DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200

REPLY TO
ATTENTION OF:

HSHE-CI

17 June 1992

SUBJECT: Minutes of the Institutional Review Board Meeting, 15 June 1992

1. The Institutional Review Board meeting was held on Monday, 15 June 1992, at 1500, in Room 142, Building 1000, in accordance with Change 1, BAMC Memo 15-1, dated 31 May 1991.

2. Members Present:
COL James M. Lamiell, MC, Department of Clinical Investigation, Chairman
COL George M. Vaughan, MC, Institute of Surgical Research
LTC Paul D. Amos, MS, Patient Administration Division
LTC Ross B. Jackson, CH, Department of Ministry and Pastoral Care
MAJ David Gaule, MS, Department of Medicine
CPT Jeannine Hinman, JA, Medical Claims Judge Advocate
Ms. Betsey Cunningham, Community Representative
Ms. Helen J. Smith, Recorder, Without Vote

Members Absent:
LTC Timothy J. O'Rourke, MC, Hematology/Oncology Representative

Others Present:
COL David A. McFarling, MC, Deputy Commander for Clinical Services
LTC Rosemarie Ritchie, Department of Nursing
MAJ James Wall, vice LTC O'Rourke, Hematology/Oncology Representative
Ms. Jean Johnson, RN, Ph.D., Department of Clinical Investigation
MAJ Steven Older, MC, Department of Medicine
CPT Carol T. Danning, MC, Department of Medicine

3. Old Business:

a. The minutes of the May meeting, dated 20 May 1992, were approved as written.

b. The following protocols were discussed.

(1) POG 9150/51/52 - Intergroup Rhabdomyosarcoma Study - IV for Stage 1, 2 and 3 Disease

Principal Investigator: COL Terry Pick, MC
Staff, Dept of Pediatrics

DISCUSSION: 16 March 1992. These companion studies are to compare the progression free survival rates of patients receiving vincristine, actinomycin D, and cyclophosphamide (VAC) vs patients receiving vincristine, actinomycin D, and ifosfamide (VAI) vs those receiving vincristine, ifosfamide, and etoposide (VIE) for treatment of rhabdomyosarcoma and undifferentiated sarcoma. This is a complicated, multi-armed study. The patient consent form must be rewritten.

Risk: More than minimal.

Medical Monitor: COL John Roscelli, MC.

Review: Annually.

RECOMMENDATION: Table.

STIPULATIONS: None.

ACTION: 22 April 1992. The committee is awaiting rewritten consent forms. 18 May 1992. The committee is awaiting rewritten consent forms. 15 June 1992 The committee is awaiting rewritten consent forms.

(2) POG 9284/85 - Barriers to Patient Enrollment into Frontline Therapeutic Clinical Trials

Principal Investigator: COL Terry Pick, MC
Staff, Dept of Pediatrics

DISCUSSION: 22 April 1992. The specific aims of these studies are to prospectively identify physician and patient factors associated with reasons as to why patients who are eligible for therapeutic protocols made available through the POG are not enrolled in the study. After a lengthy discussion the committee members stated they thought the concept of the study was good, but they were not sure the patient was being approached correctly.

Risk: Minimal.

Medical Monitor: COL John Roscelli, MC.

Review: Annually.

RECOMMENDATION: Table.

STIPULATIONS: None.

ACTION: 22 April 1992. The committee is awaiting rewritten consent forms. 18 May 1992. The committee is awaiting rewritten consent forms. 15 June 1992. The commitee is awaiting rewritten consent forms. (ACTION PENDING)

(3) C-80-90 A Phase I Evaluation of U-73,975 Brief Infusion Every 6 Weeks in Adult patients with Solid Tumors

Principal Investigator: MAJ Howard Burris III
Staff, Hematology/Oncology Svc

DISCUSSION: Colonel Lamiell reported to the committee he had discussed the risks of this protocol with LTC Timothy O'Rourke, Chief of Hematology/Oncology Service. Dr. O'Rourke has reviewed the reports from other institutions of patient deaths on this protocol. There is no need for drug dose or protocol modification in BAMC patients.

4. New Business:

a. Colonel David A. McFarling, BAMC's new Deputy Commander for Clinical Services, was introduced to the committee. Colonel McFarling has joined BAMC from HSC's Health Care Studies and Clinical Investigation Activity where he served as chief.

b. The following protocols were discussed.

