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new

#83-110

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NOV 08 1988

PROTECTION OF HUMAN SUBJECTS
LAWRENCE LIVERMORE NATIONAL LABORATORY

INSTITUTIONAL
REVIEW BOARD

(TO BE COMPLETED BY P.I. AND SUBMITTED TO INSTITUTIONAL REVIEW BOARD PRIOR TO MEETING)

718037

Project Title Whole Body Counter Calibration with Ba-133

Funding Source Not Applicable

AGREEMENT OF COMPLIANCE STATEMENT

I agree to conduct my experiments according to this protocol and conform with the policies of Lawrence Livermore National Laboratory and Biomedical Sciences Division. Before any changes in this protocol can be implemented, a written notice of the proposed changes must be submitted to the Institutional Review Board as an amendment to the protocol.

Principal Investigator signature: A. L. Anderson

Date: 10/24/88

A. NEW PROJECTS

1. What is the involvement of human subjects in this project and what human samples will be used?
The human subject will be used to obtain in-vivo measurements of Ba-133 particles already in their bodies using LLNL Whole Body Counting equipment. No human samples are used.

2. What is the present or actual benefit to society in doing this project?
Taking advantage of the data provided by humans with radioactive uptakes is a means of better calibrating the radiation detectors used in various in vivo monitoring programs. This will ultimately provide more accurate dose estimates of individuals with radioactive uptakes.

3. Outline Protocol.
In vivo measurements of the Ba-133 deposited in the subject's body will be obtained at various body sites, using counting equipment located in the Whole Body Counter, Bldg. 253. The subject will lay in a supine position for these measurements. Radiation detectors will be placed in close proximity to various measurement sites on the body for periods of time ranging from 15 to 50 minutes.

4. List source(s) of human samples
Persons employed at AERE, Harwell, United Kingdom, who have been involved in planned and approved radioactive uptake experiments.

REPOSITORY LLNL B361 Ratched
COLLECTION Institutional Review Board
BOX No. IRB Minutes
FOLDER Nov 16, 1988 - Institutional Review Board Mtg

1122526

5. How will confidentiality be insured?

We will not identify the subject by name in any study reports. The Principle Investigator (A. L. Anderson) will disclose the subject's name only to individuals performing associated research.

6. Attach copy of filled-in consent form that subjects will be asked to sign (*Use the attached copy of the Duke University checklist as a guide in completing the consent form.*)

7. List name(s) of collaborative institutions. **Approvals from those institutions must be on file with the LLNL Human Subjects Committee**

NONE.

B. RENEWAL PROJECTS

1. Outline Protocol.

2. Date of first Human Subjects Committee approval: _____
Approval No. _____

3. Date of latest approval: _____

4. Will consent form need to be changed? If so, attach revised consent form.

5. Are there any changes in protocol for human subjects from most recent review?

6. Since most recent review, have any additional potential hazards been identified?

7. List any new collaborative institutions. **Approvals from those institutions must be on file with the LLNL Human Subjects Committee**

8. List any new sources of human samples

C. PROJECTS THAT INVOLVE SAMPLES COLLECTED ELSEWHERE

1. Has this project been reviewed and approved by the other institution's human subjects institutional review board?

2. Date of approval: _____

3. Does the consent form include a statement stating that some of the work will be done at LLNL?

4. Does the LLNL Human Subjects Committee have on file a copy of the form signed by subjects?

NOTE: Copies of these documents must be provided to the LLNL Human Subjects Committee

UNIVERSITY OF CALIFORNIA
LAWRENCE LIVERMORE NATIONAL LABORATORY

Consent to Act as a Human Subject

LLNL Institutional Review Board
Approval Number: ~~88-101~~
Approval Date: ~~January 26, 1988~~

~~Lung Counter Calibration with inhaled Nb-92m as a "Mock Plutonium"~~
^{WHOLE BODY} ~~Lung Counter Calibration with inhaled Nb-92m as a "Mock Plutonium"~~ ^{Ba-133}

