

Review Due: April 18, 1979

Date: 4/9/79

PNL-9568

HSC MEMBER REVIEW
OF

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



Battelle

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709361

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 - *contents of informed consent. Recommend author contact Bob Robinson, 942-7245 for a copy of the informed consent developed following the recommendations of Fitz Harkins on a very similar proposal. It tells # of samples*
- (5) Other reason is: *expected, duration of study, use of data and means used to protect identity.*

REPOSITORY PNL
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 FOLDER HSC 79B

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: *none if informed consent*
(aggravation of anxiety status, preservation of confidentiality of data, psychological reactions due to..., inexperience or possible incompetence of researcher, etc.)
Short discussion: *is adequate*

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

See item 1

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

- 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 Disapproved
provided an adequate informed consent is developed and submitted to the HSC prior to program implementation
(Please mark.)

[Signature]
Signature

[Signature]
Title

4/12/79
Date