marrow and/or  
 testicular relapse are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on this study continues to do well. The study  
 has been closed to new entries.

Detail Summary Sheet

Date: 28 Nov 88		Proj No: POG 8304		Status: Ongoing	
Title: SIMAL #4. Combination Chemotherapy for Remission Induction and Maintenance for: 1) Recurrent Childhood Lymphocytic Leukemia After Elective Cessation of Therapy; 2) Children with Occult Testicular Leukemia After 3 Years of Continuous Complete Remission.					
Start Date 27 Jan 84			Est Comp Date:		
Principal Investigator Paul J. Thomas, M.D., COL, MC			Facility Brooke Army Medical Center		
Dept/Svc Department of Pediatrics			Associate Investigators: Allen R. Potter, LTC, MC		
Key Words: Leukemia, lymphocytic					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: 0					
Total Number of Subjects Enrolled to Date: 0					
Date of Periodic Review 12 February 1988 Results Continue					

Objective(s): 1) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in children with ALL, who relapse 6 months or greater, after elective cessation of chemotherapy.

2) To evaluate the effectiveness of prophylactic intrathecal chemotherapy, during the second remission.

3) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in patients with testicular leukemia.

4) To determine the effectiveness of two regimens of cyclic maintenance chemotherapy in children with isolated CNS relapse.

Technical Approach: Patients less than 21 years of age with pathologic verification of leukemic relapse at any site more than six months after elective cessation of initial therapy are eligible. Children with their first CNS relapse are also eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8315 Status: Ongoing  
 Title: Laboratory Study and Subclassification of Non-Hodgkin's Lymphoma.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 12 February 1988	Results Continue

Objective(s): 1) To provide a mechanism for the group wide study of biologic characteristics of lymphoma cells, by acquisition and coordination of data from reference laboratories.

2) To seek correlates of biologic characteristics, with histopathology, clinical presentation, and end results of protocol therapies.

3) To attempt the development of a comprehensive classification of childhood NHL which is both clinically and biologically relevant.

Technical Approach: Patients less than 21 years of age with tumor tissue or cells available for study who are simultaneously being entered on open, front-end POG treatment protocols for NHL are eligible for this study.

Progress: Two patients have been entered on study with satisfactory samples for classification.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8319                      Status: Completed  
 Title: Allogeneic Bone Marrow Transplantation for Acute Lymphoblastic Leukemia  
 in 2nd Hematologic Remission.

Start Date 27 Mar 84	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988                      Results Closed	

Objective(s): To study the feasibility of cytosine arabinoside (ara-C), used in high dosage in conjunction with fractionated total body irradiation, followed by allogeneic or syngeneic bone marrow transplantation, in achieving long-term disease-free survival of children with acute lymphoblastic leukemia in second hematologic remission.

Technical Approach: Patients less than 21 years of age with a diagnosis of ALL verified by examination of diagnostic bone marrow, who have suffered their first bone marrow relapse while on therapy with an established POG ALL frontline protocol are eligible. Patients will be in complete remission, without evidence of leukemia either in the bone marrow or estramedullary sites.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entires.

Detail Summary Sheet

Date: 28 Nov 88	Proj No: POG 8340	Status: Ongoing
Title: Allogeneic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study		

Start Date 12 Aug 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics/Medicine	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC John J. Posch, Jr. Barbara Reeb
Key Words: Transplantation, bone marrow, autologous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review 12 February 1988      Results Continue	

Objective(s): 1) To determine the response rate and duration of patients aged > 1 year with metastatic (Stage D) neuroblastoma to intensive chemotherapy and fractionated total body irradiation followed by allogeneic or autologous bone marrow transplantation (BMT) performed in first clinical remission.

2) To determine the response rate and duration using the same regimen in patients with Stage D neuroblastoma who fail to respond to, or recur after, conventional chemotherapy.

3) To determine the toxicity of the above regimen.

