

June 1, 1970

Dr. Frank Brooks
U. S. Atomic Energy Commission
Division of Biology and Medicine
Washington, D. C. 20545

Dear Doctor Brooks:

As promised, enclosed are three copies of our revised Policy with regard to Investigations Involving Human Subjects. I am also sending along three copies of the minutes of our latest Review Committee meeting at which this institutional policy was finalized.

Sincerely,

(Mrs.) Carole M. Marty
Secretary

CMM
Encls.

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POLICY AND PROCEDURES OF THE PACIFIC NORTHWEST RESEARCH FOUNDATION
WITH REGARD TO INVESTIGATIONS INVOLVING HUMAN SUBJECTS

I. Ethical Policy. Since 1958 the investigators of this Foundation have conducted all research under the ethical provisions of the Nuremburg Code, modified to permit consent by parents or legal guardians.

II. Administrative Review. All applications for funds must be reviewed by the Director; this review is chiefly concerned with completeness, budget accuracy and conformance with granting agency policy. The Director is also required to ascertain that projects involving human subjects have been referred to the proper committees for scientific and ethical review.

All proposals are initially submitted to the Medical Research Board for review of their scientific merit. All applications for support of research training or general research support projects, including those of fellows and trainees, which involve the use of human subjects must be approved by the Medical Research Board and the Review Committee for Research Involving Human Subjects before approval by the Director and submission to the granting agency. Specially selected consultants are called upon to comment on any scientific or ethical questions for the information of the Medical Research Board and the Review Committee for Research Involving Human Subjects.

See also Attachment A - "Institutional Assurance on Research Involving Human Subjects".

III. Membership of Review Committee for Research Involving Human Subjects.

This Review Committee bears the primary responsibility for review and approval of methods used to deal with the use of human subjects at the Pacific Northwest Research Foundation. It is made up of mature, competent individuals in the fields of surgery, internal medicine, ophthalmology and microbiology, the Director of The Swedish Hospital Medical Center, the Head of the Department of Pathology of The Swedish Hospital Medical Center, the Director of the Tumor Institute of The Swedish Hospital Medical Center, the Chaplain of The Swedish Hospital Medical Center, an attorney, a nationally respected business man, a Registered Nurse and the President of the Board of Trustees of the Pacific Northwest Research Foundation.

See Attachment B - Membership of the Review Committee for Investigations Involving Human Subjects of the Pacific Northwest Research Foundation

IV. Initial Review by Committee. All applications are considered by the Medical Research Board in the exact form to be used in submission to the granting agency. Subsequently, all proposals involving human subjects are submitted to the Review Committee for Research Involving Human Subjects and the investigators must discuss and be prepared to defend in person the following points:

1. A detailed discussion of the possible risks to the rights and welfare of human subjects, including the right of privacy and freedom from undue harassment, and a description of the provisions made to minimize these risks.
2. Methods used to acquire informed consent, with special emphasis on their appropriateness to the individual study situation.
3. The relative risks involved as compared to the probable benefits to the subject and to society,

Members of the Committee who are in any way directly involved in the work covered by any project being considered will be excused during pertinent discussion.

For each application, the Committee will either certify that these points have been properly dealt with and declare that the project may be submitted to the agency, or recommend to the Director that submission be delayed until specific deficiencies (spelled out in writing) are adequately dealt with. The Committee's findings will be transmitted in writing to the Director and the investigator.

V. Continuing Review by Committee. The Review Committee meets quarterly. The Committee, the membership of which is available at all times, will be convened by the Director for emergent problems. Investigators in charge of projects involving human subjects are required to submit status reports to the Committee, at appropriate intervals. Any unusual circumstances or procedural changes will be reported immediately to the Committee Chairman. The Chairman will maintain a project log summarizing all Committee actions, including discussions on these reports. If a report is delinquent, the Chairman will contact the investigator to ascertain the status of the study protocol. If at any time the Committee is dissatisfied with the conduct of the project or with the cooperation of the investigator, they shall recommend that financial support of the project be withheld immediately until the deficiencies are corrected.

