



DEPARTMENT OF THE ARMY
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER
TRIPLER AMC, HAWAII 96859-5006



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HSHK-CI (15-1)

25 March 1993

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

SUBJECT: Minutes of Clinical Investigation and Human Use
Committees for March 1993

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, 23 Mar 93. COL Jones asked if there was any objection to tape recording the meeting; no one objected.

2. MEMBERS PRESENT.

*+Dep Cdr for Clin Svcs, Chrmn (3/3)	COL Charles C. Jones, MC
*+Clin Investigation, Recorder (3/3)	COL Richard A. Banks, MC
*Ministry and Pastoral Care (3/3)	CH (COL) Basil Ballard
*Social Work Service (3/3)	COL David E. Hamilton, MS
*Center Judge Advocate (3/3)	LTC David A. Little, JA
+Department of Dentistry (2/3)	LTC Francis Grzejka, DC
+Obstetrics and Gynecology (3/3)	LTC Robert W. Smith, MC
+Department of Pathology (3/3)	LTC Stephen Wilkerson, MC
+Department of Pediatrics (2/3)	MAJ David Crudo, MC
*Clinical Investigation (3/3)	MAJ Carol L. Eisenhauer, VC
+Department of Medicine (2/3)	MAJ Timothy M. Winslow, MC
+Department of Radiology (3/3)	CPT Dean J. Shanley, MC
*Department of Psychology (3/3)	Raymond Folen, PhD
*Department of Nursing (3/3)	Ms. Patricia Nishimoto, PhD
+Pharmacy Service (3/3)	Ms. Debora A. Schotik, RPH
*Radiation Protection Office (2/3)	Mr. Rick Waffird
*Army Community Service Ctr, (3/3)	Mr. Melvin T. Kinoshita
Ft Shafter (noninstitutional member)	

*Human Use Committee
+Clinical Investigation Committee

MEMBERS ABSENT.

+Department of Surgery (2/3)	COL Y-T. Margaret Lee, MC
+Physical Medicine Service (1/3)	LTC John C. Reardon, SP
+Family Practice (2/3)	MAJ William F. Miser, MC
+Department of Psychiatry (2/3)	MAJ Victor L. Stevens, MC

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3. Minutes of the Clinical Investigation and Human Use Committees meeting for February were reviewed via electronic mail and approved with corrections of including the following members in attendance: COL Y-T. Margaret Lee, MC, Department of Surgery, and MAJ John C. Gililland, MC, Obstetrics & Gynecology. The remainder of the minutes stand approved in that there were no opposition or abstention votes.

4. UNFINISHED BUSINESS.

None.

5. NEW BUSINESS.

a. ~~Exempt~~ Protocols (Reviewed & Approved):

(1) TAMC 22H93: Clinical Predictors of Acne Keloidalis Nuchae, by Scott A. Norton, MC, Dept of Medicine.

(2) TAMC 23H93: A Research Utilization Study Examining How Nurses Apply Research Findings to Clinical Practice, by LTC Sylvia Wood, AN, Dept of Nursing.

b. Modification of TAMC 49H92:

Changes in Principal Investigator (from CPT Douglas Homoky to Stephen Yamada) and study plan (from two to four 7cc red top blood sample tubes) were reviewed and approved.

c. New proposals. Minutes of the last CIC/HUC meeting and protocols for this meeting were circulated on 16 Mar 93.

(1) TAMC 25H93: One Dose Lomefloxacin as Prophylaxis Against Infectious Complications of Transrectal Prostate Needle Biopsy Using the Biopty Gun, by CPT Edward K. Leventhal, MC, Dept of Surgery.

Comments: Investigator was informed that a commercially available drug (Lomefloxacin) supplied by a private company (Searle) imposes the gifting approval process. Investigators hope that if drug will prove as efficacious as those presently used, it can be added to the hospital formulary, thus providing a cost savings. Required consent revisions are as follows: (a) use lay terms to explain nature of study, (b) state that the urine culture will be done at the same time as the follow-up appointment (Evaluations paragraph, item I5, (c) add standard paragraphs (Compensation for Injury and Domiciliary Care).

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Committees' recommendations: Approval pending revisions noted above

Clinical Investigation Committee's vote: 7 in favor, 0 opposed, 0 abstained

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

Risk factor: More Than Minimal Risk

Medical Monitor: COL Martin L. Dresner, MC

Gifts: Lomefloxacin from GD Searle

Review date: One year

(2) POG 7799: Rare Tumor Protocol for Childhood Solid Tumor Malignancies, Ancillary Study, by MAJ Shirley E. Reddoch, MC, Dept of Pediatrics.

Comments: This data-tracking non-treatment protocol was inadvertently closed at TAMC in 1984, but POG verified that the study has remained active. Because of a 10-year time lapse, study is presented as a new proposal.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 7 in favor, 0 opposed, 0 abstained

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

Risk factor: Minimal Risk

Gifts: None

Review date: One year

(3) POG 9220: Phase III Randomized Trial of All-Trans Retinoic Acid Versus Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia - An Intergroup Study, by MAJ Shirley E. Reddoch, MC, Dept of Pediatrics.