(1) GOG #136 - Acquisition of Human Ovarian and Other Tissue Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer

Principal Investigator: LTC Allan Mayer
Staff, Dept of OB/Gyn

DISCUSSION: This protocol is designed to set up a tissue bank for gynecologic tumor research.

RISK: More than Minimal

MEDICAL MONITOR: COL Samuel Chaney

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review. (ACTION CLOSED)

(2) The Effect of Maternal Age on Parenting Expectations, Parenting Behavior and Infant Outcomes for Women in Military Families

Principal Investigator: LTC Rosemarie Ritchie, AN Staff, Dept of Nursing

DISCUSSION: This is a quasi-experimental, prospective study designed to compare the parenting expectations, parenting behaviors and infant outcomes of expectant women between the ages of 15-19 years with those 20-35 years old. The relationship between parenting expectations, parenting behavior and infant outcomes in the first six months after birth will also be examined. Funding for this study has been requested from U.S. Department of Defense Appropriations Act. Study will be done at BAMC and Darnall Army Community Hospital. The committee asked what conditions could require the patient to be withdrawn from the study as stated in the consent. LTC Ritchie could not think of any conditions when this might apply, but the committee agreed that this statement should remain in the consent form.

RISK: Minimal

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(3) Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Principal Investigator: CPT Carl S. Wrobleski, MC
Resident, Dept of Medicine

DISCUSSION: The purpose of this study is to determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible signoidoscopy in an asymptomatic population of aspirin or sulindac users and nonusers. The committee discussed the number of patients to be studied. The number, 310, was selected for statistical purposes. After a lengthy discussion, the committee waived informed consent with the provision that a Fact Sheet without subject identification be developed and that subjects be provided a protocol information sheet.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: The questionnaire should be redesigned as a fact sheet without patient identification and subjects should be provided a protocl information sheet. After this is accomplished, informed consent is waived.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review. (ACTION CLOSED)

(4) The Induction of the Alpha-Delta Sleep Anomaly and Fibromyalgia Symptoms in Athletes vs. Sedentary Controls: Correlations with Somatomedin-C

Principal Investigator: CPT Carol L. Danning, MC
Resident, Internal Medicine Service

DISCUSSION: Captain Danning explained this protocol is to ascertain the protective effect of physical fitness on the development of fibromyalgia symptoms induced by stage 4 sleep deprivation and to examine the relationship between Somatomedin-C and induced fibromyalgia symptoms. The subjects will be active duty personnel. The committee requested the informed consent be rewritten to outline the possible risks of

sleep deprivation. The consent also needs to state the amount of blood to be drawn. This study will be presented to U.S. Army Medical Research and Development Command for funding.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: The consent form must be rewritten to outline the risks of sleep deprivation and state the amount of blood to be drawn.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(5) Phase II Trial of RP 56976 in Patients with Advanced Cutaneous Malignant Melanoma Previously Untreated with Cytotoxic Chemotherapy

Principal Investigator: MAJ Howard A. Burris III
Staff, Hem/Onc Service

DISCUSSION: This study is to estimate the major objective response rate and duration of response in patients with advanced cutaneous malignant melanoma previously untreated with cytotoxic chemotherapy.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(6) Phase II Trial of RP 56976 in Patients with Non-Small Cell Lung Cancer Previously Treated with Cytotoxic Chemotherapy

Principal Investigator: MAJ Howard A. Burris III
Staff, Hem/Onc Service

DISCUSSION: This study is to determined the side effects of RP 56976.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(7) **Phase II Trial of RP 56976 in Patients with Advanced Anthracycline Resistant Metastatic Breast Cancer**

Principal Investigator: MAJ Howard A. Burris III
Staff, Hem/Onc Service

DISCUSSION: This study is to determined the side effects of RP 56976 in patients with advanced anthracycline resistant metastatic breast cancer.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(8) A Phase I Trial of LY231514 Administered as a 30 Minute Infusion Every 21 Days

Principal Investigator: CPT David A. Rinaldi, MC
Fellow, Hem/Onc Service

DISCUSSION: This is a new drug study to determine the maximum dose and the side effects of the drug.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(9) Blood Lead (Pb) Levels in Infants and Toddlers

Principal Investigator: CPT Deborah Baumann, MC
Resident, Dept Pediatrics

DISCUSSION: This study will ascertain the incidence of lead exposure in the military dependents attending 6-, 12-, and 24- month well-baby clinics. Questionnaires plus blood lead level testing will be used. The committee voted to table the study until the informed consent is rewritten to include a description of the study, the risks and benefits to the children, and the standard statement of DoD dependents' care.