If any investigator plans a change in study protocol, he will submit the proposed changes to the Committee for their approval, before putting them into practice.

VI. Provisions to protect the health and safety of human subjects.

Any research conducted involving possible risk to human subjects will be done at The Swedish Hospital Medical Center where complete patient care is available in a 500-bed facility. The Pacific Northwest Research Foundation is situated on the campus of The Swedish Hospital Medical Center.

VII. Applicability of this assurance. This assurance applies to the Pacific Northwest Research Foundation.

ATTACHMENT A

INSTITUTIONAL ASSURANCE ON RESEARCH INVOLVING HUMAN
SUBJECTS

The Pacific Northwest Research Foundation will comply with the principles of the Public Health Service policy with regard to research involving human subjects which requires a review independent of the investigator or director to safeguard the rights and welfare of those subjects. It assures the Public Health Service that it will establish and maintain advisory groups competent to review research plans involving human subjects, prior to the initiation of this research, in order to insure adequate safeguards. Group reviews and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved, (2) the appropriateness of the methods used to obtain informed consent, and (3) the risks and potential benefits of the proposed research.

The Pacific Northwest Research Foundation agrees to a continuing exchange of information and advice between the review group and the investigator or director, particularly to deal with proposed changes in research design, and with emergent problems which may alter the investigational situation with regard to the criteria cited above. The Pacific Northwest Research Foundation will assure itself that its policies and the advice of its review groups are followed. It will also provide whatever professional attention or facilities are required to safeguard the rights and welfare of human subjects involved in research. Records of group review and decision on the use of human subjects and of informed consent will be developed and kept by this institution.

William B. Hutchinson, M.D.
President and Director
Pacific Northwest Research
Foundation

Date: _____

ATTACHMENT B

LIST OF MEMBERS OF THE REVIEW COMMITTEE FOR INVESTIGATIONS
INVOLVING HUMAN SUBJECTS OF THE PACIFIC NORTHWEST RESEARCH
FOUNDATION

Mr. C. Spencer Clark
Chairman of the Board
Cascade Natural Gas Company, Seattle, Washington

William B. Hamlin, M.D.
Certified by the American Board of Anatomical and Clinical
Pathology
Head of the Department of Pathology
The Swedish Hospital Medical Center, Seattle, Washington

Carl G. Heller, M.D., Ph.D.
Head of the Division of Reproductive Physiology
Pacific Northwest Research Foundation, Seattle, Washington

William B. Hutchinson, M.D., F.A.C.S.
Certified by the American Board of Surgery
President and Director
Pacific Northwest Research Foundation, Seattle, Washington

Miss Olive Ihmels, R.N.
Head Nurse
The Swedish Hospital Medical Center, Seattle, Washington

Carl D. F. Jensen, M.D.
Certified by the American Board of Ophthalmology
Chairman, Medical Research Board
Pacific Northwest Research Foundation, Seattle, Washington

Reverend Richard E. Johnson, B.D.
Professional Hospital Chaplain
The Swedish Hospital Medical Center, Seattle, Washington

Allan W. Lobb, M.D., F.A.C.S.
Certified by the American Board of Surgery
Medical Director
The Swedish Hospital Medical Center, Seattle, Washington

Mr. David C. Lycette, L.L.D.
Attorney at Law
Seattle, Washington

ATTACHMENT B (Continued)

Vernon T. Riley, D.Sc.
Chairman, Department of Microbiology
Pacific Northwest Research Foundation, Seattle, Washington

Orliss Wildermuth, M.D., A.B.R.(T)
Certified American Board of Radiology
Director, The Tumor Institute of The Swedish Hospital Medical
Center, Seattle, Washington

This list may be subject to change periodically

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

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