

SUPPLEMENTAL MEMO TO PNWD HUMAN SUBJECTS COMMITTEE

DESCRIPTION OF PROPOSED HARC RESEARCH
INVOLVING HUMAN SUBJECTSProposal Number: 189-78-RK-128Proposal Title: EVALUATION OF RADIONUCLIDES IN MANSponsor: ERDA - DBERREPOSITORY PCL, Engi. Bldg, Area 3000Date Proposal Submitted:COLLECTION Human TissuesPrincipal Investigator: FT CrossBOX No. 2952FOLDER 104 SC 77-5

THE PURPOSE OF THIS QUESTIONNAIRE IS TO ELICIT FROM THE PRINCIPAL INVESTIGATOR INFORMATION WHICH WILL FACILITATE A RAPID AND THOROUGH REVIEW OF THIS PROPOSAL BY THE PNWD HUMAN SUBJECTS COMMITTEE. PLEASE ANSWER THE FOLLOWING QUESTIONS WITH THIS PURPOSE IN MIND.

I. The Research

A. What is the objective of the proposed research?

Evaluation of the radiological impact of the nuclear industry on workers and on residents in the neighborhood of the Hanford plant and development or improvement of methods to serve that end.

B. Why are human subjects involved in this research?

Analyses of human tissue samples obtained at autopsy is presently the only means of accurately quantifying radionuclides distributed within the body.

II. The Human Subjects

A. Who are these human subjects? (Describe by age, sex, SES, special characteristics, traits, etc.)

The autopsy cases are referred to BNW by the U.S. Transuranium Registry (USTR) relative to its responsibility to measure the disposition of transuranium elements in occupationally exposed individuals and by local pathologists interested in possible causative association of radioactive materials in situ and observed pathological conditions. The cooperation of local pathologists to provide tissues from residents or nonoccupationally exposed persons is encouraged by Hanford Environmental Health Foundation as a means of measuring the effectiveness of Hanford plant operating controls, safety procedures and engineering safeguards incorporated into facility designs.

HUMAN SUBJ.

MAY 5 1977

COMMITTEE

0009338

B. Are these human subjects:

Type	No	Yes
1. Fetuses?		
2. Pregnant Women?		
3. Prisoners?		
4. Mental Patients?		
5. Institutionalized?		
6. Not able to give informed consent?		

If any responses are "yes," please provide details:

Not strictly applicable - See II.A.

C. How many human subjects are involved in this research?

The number of human autopsy cases varies annually but the total number from program inception in 1949 to 1971 (see BNWL-SA-4077) was 350. A programmatic updating is currently underway.

D. How, and by whom, will the human subjects be selected?

See II.A.

III. The Risks and Benefits

A. Exactly how will the human subjects be involved in this research?

Not applicable

B. What risks, if any, will be faced by these human subjects?

Not applicable

C. What specific steps will be taken to minimize these risks?

Not applicable

D. What will be the benefits, if any, of this research to the human subjects involved?

Not applicable

E. What will be the benefits, if any, of this research to society at large?

Evaluation of human health risks (if any) in the nuclear industry.

F. Why do you feel that the benefits outweigh the risks?

There are no quantifiable or understood risks involved in this research.

IV. Informed Consent

A. How, and by whom, will informed consent be obtained?

Not applicable - Battelle merely processes tissues referred by pathologists.

(The USTR prearranges autopsy consent and obtains other necessary medical and health physics data for their purposes. The non-occupationally exposed cases are referred to Battelle at the discretion of responsible pathologists.)

B. Does the proposed informed consent procedure incorporate the following basic elements (please attach proposed consent form)?

Not applicable

Basic Element	Yes	No
1. A fair explanation of the procedures to be followed, including an identification of those which are experimental.		
2. A description of the attendant discomforts and risks.		
3. A description of the benefits to be expected.		
4. A disclosure of appropriate alternative procedures that would be advantageous for the subject.		
5. An offer to answer any inquiries concerning the procedures.		
6. An instruction that the subject is free to withdraw his consent and to discontinue participation on the project or activity at any time.		
7. Adequate documentation of informed consent.		

V. Please describe any arrangements or agreements with other institutions which will directly affect the involvement of human subjects in this research.

All tissues are analyzed within BNW facilities except for possible future interlaboratory comparisons or the use of neutron exposing facilities for neutron-induced autoradiography.

VI. Please note any unusual aspects of this research to which the Human Subjects Committee's attention should be directed.

For further clarification, see the attached information from I. C. Nelson, former principal investigator.

0009341

F.T. Cross *F.T. Cross*
Principal Investigator

HARC Study Center

5/4/77
Date

ATTACHMENT TO SUPPLEMENTAL MEMO TO PNWD HUMAN SUBJECTS
COMMITTEE FOR THE EVALUATION OF RADIONUCLIDES IN
MAN PROGRAM

There are two classes of human tissue specimens which are analyzed in this program: those provided to us by the U.S. Transuranium Registry (USTR), operated by Hanford Environmental Health Foundation (HEHF), and those provided by T. D. Mahony, M.D., Pathologist, Kadlec Hospital, in cooperation with HEHF. No other human tissue samples are accepted at this time.

Tissue samples obtained by the USTR are, as I understand it, a result of certain agreements between the USTR and individuals who have "joined" the USTR. Battelle does not solicit names of the individuals sampled and serves primarily as an analytical laboratory only. In case a USTR case had been a Hanford employee, his work history may be required and is provided from a search of radiation protection records based on the name provided by the Registry. Health physicists of the employee's organization have prior right to publication of findings (over USTR). This is the case also if Battelle is the employer.

Tissue samples are also obtained from individuals coming to autopsy under T. D. Mahony, M.D., who performs postmortem examinations at Kadlec Hospital and in Kennewick. Other licensed pathologists occasionally obtain samples at these locations while standing relief duty for Dr. Mahony. These samples are from cases coming to autopsy because of request by family, attending physicians, or possibly the State. Again, the cause of death and name of individuals are obtained from Dr. Mahony by HEHF.

At Battelle, the analytical laboratory avoids obtaining any identification of individuals sampled. HEHF may request the Environmental Occupational Safety Department of Battelle to search their records again for Hanford related work history. Names of autopsied individuals are required in that event.

The analytical program for environmental subjects serves two major purposes: that of assisting the pathologist in a determination of cause of death by determination of radionuclides present, and providing HEHF and Battelle with monitoring information on the presence of plutonium in workers and residents in the Hanford environs. Battelle, HEHF and Dr. Mahony usually co-author reports of analytical findings for the open literature.

0009342

Page 2 - Attachment
Evaluation of Radionuclides in Man

The number of cases per year and samples per case varies widely with USTR cases. On the order of five to fifteen environmental cases are obtained per year. Environmental cases may include children, infants, etc, in which case extra care is taken to avoid listing results in such a way as to make identity easy.

All tissues are obtained via pathologists. No human testing is performed in this program.

0009343