Technical Approach: This pilot study tests the efficacy and toxicity of high dose melphalan and fractionated total body irradiation supported by allogeneic or autologous BMT for neuroblastoma in first clinical remission or following relapse.

Bone marrow aspiration and therapy will follow the schema outlined in the study protocol.

Progress: Eighteen patients have been transplanted. There have been 4 early deaths (2 infection, 1 veno occlusive disease and infection, and 1 pulmonary hemorrhage), 13 successful engraftments, and 1 partial engraftment. Overall disease free survival is 6/18 (33%). Overall survival is 7/18 (39%). Disease free survival for patients transplanted when in complete response 3/7 (43%) and 3/11 (27%) for patients transplanted not in complete response.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8346                      Status: Completed  
 Title: Comprehensive Therapy for Ewing's Sarcoma: Tailored versus Standard Radiation Therapy, Phase III.

Start Date 27 Mar 84	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Ewing's sarcoma	
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 12 February 1988                      Results Closed	

Objective(s): To improve disease free survival in patients with Ewing's sarcoma utilizing a multidisciplinary approach.

Technical Approach: Patients with newly diagnosed, histologically verified Ewing's sarcoma are eligible. Patients must not have received previous chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered had recurrence of the tumor and died. The study has been closed to new entries.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8426                      Status: Completed  
 Title: Intensive Chemotherapy (MOPP-ABVD) Plus Low Dose Total Nodal Radiation  
 Therapy in the Treatment of Stages IIB, IIIB, IV Hodgkin's Disease in Pediatrics

Start Date 26 Mar 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: 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: 2	
Date of Periodic Review 12 February 1988	Results Closed

Objective(s): 1) To determine the feasibility of Administering low dose TNRT to patients who have received 8 courses of MOPP-ABVD.

2) To determine the rapidity and completeness of clinical remission (CR) in patients treated initially by a non-cross resistant CT regimen, given in an alternating fashion, followed by reduced dose TNRT.

3) To determine the effect of combined modality therapy on splenic function as determined by the pitted erythrocyte count using Normarski optics.

Technical Approach: Patients <21 years of age, with histologically proven Hodgkin's disease, previously untreated with the exception of radiation therapy for airway obstruction or spinal cord compression, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient completed therapy and is doing well. One patient refused further therapy with ABVD and was removed from protocol. The study has been closed to new entries.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8451                      Status: Ongoing  
 Title: Intergroup Rhabdomyosarcoma Study III

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 12 February 1988                      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 extrasosseous Ewing's sarcoma, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient died after multiple relapses of the tumor. One patient continues to do well.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8493 Status: Ongoing  
 Title: Infant Leukemia Protocol

Start Date 26 Mar 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia	
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 12 February 1988 Results Continue	

Objective(s): 1) To establish the qualitative and quantitative toxicity of this regimen in infants and to determine criteria for dose modification in infants.

2) To obtain an estimate of survival and disease-free survival in infants <12 months of age treated with intensive chemotherapeutic regimen.

Technical Approach: Patients with ALL (or undifferentiated leukemia) <12 months of age at diagnosis are eligible. All patients must comply with immunologic and cytogenetic criteria for diagnosis according to POG front line ALinC classification studies and must be registered on that study as well as this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8495 Status: Completed  
 Title: A Phase I Study of Hyperfractionation in Brain Stem Gliomas in Children

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Glioma	
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 12 February 1988	Results Closed

Objective(s): 1) To test the feasibility of treating children with brain stem gliomas with hyperfractionated (twice daily) radiotherapy.

2) To study the immediate and late side effects of such treatment.

3) To test the feasibility of escalation of the dose of radiotherapy in this situation.

4) To monitor the response of the patients in terms of tumor regression, disease free interv.1, and length of survival.

