



DEPARTMENT OF THE ARMY  
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER  
TRIPLER AMC, HAWAII 96859-5000



REPLY TO  
ATTENTION OF

ARM1.950119.009e

HSHK-CI (15-1)

2 Nov 92

MEMORANDUM FOR: Commander, Tripler Army Medical Center, Tripler AMC,  
HI 96859-5000

SUBJECT: Minutes of Clinical Investigation and Human Use Committees for October

1. Under the provisions of AR 40-38 and TAMC Regulation 15-1, the Clinical Investigation and Human Use Committees convened in the Commanding General's Conference Room at 1330, 27 Oct 92. COL Person asked if there was any objection to tape recording the meeting; no one objected.

2. MEMBERS PRESENT.

*+Acting DCCS, Chairman (10/10)	COL Donald A. Person, MC
*+Clin Investigation, Recorder (10/10)	COL Richard A. Banks, MC
*Ministry and Pastoral Care (10/10)	CH (COL) Basil Ballard
*Social Work Service (9/10)	COL David E. Hamilton, MS
+Department of Surgery (8/10)	COL Y-T. Margaret Lee, MC
*Center Judge Advocate (10/10)	LTC David A. Little, JA
+Physical Medicine Service (7/10)	LTC John C. Reardon, SP
+Department of Dentistry (8/10)	LTC Charles Ringgold, DC
+Department of Pathology (10/10)	LTC Stephen Y. Wilkerson, MC
+Department of Pediatrics (8/10)	MAJ David Crudo, MC
*Clinical Investigation (10/10)	MAJ Sharon S. DeRuvo, AN
+Obstetrics and Gynecology (9/10)	MAJ John C. Gililland, MC
+Pharmacy Service (8/10)	MAJ William Gilmore, MC
+Family Practice (8/10)	MAJ David C. MacDonald, MC
+Department of Psychiatry (9/10)	MAJ Victor L. Stevens, MC
*Department of Psychology (8/10)	Raymond Folen, PhD
*Army Community Service Center, (9/10)	Mr. Steven P. Kimura
Schofield Bks (noninstitutional member)	
*Human Use Committee	
+Clinical Investigation Committee	

MEMBERS ABSENT.

+Department of Medicine (7/10)	LTC L. Harrison Hassell, MC
*Radiation Protection Office (9/10)	CPT John R. Mercier, MS
+Department of Radiology (1/10)	CPT Dean J. Shanley, MC
*Department of Nursing (9/10)	Ms. Patricia Nishimoto, PhD

HSHK-CI

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3. Minutes of the Clinical Investigation and Human Use Committees meeting for September were approved as published.

4. UNFINISHED BUSINESS.

HUC review of TAMC 49H92, by CPT Douglas Homoky, was completed and final approval is granted.

(Human Use Committee's vote: 9 in favor, 0 opposed, 0 abstained)

5. NEW BUSINESS.

a. EMERGENCY USE APPROVALS. HSC approvals were obtained for two cases:

(1) Use of investigational drug (Roferon), by MAJ Shirley E. Reddoch, MC, Dept of Pediatrics.

(2) Use of investigational device (TIPS wall stent-FDA approved for biliary surgery) by CPT Mark Cockerill, MC, Dept of Radiology.

b. EXPEDITED PROTOCOL (Reviewed & Approved).

TAMC 2H93: Use of Otoacoustic Emissions to Identify Newborn Children With Hearing Loss, by Kathleen Campbell, Audiologist, Dept of Surgery.

c. MODIFICATIONS (Reviewed & Approved).

(1) TAMC 47H92: The Effect of Preoperative Teaching on Uncertainty in Surgical Patients, by MAJ Theresa Jones, AN, Dept of Nursing.

Comments: MAJ DeRuvo presented modifications in MAJ Jones' absence. Protocol was just approved at the September CIC/HUC meeting. Proposed modification in study design (one group pre- and post-test TO four groups of one pre- and one-of-three randomized post-test) is aimed at strengthening causal inferences. Consent form incorporates the new design.

(2) TAMC 29H91: Carpal Tunnel Release With and Without Release of the Fascia of the Forearm: A Prospective Randomized Approach, by COL William H. Milnor, MC, Dept of Surgery.

Comments: COL Banks presented modifications in COL Milnor's absence. As standard carpal tunnel release now includes endoscopic surgery, this option is described, and the consent form is revised accordingly.

HSHK-CI

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d. New proposals. Minutes of the last CIC/HUC meeting and protocols for this meeting were circulated on 21 Oct 92.

(1) SWOG 9108(93): A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate + Chlorambucil in Previously Untreated B-cell Chronic Lymphocytic Leukemia, by COL Jeffrey L. Berenberg, MC, Dept of Medicine, and presented by LTC Uphouse in COL Berenberg's absence.

Comments: None.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 8 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: More Than Minimal Risk, Oncology

Medical Monitor: LTC Philip P. Bruno, MC

Gifts: None

Review date: One year

(2) SWOG 9015(93): A Randomized Trial of Post-operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-small Cell Carcinoma of the Lung, Phase III, by COL Jeffrey L. Berenberg, MC, Dept of Medicine, and presented by LTC William Uphouse in COL Berenberg's absence.

