

MINUTES OF THE MEETING OF THE REVIEW COMMITTEE FOR INVESTIGATIONS
INVOLVING HUMAN SUBJECTS OF THE PACIFIC NORTHWEST RESEARCH FOUNDATION

May 21, 1970

The meeting was held at 4:30 p.m., in Room 106 of Eklind Hall,
on Thursday, May 21, 1970.

Members present: Dr. William B. Hutchinson, Dr. Carl G. Heller,
Dr. Orless Wildermuth, Dr. Allan W. Lobb, Dr. Vernon Riley, Mr.
David Lycette, Miss Olive Ihmels and Reverend Richard E. Johnson.
Dr. David Porter represented Dr. William Hamlin who was out of town.

Members absent: Dr. Carl D. F. Jensen and Mr. C. Spencer Clark.

The meeting was called to discuss the proposed outline for the
revision and defining in detail of the policy of the Pacific
Northwest Research Foundation with regard to investigations involving
human subjects. The Review Committee membership has been changed in
order for us to have the advantage of a wider representation of
community opinion. Dr. John Bakke, Dr. Carteret Lawrence and Dr.
Sherman Day consented to resign from the committee in order to include
members not directly associated with the practice of medicine. New
members are as follows: Miss Olive Ihmels, R.N., Head Nurse at The
Swedish Hospital Medical Center in Seattle, Mr. David Lycette, Attorney
at Law in Seattle, and Mr. C. Spencer Clark, prominent local and
national businessman.

The proposed policy outline was openly discussed point by point.
Each suggestion raised was considered, evaluated in detail and
appropriate changes were incorporated.

In the areas of both initial and continuing review by the committee,
it was suggested by Dr. Wildermuth that a form should be drawn up which

could be completed in duplicate, indicating in writing the committee's opinion as to approval or disapproval of any project under consideration. One copy would be kept on file by the committee chairman and the second copy be given to the Principal Investigator in charge of the project. This suggestion met with unanimous approval and a form will be drawn up for this purpose and will be submitted to the committee membership for their approval prior to being put into routine use.

After all sections of the outline had been considered, Reverend Johnson moved that the policy as revised should be approved. Mr. Lycette seconded the motion and unanimous approval was voiced by the membership present. It should be noted that all members received copies of the proposed policy three weeks prior to the meeting and those who could not attend gave their approval and suggestions by phone.

Dr. Heller outlined a project which he proposed to undertake at the Oregon State Penitentiary. He requested permission to solicit volunteers from the inmate community for the purpose of collecting specimens of testicular tissue, blood, seminal fluid and urine. This would be carried out in conjunction with Dr. Heller's routine visits to the penitentiary on behalf of his ongoing AEC contract and Ford Foundation project. These materials are to be used by Dr. Niels Skakkebaek of Dr. Heller's department at the Foundation, in his genetic studies and by Dr. Jerry Berlin at Texas Tech University in Lubbock, Texas, for his ultrastructural investigations. Dr. Berlin and Dr. Heller have been working for the past year on a collaborative ultrastructural

study under the sponsorship of the Atomic Energy Commission. Dr. Heller also requested the assistance of Mr. Lycette with regard to drawing up an Informed Consent document for use in the above mentioned project. The committee approved Dr. Heller's proposal for collecting the required samples (testicular tissue, blood, seminal fluid and urine) and agreed that an Informed Consent document was necessary. This document will be drawn up by Mr. Lycette and Dr. Heller and a copy attached as an addendum to these minutes.

All business was completed and the meeting was adjourned at 5:40 p.m.

Respectfully submitted,



Carole M. Marty, Secretary

INFORMED CONSENT DOCUMENT DRAWN UP FOR USE IN THE PROJECT PROPOSED
BY DR. CARL G. HELLER TO THE MEETING OF THE REVIEW COMMITTEE FOR
INVESTIGATIONS INVOLVING HUMAN SUBJECTS OF THE PACIFIC NORTHWEST
RESEARCH FOUNDATION - Thursday, May 21, 1970

I _____ acknowledge that
Dr. Carl G. Heller has informed me that I may submit masturbated
seminal samples, blood samples, urine samples and testicular tissue,
and I hereby consent to giving such samples.

I have been informed what a testicular biopsy is and that
there are certain inherent risks in such a surgical procedure.
These risks include but are not limited to pain, both at the time
of surgery and thereafter, and I may have internal bleeding into the
scrotum. I consent to the surgery by a licensed medical doctor.

The samples are to be used in a research project which does not
specially benefit me. I consent to the publication of the results
of the project. I waive making any claim for any reason whatsoever
against the person or persons legally responsible for taking any samples
and performing any surgical procedures herein.

Signature

Date: _____

Witnessed by:

Signature

Date: _____

3000408

REPOSITORY: DOE-RICHLAND
COLLECTION: GSS HUMAN TEST SUBJECTS SUTDIES
PRISONER STUDY

BOX: 046264

FOLDER: 1780 - HELLER PACIFIC NW RES. FOUNDA.

ASSIGNED NUMBER: RLHTS 94-0009

3000408-A