Technical Approach: Patients  $\geq 3$  and  $\leq 21$  years of age with a previously untreated tumor arising in the mesencephalon, pons, including the cerebellar peduncles and floor of the IVth ventricle, and medulla oblongata and with a life expectancy of greater than 6 weeks, shall be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into the study. The study has been closed to new entries.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8498                      Status: Completed  
 Title: Treatment of Children with Newly Diagnosed Acute Non-Lymphoblastic  
 Leukemia (ANLL) Using High-Dose Cytosine Arabinoside and Etoposide + 5 Azacyta-  
 cine for Intensificaiton of Early Therapy

Start Date 28 Mar 86	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, non-lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 February 1988                      Results Continue	

Objective(s): 1) To explore the feasibility of utilizing sequential courses of high dose cytosine arabinoside (HdA) + L-Asparaginase (L-Asp) and Etoposide (VP) + 5 Azacytidine (5-Az) for intensification of early therapy immediately following remission induciton with Daunomycin, Ara-C, and 5-Thioguanine (DAT) in children with ANLL.

2) To determine the immediate and delayed toxicity of intensification therapy that incorporates the above combination of drugs (HdA + Asp + VP + Az) during remission in children with ANLL.

Technical Approach: Therapy will follow the schema outlined in the study proto-  
 col.

Progress: One patient was entered on study. He failed to achieve remission after one first course of chemotherapy and died of complications of infection. One patient was transferred here on this study. She completed therapy and has had no sign of recurrence.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8532 Status: Ongoing  
 Title: Treatment of Intracranial Ependymomas

Start Date 31 May 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Ependymoma	
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 12 February 1988	Results Continue

Objective(s): To estimate the occurrence of subarachnoid seeding in children with well differentiated, IVth ventricular ependymoma following resection and posterior foss irradiation.

Technical Approach: Patients  $\geq 24$  months and  $\leq 21$  years with histologically confirmed primary intracranial ependymomas or ependymblastoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8552                      Status: Ongoing  
 Title: A Case-Control Study of Childhood Rhabdomyosarcoma

Start Date 31 May 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 February 1988                      Results Continue	

- Objective(s): 1) To evaluate the relationships between environmental exposures and childhood rhabdomyosarcoma (RMS).
- 2) To evaluate associations between gestational factors and childhood RMS.
  - 3) To evaluate the role of genetic factors in the etiology of childhood RMS.
  - 4) To develop new methods for using subjects from collaborative cancer clinical trials for etiologic research.

Technical Approach: This is a case-control study of childhood RMS which will identify its cases from a large national collaborative clinical trial. The study will reexamine several promising hypotheses suggested by the preliminary study of RMS.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8561 Status: Ongoing  
 Title: Phase II Study of 6-Mercaptopurine Administered as an Intravenous  
 Infusion for Malignant Solid Tumors and Acute Leukemia

Start Date 2 Aug 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Solid Tumors Acute leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988 Results Continue	

Objective(s): 1) To determine response rate of children with advanced malignatn disease for whom no effective anti-cancer therapy is known to treatment with 6-mercaptopurine (6-MP) administered as a 48 hour IV infusion.

2) To further assess the toxicity in a larger group of children.

Technical Approach: Patients must be  $\leq$  21 years of age with a measurable solid tumor or acute leukemia with either an M3 marrow or extra medullary disease. The diagnosis must be confirmed by appropriate histologic examination.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8594                      Status: Completed  
 Title: Pilot Protocol for Marrow Relapse on Continuation Therapy in Childhood  
 Acute Lymphoblastic Leukemia

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, acute lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 February 1988                      Results Closed	

Objective(s): In this pilot study, VM-26 will be used as a biochemical modulator of methotrexate (MTX) in children with acute lymphoblastic leukemia (ALL) and marrow relapse while on continuation chemotherapy. A parallel pilot study using interferon as a biological response modifier in place of the combination VM-26/MTX will be run concurrently.

Technical Approach: Children and adolescents under 21 years at diagnosis with acute lymphoblastic or undifferentiated leukemia are eligible. They must have a minimal life expectancy of one month.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient was entered on this protocol and developed a brief remission, relapsed and died.