RISK: More than Minimal

MEDICAL MONITOR: COL John Roscelli

REVIEW: Annually

RECOMMENDATION: Table

STIPULATIONS: The consent form must be rewritten to include the above mentioned items.

ACTION: Re-write and re-submit. (ACTION PENDING DEPT OF PEDIATRICS)

(10) Capillary Refill Time in the Normal Newborn
Principal Investigator: CPT Barton Cook, MC, Resident, Dept Pediatrics

DISCUSSION: This study is to determine neonates' capillary refill time using four techniques in a controlled clinical trial so that the limits of normal may be determined. The tests are routinely done and this data will be recorded to determined if any method is statistically and clinically significantly different. The committee considered the request to waive consent. Since these tests are done routinely on neonates and the recording of the results without subject identification will not change the treatment, the committee recommended the consent form be waived.

RISK: Minimal

MEDICAL MONITOR: COL John Roscelli

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review. (ACTION CLOSED)

(11) Open Study of Recombinant MCSF and Antifungal Therapy in Patients with Definitive or Probable Invasive Candida or Aspergillus Fungal Infection

Principal Investigator: MAJ W. Jeffrey Baker, MC Staff, Hem/Onc Service

DISCUSSION: This study is to determine the maxiaml tolerated dose of rMCSF in cancer, leukemia and lymphoma patients with invasive fungal infection that is refractory to standard antifungal therapy.

RISK: More than Minimal

MEDICAL MONITOR: COL Fred Goldner

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review and approval. (ACTION CLOSED)

(12) Amendment to Approved Protocol "Neoadjuvant Hormonal Therapy Prior to Radical Prostatectomy for Clinical Stage A and B Carcinoma of the Prostate"

Principal Investigator: LTC Ian M. Thompson, MC
Urology Service

DISCUSSION: The protocol was approved in August 1991. A similar protocol has been designed by Dr. Mark Soloway of the University of Miami and is beginning to accrue patients at multiple institutions. Due to the potential increase in the power of a study which will accrue 300 patients rather than the relatively modest anticipated accrual at Wilford Hall and BAMC, it is requested that the approved protocol be amended to the multiinstitution protocol. The only differences are the amended protocol will accrue only patients with stage B2 disease, both PAP and PSA will be performed by a central laboratory, an additional depot-Lupron injection will be given immediately prior to radical prostatectomy at the end of month three, and the monthly transrectal ultrasound will be deleted. The consent form was reviewed and approved.

RISK: More than Minimal

MEDICAL MONITOR: COL Johnny Alvarez

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review. (ACTION CLOSED)

(13) Amendment to Approved Protocol "A Sixteen Week, Double-Blind, Placebo-Controlled, Dose-Response Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Hypertension"

Principal Investigator: LTC Ian M. Thompson, MC
Urology Service

DISCUSSION: The amendment change is for a prostate specific antigen to be drawn one year following study entry at the 12-month visit. Since patients are already having phlebotomy at this time, the additional PSA can be done without extra phlebotomy. The original consent form informs of the blood draw so there is no need to rewrite the consent form.

RISK: More than Minimal

MEDICAL MONITOR: COL Johnny Alvarez

REVIEW: Annually

RECOMMENDATION: Approved by a vote of 7 For; 0 Against

STIPULATIONS: None.

ACTION: Submit to Clinical Investigation Program Division, HSC, for review. (ACTION CLOSED)

5. The chairman read the following memorandums from investigators regarding protocols.

a. 18 May 1992, Captain Karen J. Bowen, MC, Hematology/Oncology, enrolled a patient on her study "Randomized Double Blind Study Comparing Medroxyprogesterone Acetate and Placebo in Cancer Cachexia" who does not strictly meet the eligibility criteria. His weight loss predates the six month time period but is progressively getting worse.

b. 18 May 1992, Major Howard A. Burris III, MC, Hematology/Oncology Service, has received new safety information on intravenous and oral Navelbine from the Burroughs Wellcome

Company dated 24 April 1992. Revised informed consents were submitted as well.

