PNL-9639

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DHSC ~~76-31~~ 77-2

SUPPLEMENTAL MEMO TO PNWD HUMAN SUBJECTS COMMITTEE

DESCRIPTION OF PROPOSED HARC RESEARCH
INVOLVING HUMAN SUBJECTS

Proposal Number:

Proposal Title: Measurement of Muscular-Skeletal Changes Which Occur During Space Flight

Sponsor: NASA

Date Proposal Submitted: Will be submitted by November 10, 1976

Principal Investigator: H. E. Palmer

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?

To test a procedure with human subjects which was found to be successful on animals before it is applied in studies with astronauts. To determine a normal distribution of ^{85}Sr in humans.

B. Why are human subjects involved in this research?
There is no other way to test the procedure.

II. The Human Subjects

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

Three (3) normal male subjects between 21 and 45 years of age and average size.

Three patients who have had leg injuries requiring a leg cast for at least six weeks. Patient subjects will be between 21 and 45 years old.

REPOSITORY PNL, ENG. BLDG, AREA 3000
COLLECTION STRONTIUM 85
BOX No. 2952
FOLDER HSC 77-2

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HUMAN SUBJ.
OCT 25 1976
COMMITTEE

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?
Six

D. How, and by whom, will the human subjects be selected?
Patients will be located through orthopedic clinics by advertisement given to them by a physician.

Normal volunteers will be located by advertisement.

III. The Risks and Benefits

A. Exactly how will the human subjects be involved in this research?
Subjects will be injected with a small quantity of ^{85}Sr by the cooperating medical institution. The deposition of the ^{85}Sr will be studied by Battelle personnel in Battelle facilities.

B. What risks, if any, will be faced by these human subjects?
Extremely low risk of radiation damage.

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

Careful in preparation of injected doses.

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

A satisfaction of contributing to research in the space program.
A financial benefit of $200.

E. What will be the benefits, if any, of this research to society at large?
This research will provide methods to study the effect of space travel on the human body.

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

The risk is extremely low.

IV. Informed Consent

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

Will be determined later, but will be done through the cooperating medical institution.

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.		
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.

The University of Washington has a companion contract with NASA and is under obligation to help Battelle complete these studies by dealing directly with the human subjects.

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

H. E. Palmer
Principal Investigator

Occup. & Env. Safety Dept.
~~XXXX Study Center~~

10/25/76
Date

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SUPPLEMENTAL MEMO TO PNWD HUMAN SUBJECTS COMMITTEE

HUMAN SUBJ.
OCT 25 1976
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BEST COPY AVAILABLE

I. The Research

A. What is the objective of the proposed research?

To test a procedure (used from any subjects which were) found to be successful on animals before it is applied in studies with astronauts. To determine a normal distribution of ^{85}Sr in humans.

B. Why are human subjects involved in this research?

There is no other way to test the procedure

II. The Human Subjects

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

3 normal male subjects between 21 and 45 years of age and average size.

3 patients who have had leg injuries requiring a leg cast for at least 6 weeks. Patients subjects will be between 21 & 45 years old.

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B. Are these human subjects:

Type	No	Yes
1. Fetuses?	X	
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:

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

6

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

Patients will be located through orthopedic clinic by advertisement given to them by a physician

Normal volunteers will be located by advertisement

III. The Risks and Benefits

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

They will be injected with a small quantity of ^{45}Ca by the cooperating medical institution. The deposition of Ca^{45} in the bone will be studied by Battelle personnel in Battelle facilities.

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

Extremely low risk of radiation damage

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

Careful in preparation of injected doses.

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

a financial benefit of $200
a satisfaction of contributing to research in space program

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

This research will provide methods to study the effect of space travel on the human body

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The risk is extremely low

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H E Palmer
Principal Investigator

HARC Study Center

10-25-76
Date