

7-1-6 Due 4/19

PNL-9522

HSC MEMBER REVIEW
OF



Pacific Northwest Laboratories
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Richland, Washington 99352
Telephone (509)
Telex 32-6345

SEMI-PORTABLE BLOOD IRRADIATOR

702829

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 -

REPOSITORY PNL

COLLECTION BLOOD IRRADIATOR STUDY

BOX No. 29-51

FOLDER HSC 74-6

(5) Other reason is:

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:

that there could be misuse or breakdown of the equipment. However, this seems remote and ~~not~~ should not stand in the way of approval.

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

Developing a portable blood incubator could be an important contribution to medical practice. With the time, its units might become inexpensive enough to be a standard hospital/operating device.

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

- a. ~~A fair explanation of the procedures to be followed, including an identification of those which are experimental.~~ *Informed consent okay - to be handled by VA Hosp under separate contract with AR.*
- 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~~ am not involved in the conduct of the project.

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

9. This program is (approved/~~disapproved~~).

George M. Dalen
Signature

Asst. Communications Dept., B/W
Title

4/9/74
Date