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The next meeting of the Human Studies Review Committee will be held September 11, 1974, at 1:30 P.M. in the H-DO Conference Room.

Meeting of the Human Studies Review Committee

August 13, 1974 1:30 pm

Committee Members Present

Robert S. Grier M.D. Chairman
Rosemary H. Griffiths
Paul L. Flynn M. D.
Donald F. Petersen
David Law, M.D. UNM Medical School
Hary F. Schulte, Secretary

Committee Members Absent

None

Others Present

Richard F. Taschek, Dir. Off.
George L. Voelz, H-DO
Edward A. Knapp, MP-3

The meeting opened with a discussion of the letter of May 24, 1974, Kligerman to Voelz. It was noted that the protocols referred to in the fourth paragraph have not, in fact, been approved as yet by the UNM Human Research Review Committee. This was followed by a discussion of the division of responsibility between LASL and UNM for the radiobiology studies to be done this calendar year. According to Knapp, LASL will be responsible for handling the equipment, enabling it to deliver a dose as requested. LASL will check the delivery dose with their own equipment. The UNM representative will then check this calibration with their equipment. MP Division prefers to have UNM control the beam and dose by turning it on and off. This cannot actually be done at present. LASL, then, will maintain the machine and have an independent check on the dosage. UNM schould have a high level physicist present but they do not have one at present.

The next question discussed was regarding who was to be responsible for the patient's care during his stay in Los Alamos, e.g. for medical care for disorders not related to treatment. The protocol is not clear on this point. Other questions raised were those

of what the patient will do between treatments, provision for relatives and transportation. There must be an attending physician (and alternate) at LAMC. A sort of "social chairman" may be necessary. Petersen answered most of these questions. Clinical responsibility resides primarily with Kligerman. During treatment the patient will be at LAMC and a relative or other attending person can share the room at LAMC. At other times the patient and attendent can stay in a nearby apartment paid for by the project. There will be an attending nurse cooperating with the relative attendent for the "welfare" responsibility of the patient. Social activities and transportation have not yet been considered. Patients will be fed at the hospital.

Biopsies will be handled through the hospital facilities and Dr. Oakes may do these. The question was raised with reference to insurance whether Dr. Oakes will be acting as a LASL employee or as and independent contract physician.

The protocol itself was then discussed. Some items (page 3 paragraph 2) have not been accomplished as yet and will not be done in time for the first tests. Also the composition of the beam and the incidence of stray neutrons have not been measured.

The primary objective of these early tests is to determine the RBE of the skin. At present it is proposed to do the comparison X-ray treatment at the LAMPF by MP using a 15 year old machine to be obtained from the Gallup Indian Hospital.

Dr. Law said that the UNM Committee was concerned about the lack of any information in the protocol on animal studies for pion effects. Some of this is available and the beam composition data is being obtained.

The consent form was next discussed. The committee approved it unanimously provided the last line is removed from the first paragraph under "Patient Costs" on p. 3.

Peterson will ask Kligerman to prepare an updated protocol in view of changes in information available and new schedules. When this is available it will be considered by this committee.

The meeting was adjourned at 5:00 pm.

LOS ALAMOS SCIENTIFIC LABORATORY
UNIVERSITY OF CALIFORNIA
LOS ALAMOS, NEW MEXICO 87544

OFFICE MEMORANDUM

TO: R. S. Grier, M.D., H-2 Group Leader DATE: July 16, 1974

FROM: George L. Voelz, M.D., Health Division Leader

SUBJECT: REQUEST FOR HUMAN STUDIES COMMITTEE REVIEW OF THE USE OF NEGATIVE PI MESONS IN HUMANS

I have included a copy of the material received from Dr. Kligerman on his proposal to evaluate the radiobiological effects of negative pi mesons on skin and superficial metastatic nodules. Since he proposes to do this in August I would urge that a meeting of the Human Studies Committee be organized for an opinion on this study and at least a preliminary discussion on the other protocols for phase III, Clinical Trials, which I forwarded earlier.

GLV/mjt

Encl: Protocol for Human Radiobiology Studies of Pi Meson Radiation Therapy at UNM/LASL, "Evaluation of Radiobiological Effects of Negative Pi Mesons on Skin and Superficial Metastatic Nodules of the Skin and Cervical Lymph Nodes".

THE UNIVERSITY OF NEW MEXICO ▢ ALBUQUERQUE, NEW MEXICO 87131
CANCER RESEARCH AND TREATMENT CENTER
MORTON M. KLIGERMAN, M.D., DIRECTOR ▢ TELEPHONE 505: 277-3631

July 11, 1974

George Voelz, M.D.
Director, Health Research Laboratory
Los Alamos Scientific Laboratory
Los Alamos, New Mexico 87544

Dear George:

Attached is a copy of a protocol for evaluation of radiobiological effects of negative pi mesons on skin and superficial metastatic nodules of the skin and cervical lymph nodes, which is the first in a series of studies to determine radiobiological effects of pions on human tissue, prior to starting pilot studies and ultimately clinical trials of pion radiation therapy.

An earlier version of this study was reviewed and approved for funding support by the National Cancer Institute under Grant No. 1-P01-CA-16127-01 to the UNM Cancer Research and Treatment Center. The study has recently been revised somewhat to accommodate practical considerations of the operating schedule at LAMPF. We hope to start these studies in August, although it is doubtful whether we will be able to begin as early as August 10. However, due to the critical timing and scheduling requirements at LAMPF, I would appreciate it if the LASL human research committee could review it at the earliest opportunity.

Also attached is a copy of the consent form developed for this protocol. You will note there is no signature line for parent or guardian. Because of the nature of this study, we intend to accept only patients over 21 who are physically and mentally competent to give consent for themselves.

Please let me know if you have any questions concerning the material.

Sincerely,

Morton M. Kligerman, M.D.

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Attachments

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