Detail Summary Sheet

Date: 28 Nov 88      Proj No: POG 8600/01/02      Status: Ongoing  
 Title: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia in Childhood  
 (AlinC #14) - A Pediatric Oncology Group Phase III Study

Start Date 28 Mar 86	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, lymphoid	
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 12 February 1988	Results Continue

Objective(s): 1) To test the concept that intensive asparaginase (ASP) therapy, designed to maintain low asparagine levels for the first six months of maintenance will improve the outcome of patients with standard risk acute lymphocytic leukemia (ALL) when added to pulses of intermediate dose methotrexate (MTX), as compared to intensification with IDM alone.

2) To study the effectiveness in standard risk patients of intensification with a potentially synergistic or additive drug pair, i.e., IDM plus AraC, as compared to that of intensification with IDM pulses alone.

3) To determine if administering a pulse of IDM + AraC at 3 week intervals during the first 4 months of complete remission in children with ALL is superior to administering the same number of IDM + AraC pulse at 23-week intervals during the first 2 years of complete remission in children with ALL with either "lower" or "higher" risk of relapse.

4) To obtain further information on the immediate and delayed toxicity of the continuation of chemotherapy program that incorporates these combinations of MTX and AraC or MTX and ASP in moderately high doses.

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

Progress: All patients have entered into a satisfactory remission and have remained in remission. One patient was transferred here and is continuing on therapy.

Detail Summary Sheet

Date: 28 Nov 88	Proj No: POG 8615	Status: Ongoing
Title: A Phase III Study of Large Cell Lymphomas in Children and Adolescents: A Comparison of Two Treatment Regimens - ACOP+ vs AOP		

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
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 12 February 1988      Results Continue	

- Objective(s):
- 1) To determine the influence of alkylating agent (cyclophosphamide) therapy in advanced-stage large cell lymphomas in children and adolescents, by comparing in a randomized prospective study the efficacy and toxicity of a modified ACOP+ versus a modified APO regimen.
  - 2) To reduce the adverse effects of treatments by elimination of involved field and cranial radiation in the treatment of large cell lymphomas.
  - 3) To evaluate the adequacy of one year of total therapy for advanced large cell Non-Hodgkin's lymphoma (NHL).
  - 4) To study clinical pathologic patterns and biologic characteristics of large cell lymphomas in children and adolescents.

Technical Approach: Previously untreated patients under 21-years of age, available for periodic follow-up are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8616                      Status: Ongoing  
 Title: Intensive Chemotherapies for Stage III Diffuse Undifferentiated Lymphoma  
 (DU NHL Burkitt and Non-Burkitt)

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
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 12 February 1988                      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: 28 Nov 88 Proj No: POG 8617 Status: Ongoing  
 Title: Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, acute lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 February 1988 Results Continue	

Objective(s): 1) To estimate the complete remission (CR) rate in patients with Stage IV diffuse undifferentiated non-Hodgkin's Lymphoma (DU NHL) and B-Cell acute lymphocytic leukemia (B-ALL) with a new schedule of administration of 3 active agents: "split-dose" cyclophosphamide (cyclo) - Adriamycin (Adria) + vincristine (VCR).

2) To estimate the chemotherapeutic cure rate in Stage IV DU NHL and B-ALL with a brief (6 month) intensive rotational chemotherapy program designed to confer greater protection against central nervous system (CNS) disease and marrow relapse.

3) To estimate the reinduction rate and disease-free survival rate for patients in relapse with non-lymphoblastic lymphoma.

Technical Approach: Patients must be under 21 years of age at time of initial diagnosis in order to be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on study had an initially good response but relapsed after about six months and died.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8625/26 Status: Ongoing  
 Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA<sub>1</sub> Hodgkin's Disease in Pediatric Patients

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
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: 1	
Date of Periodic Review 12 February 1988	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: One patient has been entered and has completed treatment and is continuing to do well.

