PNL 10616-006

SUPPLEMENTAL MEMO TO PNWD HUMAN SUBJECTS COMMITTEE

DESCRIPTION OF PROPOSED ~~[illegible]~~ Bmd RESEARCH INVOLVING HUMAN SUBJECTS

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Proposal Number: 300A 01198

Proposal Title: Translocation of Yellowcake from the Human Respiratory Tract

Sponsor: NRC

Date Proposal Submitted: March 14, 1978

Principal Investigator: Bob Robinson

REPOSITORY PNL
COLLECTION Yellowcake
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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?

The primary objective of the proposed research is to determine the solubility of yellowcake inhaled by mill workers.

B. Why are human subjects involved in this research?

Human subjects are involved in this research for the following reasons:
1) Humans who have inhaled yellowcake from normal, routine mill operations would be available.
2) The data obtained from the study will be used to modify or verify existing radiation protection standards for humans.

II. The Human Subjects

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

The human subjects could be any mill workers, male or female between the ages of 18 and 65.

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B. Are these human subjects:

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

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

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

Ten.

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

The human subjects will be selected based on their inhalation of yellowcake as a result of work assignment at selected uranium mills. The subjects will be selected jointly by NRC, PNL personnel and appropriate mill representatives.

III. The Risks and Benefits

A. Exactly how will the human subjects be involved in this research?
The human subjects, after a yellowcake intake, will be asked to collect urine voidings and travel to the Hanford area for in vivo organ counting and back to the mill. The data collected will be used for statistical analysis only and the identity of the subject will not be revealed.

B. What risks, if any, will be faced by these human subjects?
Only those risks involved in travel to the Hanford area and back to their home at the mill location. However, it is possible that the subject, family, friends, and/or co-workers might assign more significance to the special examinations than really warranted causing concern to the subject.

C. What specific steps will be taken to minimize these risks?
Orientation of management and employees at the mill involved of the purpose for the extensive examination and evaluation to be conducted.

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

The benefits of this research to the human subjects involved will be the establishment of a better basis for health surveillance procedures and standards for uranium mill workers.

E. What will be the benefits, if any, of this research to society at large?
A better understanding of the occupational risks involved in energy extraction

F. Why do you feel that the benefits outweigh the risks?
The study will not involve any appreciable rists and will give benefits as given in items D and E above.

IV. Informed Consent

A. How, and by whom, will informed consent be obtained?
If it is determined that informed consent is appropriate for this study we will obtain the subject's consent through appropriate management.

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

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

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

None.

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

None.

Bob Robinson by [illegible] 3/22/78

Principal Investigator ~~HARC Study Center~~ BNW Date

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