

Review Due: April 18, 1979

709363

Date: 4/9/79

PNL-9570

HSC MEMBER REVIEW
OF

A PROPOSAL TO STUDY ²³⁰Th IN URANIUM MILL WORKERS
(300A01348) PHSC 79-B



Pacific Northwest Laboratories
Battelle Boulevard
Richland, Washington 99352
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Telex 32-6345

1. The rights of the subject are:

a. Adequately protected

b. Not adequately protected because:

- (1) Written or verbal informed consent inadequate.
- (2) Coercion may be possible (e.g., employees).
- (3) Special assurance needed because of type personnel.
- (4) Insufficient information presented. Need to know -

No discussion of consent procedures

(5) Other reason is:

REPOSITORY PNL
 COLLECTION Thorium
 BOX No. 2951
 FOLDER HSC 7A B

2. The welfare of the subject is:

a. Adequately protected

b. Not adequately protected because:

- (1) The risks are greater than potential benefits.
- (2) The risks are greater than the importance of the knowledge to gain.
- (3) Psychological repercussion likely due to possible or real existence of adverse or degrading nature of experiment, public reactions, religious impact, etc.
- (4) Insufficient information presented. Need to know -

(5) Other reason is:

3. The possible risks associated with this project are:

(aggravation of anxiety status, preservation of confidentiality of data, psychological reactions due to..., inexperience or possible incompetence of researcher, etc.)

Short discussion:

invasion of privacy, coercion from management, etc.

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4. The benefits outweighing the risks are:
(Brief statement or discussion.)

Risks are small, but the proposal doesn't really address the human subjects consent directly. I presume that the information gathered would be of significance to society at large.

includes

5. The informed consent data following basic elements: does not include to my satisfaction the

- a. A fair explanation of the procedures to be followed, including an identification of those which are experimental.
- b. A description of the attendant discomforts and risks.
- c. A description of the benefits to be expected.
- d. A disclosure of appropriate alternative procedures that would be advantageous for the subject.
- e. An offer to answer any inquiries concerning the procedures.
- f. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

6. This project requires continuing review and I desire progress reports at _____ intervals.

I desire personal interviews before the Committee each _____

7. I am involved in the conduct of the project.
 I am not

8. Program is to be resubmitted when the intended use of human subjects becomes more definitive.

9. This program is Approved *Conditional on the development of a proposal to address the issue of consent of the "volunteers" satisfactory to the Committee.*
 Disapproved (Please mark.)

Elizabeth B. Harkins

Signature

Research Scientist

Title

4/12/79

Date