Detail Summary Sheet

Date: 28 Nov 88		Proj No: POG 8631		Status: Ongoing	
Title: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs Standard Dose Irradiation - A Phase III Study.					
Start Date 27 Mar 87			Est Comp Date:		
Principal Investigator Paul J. Thomas, COL, MC			Facility Brooke Army Medical Center		
Dept/Svc Department of Pediatrics			Associate Investigators: Allen R. Potter, LTC, MC		
Key Words: Medulloblastoma					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: 0					
Total Number of Subjects Enrolled to Date: 0					
Date of Periodic Review 12 February 1988      Results Continue					

Objective(s): 1) To determine patterns of recurrence, disease free survival, and survival in patients with favorable prognosis medulloblastoma who receive a neuraxis dose of 2340 rad compared to those who receive 3600 rad.

2) To study the quality of survival obtained by decreasing the dose of radiotherapy to cerebrum and spinal cord.

3) To evaluate prospectively the central nervous system (CNS) functions of these children with IQ tests, CT scans, neurological examinations, psychometric testing and neuroendocrine tests.

Technical Approach: Patients  $\geq 36$  months and  $< 21$  years of age at diagnosis are eligible. Patients must have no evidence of dissemination beyond the posterior fossa confirmed by myelogram, chest x-ray, bone scan, bone marrow and CSF exam, i.e. M<sub>0</sub>.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8633/34 Status: Ongoing  
 Title: Treatment of Children 3 years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988	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.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8638                      Status: Ongoing  
 Title: Randomized Phase II Study of Carboplatin (CBCDA) vs CHIP in the Treatment of Children with Progressive or Recurrent Brain Tumors

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988	Results Continue

Objective(s): 1) To determine the effectiveness of Carboplatin (CBCDA) and CHIP in the treatment of children with progressive or recurrent brain tumors.  
 2) To compare the toxicities associated with the use of each agent.

Technical Approach: To be eligible for this study, the patient must be <21 years of age at initial diagnosis, with a recurrent or progressive brain tumor, and who has not been entered on more than one phase II new agent study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8650 Status: Ongoing  
 Title: National Wilms' Tumor Study - 4: Stage I/Favorable or Anaplastic  
 Histology

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Wilms' tumor	
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 12 February 1988 Results Continue	

Objective(s): To gain a better understanding of the Wilms' tumor by gathering detailed information regarding gross and histologic morphology and to correlate this information with treatment and clinical outcome.

Technical Approach: Patients will be randomized according to stage and histology.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered as a "followed" patient because the primary was non-resectable. Two additional patients were transferred here as "followed" patients. Two patients have relapsed while on therapy.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8651                      Status: Ongoing  
 Title: Osteosarcoma #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Non-Metastatic Osteosarcoma.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988	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: 28 Nov 88 Proj No: POG 8653/54 Status: Ongoing  
 Title: A Study of Soft Tissue Sarcomas Other than Rhabdomyosarcoma and Its Variants

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988	Results Continue

Objective(s): 1) To determine whether adjuvant chemotherapy with vincristine, Adriamycin, cyclophosphamide, and actinomycin D (VACA) increases the relapse-free survival (RFS) of patients with localized soft tissue sarcoma (STS) who are in complete response (CR) status after surgery with or without postoperative radiation.

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

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

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8661                      Status: Ongoing  
 Title: Evaluation of CHIP in Malignant Solid Tumors, A Phase II Study

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988                      Results Continue	

Objective(s): 1) To evaluate the response rate to CHIP in patients with recurrent malignant tumors resistant to conventional therapy.  
 2) To evaluate the toxicity of CHIP in these patients.