Comments: None.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 8 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: More Than Minimal Risk, Oncology

Medical Monitor: LTC Philip P. Bruno, MC

Gifts: None

Review date: One year

(3) POG 8945(93): Intergroup Hepatoblastoma Hepatocellular Carcinoma Study, by MAJ Shirley E. Reddoch, MC, Dept of Pediatrics, and presented by MAJ Braden Shoupe in MAJ Reddoch's absence.

Comments: None.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 8 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: More Than Minimal Risk, Oncology

Medical Monitor: COL James W. Bass, MC

Gifts: None

Review date: One year

HSHK-CI

SUBJECT: Minutes of the Clinical Investigation and Human Use Committees for October

(4) POG 9227(93): Treatment of Recurrent or Refractory Hodgkins Disease with Cyclosporine-A, Actinomycin-D, Vincristine, by MAJ Shirley E. Reddoch, MC, Dept of Pediatrics, and presented by MAJ Braden Shoupe in MAJ Reddoch's absence.

Comments: None.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 8 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: More Than Minimal Risk, Oncology

Medical Monitor: COL James W. Bass, MC

Gifts: None

Review date: One year

(5) TAMC 3H93: Effects of the Postero-anterior Mobilization Technique on Lumbar Extension and Flexion, submitted and presented by CPT Rebecca L. McCollam, SP, Physical Medicine Service.

Comments: Normal subjects will be used for this study. Investigator was complimented on a well-written proposal.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 8 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: Minimal Risk

Gifts: None

Review date: One year

(6) TAMC 4H93: Postoperative Bleeding in Open Heart Patients Receiving Infusion of Cell-Saver Erythrocytes-Clinical Intervention Study, submitted and presented by CPT Bradley Roth, MC, Dept of Surgery.

Comments: Dr. Banks stated that funding for research supplies/equipment must be defined and verified prior to study initiation. He also identified the need for an updated signature sheet and DA 5303-R (as there has been a switch of PI and associate investigator since initial proposal review).  
[MAJ Victor Stevens enters meeting.]

Committees' recommendations: Approval with revisions stated above

Clinical Investigation Committee's vote: 9 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: More Than Minimal Risk

Medical Monitor: COL David B. Crandall, MC

Gifts: None

Review date: One year

HSHK-CI

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(7) TAMC 5H93: Skin Manifestations in Patients with Hepatitis C Virus, submitted by MAJ Curt Samlaska, MC, and presented by CPT Carri Homoky in Dr. Samlaska's absence.

Comments: The study was described as purely observational data collection with attempts to identify dermatologic manifestations of patients with HCV. Noting that the referenced checklist included linear IgA, Dr. Person asked if personnel were prepared to perform these lab tests on all subjects. Dr. Homoky replied that the checklist includes any possible skin manifestation which may be observed; study design is not to ambitiously explore beyond observation documentation.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 9 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: Minimal Risk

Gifts: None

Review date: One year

(8) TAMC 6H93: Metoclopramide: An Anesthesia Adjunct for Patients Under General Anesthesia, submitted and presented by CPT Charles Price, AN, Department of Nursing.

Comments: This study has been approved by the Nursing Research Committee. Dr. Gililand queried when drug would be given (ie, might surgery be delayed). CPT Price replied drug will be given upon entry into the OR, with a five-minute interim before anesthesia induction. The difference from prior studies is the use of a different induction agent (propofol) and this double-blind design.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 9 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: More Than Minimal Risk

Medical Monitor: MAJ Adrian I. Sanders, MC

Gifts: None

Review date: One year

(9) TAMC 7H93: Immunosuppressive Factors in Ovarian Ascites, submitted and presented by MAJ Steven A. Elg, MC, Department of Obstetrics & Gynecology.

Comments: Dr. Elg referred to this as a laboratory study and stated intentions of seeking NIH funding. MAJ DeRuvo asked about the paragraph, page 18, referencing use of rabbits for antibody production. Dr. Elg replied this portion of the study will only be implemented in the event of grant awarding. Dr. Banks confirmed the inability of DCI to support this project. A liquid nitrogen cylinder/tank is the only identified purchase need at this time, so tissue sampling can be started.

HSHK-CI

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Committees' recommendations: Approval

Clinical Investigation Committee's vote: 9 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 7 in favor, 0 opposed, 0 abstained

Risk factor: Minimal Risk

Gifts: None

Review date: One year

e. PRINCIPAL INVESTIGATOR CHANGE: MAJ Shirley E. Reddoch, MC, assumes PI role for all POG protocols and for TAMC 26D84 (with PCS of LTC Bruce A. Cook, MC).

6. CONCLUSIONS/RECOMMENDATIONS/ACTIONS.

- a. Approval of modifications, paragraph 5c(1-2).
- b. Approval of proposals, paragraph 4, 5b, 5d(1-5), and 5d(7-9).
- c. Approval of proposal with revisions, paragraph 5d(6).
- d. No referrals to the Executive Committee.

7. The meeting was adjourned at 1418.

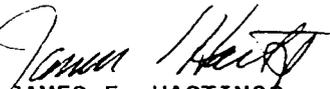


RICHARD A. BANKS  
Colonel, MC  
Chief, Dept of Clinical Investigation  
Recorder, CIC/HUC Cmte



DONALD A. PERSON  
Colonel, MC  
Acting Dep Cmdr for Clin Svcs  
Chairman, CIC/HUC Cmte

APPROVED:



JAMES E. HASTINGS  
Brigadier General, MC  
Commanding  
Chairman, Executive Committee

11/13/92  
Date

DISTRIBUTION:

Each committee member, 1 copy  
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