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 Mar 1974

TO: SG

1. The Human Experimentation Committee Meeting was held at 1000 hours on 28 March 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 (SGHH) - Member
L/C Burkhardt(SGHN) - Member
Col Whiteside (SGX) - Member
Maj Sebesta (SGJ) - Member

b. The following members were absent:

Col Collier (SGHN)

c. The following additional personnel/guests were present:

Maj Steven Pedro (SGHMD)
Maj Ellis P. Couch (SGHOA)

2. Old Business: The following consent forms were scheduled for review at our February meeting but were not in the proper format, therefore they were again reviewed.

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

Of the thirty-seven (37) consent forms submitted four (4) were not dated. They were properly filled out and documented and a copy had been submitted to the Director of Clinical Research. Maj Pedro was advised that all consent forms should be dated.

3. New Business: The following consent form was reviewed and discussed:

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

Maj Couch stated that he did not have any consent forms to be reviewed since there had not been any patients placed in the study since the protocol had been approved. However, during the discussion it was revealed that several patients (5 or 6) had received Tc-Phosphate complexes under the guidelines of the protocol to the Medical Center Research Committee. Maj Couch was informed of such impropriety.

Maj Couch requested that the requirement to obtain consent forms (Informed Consent - AFR 169-8) from patients be discontinued since the use of Technetium disphosphonate (Osteoscan) has been released for general medical use by the FDA and federal regulation does not require informed consent. Col Halki requested that a written statement be submitted to the Human Experimentation Committee to this effect. It was the consensus of the Committee that even though an informed consent would not be required in this protocol the patient must be informed and a note made in the patient's chart that such was done.

b. The following protocol was reviewed and explained.

(1) Title: "Combination Chemotherapy Study of Metastatic Sarcomas: A Phase III Study"
Primary Investigator: Charles A. Coltman, Col, USAF, MC
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 169-8) is adequate and will be used for the requirement stipulated.

4. The meeting adjourned at 1045 hours.

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

Atch
Protocol as stated in para 3b(1)

Cy furn:
SGHOA/Maj Couch (w/o atch)
SGHMD/Maj Pedro (w/o atch)