Technical Approach: To be eligible for this study, the patient must be <21 years of age, have a life expectancy of >4 weeks and absence of significant uncontrolled infection.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8662 Status: Completed  
 Title: Mitoxantrone (DHAD) in ALL, A Phase II Trial

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, acute lymphatic	
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 12 February 1988 Results Continue	

Objective(s): 1) To determine the response rate for mitoxantrone (DHAD) administered to children with acute lymphatic leukemia who have failed all known effective therapy.

2) To further determine the toxicity of mitoxantrone in children with acute lymphatic leukemia.

Technical Approach: To be eligible for this study, the patient must be <21 years of age, have an M<sub>3</sub> marrow, and a life expectancy of >3 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed 16 May 1988.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8691 Status: Ongoing  
 Title: T-Cell #3 Pilot Study

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 12 February 1988 Results Continue	

Objective(s): 1) To determine the toxicity and complications associated with the administration of this intensive chemotherapy regimen to children with T-cell leukemia and advanced stage T-cell lymphoma.

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

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

Progress: Two patients have been entered. One patient achieved remission but relapsed after about one year. The other patient remains on therapy with good response.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8693 Status: Ongoing  
 Title: VP-16, AMSA + 5-Azacytidine in Refractory ANLL

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988 Results Continue	

Objective(s): 1) To determine the toxicity of VP-16, AMSA combination on patients with refractory ANLL.

2) To determine the toxicity of the three drug combination - VP-16, AMSA and 5-Azacytidine.

Technical Approach: Patients with ANLL  $\leq$  21 years of age at the time of initial diagnosis who have either failed to respond to induction therapy or who have relapsed will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered on this study to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8695 Status: Ongoing  
 Title: A POG Pilot Study of Front Loading Chemotherapy in Children with  
 Increased Risk Medulloblastoma

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Medulloblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988 Results Continue	

Objective(s): 1) To evaluate the feasibility and acute toxicity of chemotherapy prior to radiation therapy in the treatment of newly diagnosed children with medulloblastoma who are at increased risk for recurrence.

2) To measure tumor response to the entire chemotherapy regimen of cis-platinum, vincristine, and high-dose cyclophosphamide prior to irradiation.

3) To evaluate the feasibility of a centralized rapid neuroradiology review of pre-study CT scans and myelograms in determining patient eligibility.

Technical Approach: To be eligible for this study, patients must be >3 years and <21 years of age and must have presence of advanced medulloblastoma.

Therapy will follow the schema outlined in the study protocol.

Progress: No patient have been entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8696/97                      Status: Ongoing  
 Title: Treatment of Hepatoblastoma (HB) with Surgery and Chemotherapy and  
 Radiation Therapy

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Hepatoblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988                      Results Continue	

Objective(s): 1) To obtain preliminary data on the natural disease course of patients with carefully staged, completely resected, "favorable histology" hepatoblastoma, given no further therapy after surgery.

2) To obtain preliminary data on the toxicity of a combination of cis-platin, vincristine and 5-fluorouracil (DDP/VCR/5-FU) in the treatment of patients with hepatoblastoma.

3) To assess tumor response to DDP/VCR/5-FU in those patients with Stage III and IV hepatoblastoma.

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

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 28 Nov 88	Proj No: POG 8704	Status: Ongoing
Title: T-Cell #3 Protocol - A POG Phase III Study		

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 12 February 1988      Results    Continue	

Objective(s): 1) To estimate the disease-free survival of a multiagent chemotherapy regimen designed to be particularly effective for patients with T-cell derived lymphoid malignancies in children with advanced stage lymphoblastic lymphoma and T-cell acute lymphoblastic leukemia.

2) To determine the efficacy of adding intensive high-dose L-asparaginase to the backbone chemotherapy regimen in an attempt to improve disease-free survival.

Technical Approach: Patients <21 years and >12 months with a diagnosis of ALL or patients age <21 years with a diagnosis of lymphoblastic lymphoma will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient with lymphoblastic lymphoma was entered, has achieved a satisfactory remission, and remains on treatment.

