

Institutional Review Committee Meeting

1. Place: Administrator's Conference Room
2. Time and Date of Meeting: 1300 hours, 10 April 1979
3. Chairman: Colonel Gunter R. Meng, Director of Hospital Services
4. Members Present:

Colonel Casper H. Burke, Dental Services
Colonel Clint E. Chambers, Department of Surgery
Colonel Robert C. Walters, Director of Dental Services
Lt Colonel John L. Baldwin, Department of Medicine
Lt Colonel Enrique Pantoja, Chairman, Department of Radiology, SGE Representative
Lt Colonel Richard E. Smith, Director of Veterinary Services
Captain Teresa F. McMahon, Assistant Director of Medical Education, Recorder

Members Absent:

Lt Colonel Gary W. Hinzman, Director of Medical Education, (TDY)
Lt Colonel Dwight D. Smith, Department of Medicine (leave)

Guest Present:

Lt Colonel William K. Rundell, Department of Surgery
Major Richard W. Houston, Department of Medicine
Major Stephen P. Donohue, Legal Consultant

5. The Institutional Review Committee convened jointly with the Medical Isotopes Committee and the Human Experimentation Subcommittee to review the proposal for one time use of Copper-64 Cupric Acetate, to be administered to a patient for a Liver Function Study for Wilson's Disease. The committee also reviewed the proposed patient "Radioactive Study of Wilson's Disease Consent Form" to be used, if the study is approved.

a. Lt Colonel Rundell, the surgeon, scheduled to operate on the patient, presented the following case history:

(1) This is a 21 year old female first seen at this Medical Center in September 1977 and a suggestion of demyelinating disease was made at that time. She was followed and ultimately returned in January 1978 when a diagnosis of Wilson's Disease was made based upon finds of Kaiser-Fleischer rings in the cornea, decreased serum ceruloplasmin, increased copper stores in the liver on liver biopsy and her general neurologic picture. She was begun on penicillamine at that time and has shown a progressive improvement in her neurologic picture.

(2) In August 1978 the patient was evaluated by Dr. I. Herbert Scheinberg at the Albert Einstein College of Medicine in New York. In

addition to penicillamine he started her on BAL and has maintained an interest in this patient.

(3) The patient had her first episode of upper GI hemorrhage in August 1978. She had a recurrent bleed in October 1978 and at that time was found to have upper GI hemorrhage from bleeding esophageal varices. She also had an episode of hepatic coma and required nine units of whole blood transfusion. In February 1978 she had a recurrent upper GI hemorrhage from her varices which required six units of whole blood transfusion. Because of the recurrent variceal hemorrhage, she was ultimately referred back to this medical facility for consideration for a porto-systemic shunt procedure. At the time of this hospitalization, rather massive esophageal varices were again noted. She has had two episodes of minor upper GI hemorrhage while under observation at this hospital. Each required approximately three units of blood transfusion. The diagnosis is; (A) Wilson's Disease; (B) Esophageal varices secondary to Wilson's Disease; (C) Recurrent hemorrhage secondary to esophageal varices.

(4) Lt Colonel Rundell first saw this young woman approximately three weeks ago. Because of recurrent episodes of upper GI hemorrhage, esophageal varices and a massive enlargement of the spleen, he is recommending that the patient undergo a; (A) spleno-renal shunt; (B) splenectomy.

(5) Lt Colonel Rundell and Major Houston have contacted Dr. I. Herbert Scheinberg, a Professor of Medicine and Head of the Division of Genetic Medicine at Albert Einstein College of Medicine, Yeshiva University, Bronx, New York. He has been studying Wilson's Disease well over twenty-five years and is considered an expert on this extremely rare condition. He feels that there is a basic underlying enzyme defect in the liver, which accounts for the problem of the body's inability to handle copper and its subsequent deposit in the liver, ganglion of the brain and other areas of the body. For this reason, he has recommended that prior to surgery, the patient be given radioactive Copper-64 and at the time of surgery, a liver biopsy (approximately 5gm) be taken for radio-assay. Dr. Scheinberg is experienced with this radiopharmaceutical and authorized to use it at the Albert Einstein College of Medicine.

(6) Lt Colonel Rundell has counselled the patient on this proposal. She understands the proposal, the lack of provable benefit to her, and the lack of any known harmful effects occurring as a result of the administration of radioactive copper.

b. The Medical Isotopes Committee discussed the physical properties of Copper-64 Cupric Acetate, the dosage to be administered, hazards to the patient and to medical personnel, precautions and monitoring procedures and the approvals and licenses required prior to use at this medical center. All approvals and licenses have been obtained and the Medical Isotopes Committee granted approval for use of this radiopharmaceutical on a one-time basis and authorized Dr. Scheinberg to administer the radioisotope at this Medical Center.

c. The Human Experimentation Subcommittee reviewed and approved the proposal and the consent form.

d. The Institutional Review Committee reviewed the protocol for administering the Copper-64, Cupric Acetate. After discussion, each committee member was polled and each approved the following procedures:

(1) The patient will be given radioactive Copper-64 in an amount of approximately 1-2 mg copper and 1 millicurie of Copper-64 in approximately 4 oz of skim milk.

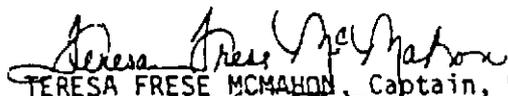
(2) Dr. Scheinberg will administer the radiopharmaceutical, in the presence of Lt Colonel Rundell and Major Houston, at approximately 0600 the morning of surgery.

(3) At the time of the operation, approximately two hours after the radioisotope has been administered, a biopsy of the liver, in the amount of approximately 5 gm will be taken.

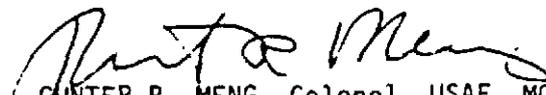
(4) The specimen will be given to Dr. Scheinberg for quick freezing and return to his laboratory for radio-assay and evaluation of the enzymatic defect of Wilson's Disease.

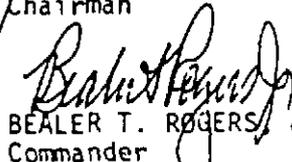
e. The Institutional Review Committee reviewed the "Radioactive Study of Wilson's Disease Consent Form" (Copy Atch) and made the following change. After the first sentence in paragraph 2 add: "This is an experimental procedure, since radioactive copper has not been generally accepted as a diagnostic or therapeutic drug". Each committee member was polled and each approved the informed consent, as amended.

6. The next meeting of the Institutional Review Committee will be at the call of the chairman.


TERESA FRESE MCMAHON, Captain, USAF, MSC
Recorder

2 Atch
1. Medical Statement
2. Informed Consent


GUNTER R. MENG, Colonel, USAF, MC
Chairman


BEALER T. ROGERS, Jr., Colonel, USAF, MC
Commander