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Department of the Air Force
 Wilford Hall USAF Medical Center (AFSC)
 Lackland AFB, Texas 78236

REPLY TO

ATTN OF: SGH/Human Experimentation Committee, Col Halki/7756

SUBJECT: Minutes of the Human Experimentation Committee, 28 Feb 74

TO: SG

1. The Human Experimentation Committee Meeting was held at 1000 hours on 28 February 1974 in the office of the Chairman, Room A1-17, Wilford Hall USAF Medical Center.

a. The following members or representatives were present:

Col Halki (SGH) - Chairman
 Col McPhaul (SGS) - Member
 Col Sparks (SGIII) - Member
 Col Collier (SGIIN) - Member
 Col Whiteside (SGX) - Member
 Maj Sebesta (SGJ) - Member

b. The following members were absent: None

c. The following additional personnel/guests were present:

Maj Steven Pedro (SGIIMD)

2. Old Business: None

3. New Business: The following consent forms were reviewed and discussed:

a. Title: "An Efficacy Study of Minocycline in Patients with Staphylococcal Skin and Soft Tissue Infections."
Primary Investigator: Steven Pedro, Maj, USAF, MC

The 32 consent forms presented for review by Major Pedro were not the proper format and documentation. The forms presented were the instruction sheets sent out with the consent forms to be filled out. Maj Pedro was instructed on how to fill out these forms and was told that a copy of each consent form should be sent to the Director of Clinical Research as it is obtained. The proper consent forms will be reviewed at our next meeting scheduled for 28 March 1974.

- b. Title: "Double Blind Evaluation of Topical Vitamin A Acid in Treatment of Pseudofolliculitis Barbae."
Primary Investigator: Steven Pedro, Maj, USAF, MC

This study has been removed from the list and is no longer in progress.

- c. Title: "Tc-Phosphate Complexes in the Radioisotopic Diagnosis of Avascular Necrosis"
Primary Investigator: Ellis P. Couch, Maj, USAF, MC

No consent forms were reviewed on the above since Major Couch was in the Operating Room and unable to present at the meeting. His consent forms will be reviewed at our next scheduled meeting which will be 28 March 1974.

- d. The following protocols were reviewed and explained.

- (1) Title: "An Investigation of an Ultraviolet Catalyzed Restorative Material for Restoration of Defects in Anterior Teeth."
Primary Investigator: James E. McIlwain, Maj, USAF, DC
Action: Approved

This protocol falls into Category II of the "Declaration of Helsinki," Clinical Research Combined with Patient Care. The project will be explained to the patient and the standardized format for "Informed Consent" (AFR 169-B) is adequate and will be used for the requirement stipulated.

- ✓(2) Title: "Comparison of Continuous Catheter Spinal Anesthesia with Single Dose Spinal Anesthesia for Transurethral Resection of the Prostate"
Primary Investigator: Louis A. Mitchell, Capt, USAF, MC
Action: Approved

This protocol falls into Category II of the "Declaration of Helsinki," Clinical Research Combined with Patient Care. It is recognized that there is no new treatment, regime or diagnostic technique involved that deviates from accepted professional practice. Therefore, the Committee is of the opinion that the requirement for informed consent can be waived but that Anesthesia consent form that is obtained routinely on all surgical patients is required.

- (3) Title: "A Phase III Comparison of Parenteral Formulations of Haldol (Haloperidol), Prochlorperazine, and Placebo for the Therapeutic Control of Post-Operative Nausea and Vomiting"

Primary Investigator: *Louis A. Mitchell, Capt, USAF, MC
Action: Approved

This protocol falls into Category II of the "Declaration of Helsinki." Clinical Research combined with Patient Care. It is recognized that there is no new treatment, regime or diagnostic technique involved that will be a detriment to accepted medical practice or patient care. Therefore, the Committee is of the opinion that the requirement for informed consent can be waived.

4. The meeting adjourned at 1100 hours.

JOHN J. HALKI, Colonel, USAF, MC
Director, Hospital Services

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1. Protocol as stated in para 3d(1)
2. " " " " " 3d(2)
3. " " " " " 3d(3)

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SC IOA/Maj Couch (w/o atch)
SC IMD/Maj Pedro (w/o atch)
SC JG/Maj McIlwain(w/o atch)