Detail Summary Sheet

Date: 28 Nov 88	Proj No: POG 8710	Status: Ongoing
Title: Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia (SIMAL #5)		

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To 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: No patients enrolled to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8719 Status: Ongoing  
 Title: Trial of Shortened Therapy without Maintenance for the Treatment of  
 Localized Non-Hodgkin's Lymphoma

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988 Results Continue	

Objective(s): 1) To determine if 24 weeks of maintenance chemotherapy with daily oral 6-MP and weekly methotrexate contributes to relapse-free survival and survival for patients with localized non-Hodgkin's lymphoma when added to a 9 week induction and consolidation regimen as administered in 8314.

2) To maintain a high cure rate with minimum toxicity for children with localized non-Hodgkin's lymphoma in favorable sites.

Technical Approach: Patients <21 years of age at time of diagnosis will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8725                      Status: Ongoing  
 Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) +/- Low Dose  
 Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIA<sub>2</sub>, IIIB, and  
 IV Hodgkin's Disease in Pediatric Patients.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic 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: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8726 Status: Ongoing  
 Title: Alpha-Interferon in Histiocytosis X and Other Non-Malignant Histiocytic Disease, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Histiocytosis X	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988	Results Continue

Objective(s): 1) To evaluate the response rate of patients with histiocytosis X and related diseases to treatment with alpha interferon ( $\alpha$ -IFN).

2. To determine the toxicities of  $\alpha$ -IFN in children with histiocytosis X and related diseases.

Technical Approach: Eligible patients must have biopsy-proven diagnosis of reactive histiocytosis and must be <21 years of age at time of protocol entry.

Therapy will follow the schema outlined in the study protocol.

Progress. No patients entered to date.

Detail Summary Sheet

Date: 28 No 88                      Proj No: POG 8731                      Status: Ongoing  
 Title: Phase II Study of Low-dose "Continuous" Oral Methotrexate in the  
 Treatment of Children with Progressive or Recurrent Brain Tumors.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effectiveness of low-dose "continuous" oral methotrexate in the treatment of children with progressive or recurrent brain tumors and to evaluate the toxicity associate with the use of this agent given in this manner.

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

Progress: No patients have been entered to date

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8739 Status: Ongoing  
 Title: Evaluation of Alpha Interferon in the Treatment of Recurrent Brain Tumors in Children, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988	Results Continue

Objective(s): 1) To determine the efficacy of alpha<sub>2</sub>-interferon (α-IFN) in children with recurrent brain tumors resistant to standard therapy in regard to response rate of different histologic subtypes to α-IFN.

2) To further assess the toxicity of α-IFN in children.

Technical Approach: To be eligible for this study, patient must be <21 years of age with a biopsy-proven diagnosis of astrocytoma, malignant glioma, brainstem glioma, medulloblastoma or ependymoma with clear evidence of progression or recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 87                      Proj No: POG 8741/42                      Status: Ongoing  
 Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma in Children >365 Days  
 at Diagnosis

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Neuroblastoma	
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 12 February 1988                      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: No patients from BAMC entered to date. One patient transferred here on study remains on study and has had a complete response.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8743                      Status: Ongoing  
 Title: Treatment in 'Better Risk' Neuroblastoma: POG Stge B (All Ages) and POG Stage C, D, and DS (VS) <365 Days

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Neuroblastoma	
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 12 February 1988                      Results                      Continue	

Objective(s): 1) To prospectively identify patients <365 days of age at diagnosis who will fail to achieve CR with cycophosphamide (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: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8751                      Status: Ongoing  
 Title: Low-Dose Methotrexate in the Treatment of Rhabdomyosarcoma, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL,	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988                      Results Continue	

Objective(s): 1) To determine the response rate of children with rhabdomyosarcoma treated with low-dose methotrexate (LDMTX) given every 6 hours for 8 doses, followed by leucovorin rescue.

2) To determine the type and duration of toxicity of low-dose sustained oral methotrexate.