c. 18 May 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted an administrative change on "Phase I Trial of RP 56976 Administered as a 6-Hour Infusion Every 21 Days." No consent form changes were needed.

d. 18 May 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted a report of a pulmonary reaction following Navelbine administration. These results have not been seen in any BAMC patient.

e. 18 May 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted a report of an adverse drug reaction on a BAMC patient. A 58-year-old patient developed mild diarrhea and decreased oral intake probably related to Taxotere. The patient recovered after 2 to 3 days.

f. 19 May 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted two amendments (A & B) to his protocol "Open Label Dose Tolerance Study of Intravenous Ilmofosine Administered 120 Hours by Continuous Infusion Every 21 Days to Patients with Cancer Refractory to Standard Treatment (ILM-04)" Revised consent forms were submitted.

g. 21 May 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted corrected consent forms for protocols (1) "Elimination of Extrachromosomal DNA from Ovarian Cancer Patients Tumors with Hydroxyurea Treatment," (2) "A Phase I Trial of 2-Chlorodeoxyadenosine by 5-Day Continuous Intravenous Infusion," (3) "Phase II Trial of RP56976 in Patients with Non-Small Cell Lung Cancer Previously Untreated with Cytotoxic Chemotherapy," and (4) "Phase II Trial of RP56976 in Patients with Advanced Epithelial Ovarian Cancer Refractory to Treatment with Cisplatin and/or Carboplatin Chemotherapy." The consent forms were approved by the committee.

h. 26 May 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted amendments and revised consent forms to protocols "An Open Label Dose Tolerance Study of Intravenous Ilmofosine Administered Once a Day for Five Days Every Twenty-eight Days to Patients with Cancer Refractory to Standard Treatments" and "Open Label Dose-Tolerance Study of Intravenous Ilmofosine Administered by A 120-Hour Continuous Infusion Every 21 Days to Patients with Cancer Refractory to standard Treatments." Adverse reactions have indicated prestudy and

followup eye examinations are needed. Consents accepted by the committee.

i. 27 May 1992, LTC Timothy J. O'Rourke, MC, Hematology/ Oncology Service, submitted an adverse reaction report from another institution of a patient on protocol "Phase I Trial of Tetraplatin Administered Daily for Five Consecutive Days Every 28 Days." The death was judged to be due to disease progression.

j. 8 June 1992, Major John H. Schrank, Jr., MC, Infectious Disease Service, submitted an adverse reaction report of the deaths of two patients on "An Open-Label Multi-Investigator Comparative Study of the Safety and Efficacy of Cefipime and Ceftazidime in the Treatment of Hospitalized Patients with Septicemia." After thorough review of the charts, it was concluded that the cause of death in both cases was unrelated to the study drug or the protocol.

k. 9 June 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted an amendment to "A Phase I Trial of RP56976 Administered as a 2-Hour Infusion Every 21 Days." This is a change to randomized dosage between 2 and 3 hours rather than 1 and 6 hours. A revised consent form was approved by the committee.

l. 12 June 1992, Major Howard A. Burris III, MC, Hematology/ Oncology Service, submitted amendments 2 and 3 to "Phase I Trial of RP60475 Administered as a 1/2 Hour Infusion Every 21 Days." The amendments involved blood sampling and dose escalations. The committee approved the revised consent forms.

6. Actions Pending:

a. POG 9150/51/52 - Intergroup Rhabdomyosarcoma Study - IV for Stage 1, 2 and 3 Disease by COL Terry Pick, Department of Pediatrics

b. POG 9284/85 - Barriers to Patient Enrollment into Frontline Therapeutic Clinical Trials by COL Terry Pick, Department of Pediatrics

c. Blood Lead (Pb) Levels in Infants and Toddlers by CPT Deborah Baumann, Department of Pediatrics

HSHE-CI 17 June 1992
SUBJECT: Minutes of the Institutional Review Board Meeting, 15 June 1992

7. Actions Forwarded: None.

Helen J. Smith
HELEN J. SMITH
Recorder

James M. Lamiell
JAMES M. LAMIELL
COLONEL, MC
Chairman

Approved/~~Disapproved~~ 25 June '92
Date

Thomas P. Hamilton II
RUSS ZAJTCHUK
Brigadier General, MC
Chairman, Executive Committee

THOMAS P. HAMILTON II
COLONEL, MC
ACTING COMMANDER