Comments: IND; All-Trans retinoic acid, will be provided by NCI. There was no discussion.

Committees' recommendations: Approval

Clinical Investigation Committee's vote: 7 in favor, 0 opposed, 0 abstained

Human Use Committee's vote: 9 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

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(4) TAMC 24H93: A Randomized Blinded Evaluation of Two Doses of Stavudine (2'3'-didehydro-3'-deoxythymidine, d4T) to Make Treatment Available to Severely Immunocompromised Patients with HIV Infection Who Have Failed or are Intolerant of Alternative Antiretroviral Therapy, by Arthur C. Johnson III, MD, Dept of Medicine.

Comments: Ms. Jo McKeague, RN, presented the plans and objectives of this study. IND, Stavudine, will be provided by Bristol Myers Squibb. The only required revision includes consent changes to include Compensation for Injury paragraph and make noted grammar corrections.

Committees' recommendations: Approval pending revisions noted above

Clinical Investigation Committee's vote: 7 in favor, 0 opposed, 0 abstained

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

Risk factor: More Than Minimal Risk, IND

Medical Monitor: COL J. Craig Holland, MC

Gifts: None

Review date: One year

(5) TAMC 26H93: Evaluation of ¹³¹I-MIBG (¹³¹I-Meta-iodobenzylguanidine Sulfate) In Patients Suspected of Having Pheochromocytoma, Paraganglioma, Neuroblastoma or Medullary Hyperplasia, by LTC Calvin Delaplain, MC, Dept of Radiology.

Comments: A physician-sponsored IND is being submitted as part of this protocol for the use of this orphan agent at TAMC. A review and approval by the Radiation Safety Committee is pending. Neuroblastoma will be listed as part of the inclusion criteria.

Committees' recommendations: Approval pending revision noted above

Clinical Investigation Committee's vote: 7 in favor, 0 opposed, 0 abstained

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

Risk factor: More Than Minimal Risk, IND

Medical Monitor: LTC Michael Berndt, MS

Gifts: None

Review date: One year

(6) TAMC 27H93: ¹¹¹In-CYT-103 as Diagnostic Imaging Agent in the Preoperative Differentiation of Benign and Malignant Mammographic abnormalities, by CPT Martin G. Radvany, MC, Dept of Radiology.

Comments: As with the last proposal, a review and approval by the Radiation Safety Committee is pending. COL Banks asked if the medication was an IND and initially stated the gift-approval

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process was in order. The following explanation, however, revealed the medication to be a "part 'n parcel" package. CYT-103 is an IND supplied by Cytogen. ¹¹¹Indium-Chloride is commercially available from Medipysics/Amersham; however, Cytogen will be purchasing and supplying ¹¹¹Indium-Chloride required for labeling CYT-103. Consequently, ¹¹¹In-CYT-103 is considered [part of] an IND. Consent spelling corrections are in order.

Committees' recommendations: Approval with revisions noted above.

Clinical Investigation Committee's vote: 7 in favor, 0 opposed, 0 abstained

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

Risk factor: More Than Minimal Risk, IND

Medical Monitor: COL Mark Hansen, MC

Gifts: None

Review date: One year

(7) TAMC 28H93: Prevalence of Antiphospholipid Antibodies in Isolated Mitral Valve Prolapse, by MAJ Timothy M. Winslow, MC, Dept of Medicine.

Comments: Nature of Study para of consent form should be reworded - presently stated, "...compared to normal" implies subjects are somewhat inferior. When questioned, Dr. Winslow replied that the control group will be made up of healthy house staff volunteers. Dr. Banks encouraged consultation with CI statistics people to ensure adequate sample size.

Committees' recommendations: Approval pending revision noted above

Clinical Investigation Committee's vote: 8 in favor, 0 opposed, 1 abstained (principal investigator)

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

Risk factor: Minimal Risk

Gifts: None

Review date: One year

d. Announcements:

The 1992 Annual Progress Report is completed and available for review in the Medical Library. Diskette copies are also available (POC is COL Richard Banks, CI).

6. CONCLUSIONS/RECOMMENDATIONS/ACTIONS.

a. Approval of modification, paragraph 5b.

b. Approval of proposals, paragraph 5a(1-2) & 5c(2-3).

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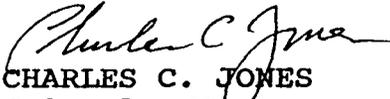
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c. Approval of proposals with revisions, paragraph 5c(1) &
5c(4-7).

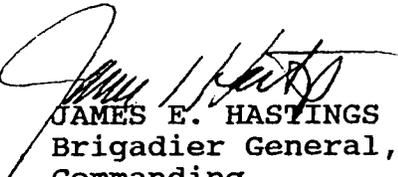
d. No referrals to the Executive Committee.

7. The meeting was adjourned at 1406.


RICHARD A. BANKS
Colonel, MC
Chief, Dept of Clin Invest
Recorder, CIC/HUC Cmte


CHARLES C. JONES
Colonel, MC
Deputy Cmdr for Clin Svcs
Chairman, CIC/HUC Cmte

APPROVED:


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

14 Jul 93
Date

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