Technical Approach: To be eligible for entry into this study, patient must be <21 years of age and have biopsy-proven rhabdomyosarcoma unresponsive to standard therapy for which there is no known potentially curative therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8759                      Status: Ongoing  
 Title: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Osteosarcoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988                      Results Continue	

- Objective(s):
- 1) To estimate the response rate to Ifosfamide in patients presenting with metastatic osteosarcoma or unresectable primary osteosarcoma prior to treatment of those patients with other chemotherapeutic reagents.
  - 2) To estimate the response rate to Ifosfamide in previously treated patients with osteosarcoma.
  - 3) To explore the feasibility and toxicity of the addition of Ifosfamide to a multi-agent combination chemotherapy regimen which includes drugs known to be active in the treatment of osteosarcoma.
  - 4) To study the DNA content of primary and metastatic tumors.

Technical Approach: In order to be eligible for this study, patient must be <30 years of age with no prior history of cancer for Stratum 1 or no prior history of cancer other than osteosarcoma for Stratum 2.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8760 Status: Ongoing  
 Title: Trimetrexate in the Treatment of Childhood Acute Leukemia, Phase II.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine the remission rate obtained with the administration of trimetrexate to children with acute lymphoblastic or acute myelogenous leukemia which is refractory to standard therapy and to further evaluate the toxicity of trimetrexate in children.

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

Progress: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8761                      Status: Ongoing  
 Title: A Phase II Study of Homoharringtonine for the Treatment of Children with  
 Refractory Non-Lymphoblastic Leukemia

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, non-lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 12 February 1988                      Results Continue	

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

2) To assess the toxicity of 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: No patients entered to date.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8763                      Status: Ongoing  
 Title: Evaluation of Response and Toxicity of Ifosfamide and VP-16-213 in  
 Children with Resistant Malignant Tumors

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 12 February 1988                      Results Continue	

Objective(s): To determine the antitumor activity and toxicity of ifosfamide (IFX) plus Etoposide (VP-16) against malignant solid tumors resistant to conventional chemotherapy.

Technical Approach: Eligible patients must be <21 years of age and have documented measurable disease, confirmed with appropriate histologic examination. Patients must have progressive or recurrent disease that is resistant to conventional therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been entered on study. One patient with recurrent Ewing's sarcoma had no response. One patient with recurrent Wilms' tumor had an initial partial response then recurred. One patient with recurrent Wilms' tumor is too early to evaluate for response.

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8764                      Status: Ongoing  
 Title: Chemotherapy Regimen for Early and Initial Induction Failures in  
 Childhood Acute Lymphoblastic Leukemia: Phase II Study

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regimen of VM-26 and continuous infusion cytosine arabinoside (ara-C).

To estimate the one-year disease-free survival for early and initial induction failures in childhood ALL, based on a new regimen.

To try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

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

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 28 No 88                      Proj No: POG 8821                      Status: Ongoing  
 Title: AML#3 Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant  
 Early in 1st CR for Children with Acute Myelocytic Leukemia.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review _____ Results _____	

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/Cytosan 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: Two patients have been sent ere for autologous bone marrow transplant and will return to their parent institution when received. A third patient is being sent for transplant only. (Note: We are the designated transplant center for military dependents on this study.)

Detail Summary Sheet

Date: 28 Nov 88                      Proj No: POG 8833                      Status: Ongoing  
 Title: Pre-radiation Chemotherapy in the Treatment of Children with Brain Stem Tumors - A Phase II Study

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To evaluate the response of children with brain stem gliomas to four courses of combination high-dose cyclophosphamide and cis-platinum prior to radiation therapy. Response will be measured by CT and/or MRI scan and neurological exam.

To monitor possible acute and chronic toxicities of the chemotherapy, including neurological and audiological toxicity. To assess unusual irradiation-related toxicity post-chemotherapy.

To Estimate the disease control interval for the population under study following chemotherapy and radiation therapy.

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

Progress: No patients have been entered to date.