

REPOSITORY DOE-FORRESTAL

COLLECTION MARKY FILES

BOX No. 2 OF 6

FOLDER CONSENTS FILED REPORTS

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Re: 3 R01 HD 00804-03S1

Examples of the completed forms will be gladly submitted upon request.

Respectfully submitted,

William B. Hutchinson
William B. Hutchinson, M.D.
President

Joseph E. Primeau
Joseph E. Primeau,
Business Manager

Carl G. Heller
Carl G. Heller, M.D., Ph.D.
Head, Division of Reproductive
Physiology

cc: Paul Henshaw, Ph.D., Division of Biology and Medicine,
AEC Washington, D.C.
Mrs. Neil Warner Fraser; Operations Office,
AEC, Richland, Washington
C. T. Gladden, Warden, Oregon State Penitentiary
Daniel DiIaconi, M.D., Consultant to AT (45-3)1780 and
HD 00804-03S1

cmm:

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The committee concluded:

1. The rights and welfare of the research candidates are assured. The subject is not solicited to participate in the program but submits an application with the knowledge and approval of the authorities at the institution and of its physicians. When new drugs are under investigation, repeated observations are made relative to renal, hepatic, hematopoietic, etc. functions by applying appropriate tests. A subject may retire from the program for any reason whatsoever, and at any time, without penalty (other than withholding a bonus that is paid at the satisfactory completion of the experiment).
2. The methods used to secure informed consent are appropriate and comprehensive in that documents pertinent to various aspects of the research must be signed before a witness, prior to acceptance to any particular stage of the program. These forms include:
 - a. Application to participate, (one of eight is accepted.)
 - b. Proof of approval from his religious advisor.
 - c. Request for sterilization (having been given full knowledge of its effects).
 - d. Request for vasectomy (accompanied by signature of the wife if individual is married).
 - e. Contract between inmate and Dr. Heller (outlining some of the obligations of each).
 - f. Acknowledgement form (indicating an investigational drug is being applied).
3. Risks are negligible and the individual is made fully aware of any such possibility of risk. Benefits have been and will be documented in publications and in the progress report of this investigation. These experiments have been conducted since 1956 and the staff physician at the institution has assisted in this program with knowledge and approval of the authorities of the Penitentiary.

The committee voted unanimously that Dr. Heller had complied with the Surgeon General's memorandum of February 8, 1966 in all respects (and indeed long before the memorandum was issued).

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The committee determined that Dr. Heller's research subjects, who are inmates at the Oregon State Penitentiary, volunteer to participate in his research program. It was at once apparent that "informed consent", in a general sense, was already involved before any subject was interviewed by Dr. Heller. This has evolved because the same general research program has been in operation by Dr. Heller at the Oregon State Penitentiary since 1956 and the inmates are well informed by fellow inmates regarding the general procedures concerned (i.e., collecting seminal samples, collecting urines for hormone studies, submitting to testicular biopsies, receiving medication orally or by injection, and having vasectomies if they have received intratesticular labeling doses of Thymidine-H³ or exposure of the scrotum to ionizing radiation). The inmates are not urged to apply to participate in the program by anyone. They apply by submitting an "Interview Request" directed to either the Hospital Administrator or to Dr. Heller. Only one in eight applicants is admitted to the program. The volunteers are carefully screened as to their past medical history and medical status, their emotional status and their religious status. If the program could be judged to be deleterious to an inmate in any way, he is refused. For instance, if his religious status is labeled "Catholic" on his Hospital chart, he is refused admission to the program because he would be asked to submit masturbated semen samples. If he denies being Catholic, he is referred to the Catholic Chaplain. If the priest decides he is not, indeed, a baptized Catholic, he writes a letter so stating and the applicant reapplies.

If the applicant wishes to be vasectomized, he signs an "Application for Sterilization". At this juncture he (after satisfying Dr. Heller he has a valid reason for this desire) is referred to a psychiatrist for an objective review of his feelings and for the opinion of the psychiatrist as to whether the subject's ego-structure can handle becoming sterile. If the inmate decides, or the psychiatrist decides, that vasectomy is not in his best interests, the applicant has the option of choosing a program in which vasectomy is not necessary.

File: Heller



PACIFIC NORTHWEST RESEARCH FOUNDATION

LABORATORIES FOR MEDICAL RESEARCH

1102 COLUMBIA STREET, SEATTLE, WASHINGTON 98104 ☐ MUTUAL 2-1582 (Area Code 206)

May 12, 1966

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Assistant to Director for Operations
National Institute of Child Health
and Human Development,
National Institutes of Health
Bethesda, Maryland 20014

Re: 3R01 HD 00804-03S1/

Dr. Heller's grant

Dear Dr. McDougall:

This letter is in response to your letter of May 3, 1966 regarding the Surgeon General's memorandum of February 8, 1966 concerning clinical investigations involving human beings.

The Pacific Northwest Research Foundation has named a committee to review each application for Public Health Service funds and other funds involving human subjects. The committee members also serve and have served as members of the Medical Board of the Pacific Northwest Research Foundation. This Board, among other duties, has the function of reviewing each research grant application from any Pacific Northwest Research Foundation investigator to any granting agency. The members therefore are thoroughly familiar with the principal investigators of the Foundation and their investigations.

There are eight members, and two ex-officio members. The members include principal investigators in the fields of surgery, internal medicine, ophthalmology, and pathology, the Director of the Swedish Hospital (a surgeon), the Head of the Division of Pathology of the Swedish Hospital, the Director of the Tumor Institute (a radiologist). The two ex-officio members are the President of the Board of Trustees of the Pacific Northwest Research Foundation (a surgeon) and the Business Manager of the Foundation.

The committee convened on May 9, 1966 to review the methods involved to assure the rights and welfare of human subjects involved in Dr. Carl G. Heller's research projects (including 3R01 HD 00804-03S1 and AEC AT(45-3)-1780).

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