Subject's Name: _____
Date: _____

1. I hereby authorize Arthur L. Anderson and/or such assistants as may be selected by him, using LLNL ~~WHOLE BODY~~ counting equipment, to obtain from me in-vivo measurements of ~~Nb-92m~~ particles, said measurements to be utilized for experimental purposes. ^{Ba-133}
2. I understand that ~~plutonium lung~~ ^{whole body} counting procedures for obtaining these measurements are standard (not of an experimental nature), and that it is expected that I will be able to function normally immediately.
3. I understand that any possible risks and discomforts that may result from the procedure(s) are considered unlikely but include:
 - a. possible injuries from falls.
 - b. discomfort from laying in supine position for extended periods of time.
 - c. normal hazards associated with everyday work activities
4. Since this activity does not involve medical treatment, there is no alternative procedure which might be advantageous to me.
5. I understand that this study may result in no direct benefit to me but it ~~may contribute to the understanding of the capabilities and limitations of a phantom that has become an international standard for the calibration of plutonium lung counters, and~~ may be of some benefit to individuals in the future.
6. I understand that Arthur L. Anderson will disclose my name only to the individuals performing associated research.
7. I understand that Arthur L. Anderson and/or such assistants as may be selected will answer any inquiries I may have at any time concerning the procedures and/or investigation.
8. Any publication arising from this study will be made without specific reference to my name.
9. I recognize that my participation in this experiment is entirely voluntary and I may refuse to participate or may withdraw at any time without jeopardy. Owing to the scientific nature of the study, the investigator may in his absolute discretion terminate the procedures and/or investigations at any time.

Subject's Initials _____

LLNL Institutional Review Board
Approval Number ~~00-101~~
Approval Date: ~~January 26, 1988~~

10. I acknowledge the receipt of a signed copy of this consent form and the LLNL Experimental Subjects Bill of Rights.
11. Arthur L. Anderson, an employee of the University of California, Lawrence Livermore National Laboratory, is responsible for the conduct of the research in which I am to participate. ~~This research is sponsored by the AERE, British Nuclear Fuels, and the U.K. Central Electricity Generating Board, and the Hazards Control Department of the Lawrence Livermore National Laboratory which is operated by the University of California under Contract W-7405-Eng-48 with the United States Department of Energy.~~
12. I understand that if I have any complaints or concerns about the procedures, I may address them to Dr. Barton L. Gledhill, Chairman of the Institutional Review Board, in person, by telephone, or in writing. Dr. Gledhill can be reached at (415) 422-3883, L-452, Lawrence Livermore National Laboratory, P.O. Box 5507, Livermore, California 94550.

Subject's Signature: _____

Date: _____

Witness' Signature: _____

Date: _____



EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The management and staff of the University of California, Lawrence Livermore National Laboratory, wish you to know:

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment, if complications should arise.
7. Be given the opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If at any time you have any questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may also seek assistance from the Human Subjects Committee which was established for the protection of volunteers in research projects. The Chairman of that Board, Dr. Barton L. Gledhill, may be reached by calling (415) 422-3883, from 8:00 a.m. until 5:00 p.m., Monday through Friday, or writing to the Institutional Review Board, L-452, Lawrence Livermore National Laboratory, P.O. Box 5507, Livermore, CA 94550.

Interdepartmental letterhead

Mail Station L- 383

Ext: 2-5181/2-5199

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INSTITUTIONAL
REVIEW BOARD

October 24, 1988

TO: Bart Gledhill, Chairman, Institutional Review Board
c/o Gerry Wyman

FROM: A. L. Anderson
Deborah Kruchten

SUBJECT: Whole Body Counting of Employee from AERE Harwell, U.K.

Approval is requested from the LLNL Institutional Review Board for LLNL to participate in radioactivity measurements on [REDACTED], the Division Leader of the Environmental and Medical Sciences Division at AERE Harwell, United Kingdom.

[REDACTED] received an administration of ^{76 Ktg (2.05 nCi)} ~~76 Bq (2.05 nCi)~~ of Ba-133 in March 1986 in a planned AERE experiment formally approved by their Tracer and Irradiation Studies Approval Committee. This committee is an ethics committee similar in human use oversight to our own (LLNL) Institutional Review Board.

The Ba-133 uptake (primarily now in bone) is known to within 5% and will provide useful additional data to that taken from [REDACTED], who was counted at LLNL in October 1987. An uneven distribution of activity was observed in the bones of [REDACTED]. This uneven distribution contributes error to activity calculations since it is standard practice to calibrate the counting equipment using phantoms with known even distributions of radionuclides. [REDACTED] will provide additional data on the question of uneven radionuclide distributions in the body. This data is useful to LLNL and other DOE facilities as a means of better calibrating radiation detectors used in various in vivo monitoring programs which will ultimately provide more accurate dose estimates of individuals with radioactive uptakes.

Similar studies have been performed in the past with LLNL participation concerning subjects with Pd-103, Cr-51, Nb-92m, and various other radionuclides, including heavy elements such as Am-241 and Pu-239 that were taken up in the body as a result of accidental or occupational exposure. Usually, LLNL has been involved only in a passive sense, that is in performing measurements only on the subjects. However, approval was received from the LLNL Human Subjects Committee in 1981 and 1982 to allow participation of two LLNL employees in a program involving the direct inhalation of Nb-92m labeled particles at AERE Harwell. Both employees,

University of California

 Lawrence Livermore
National Laboratory

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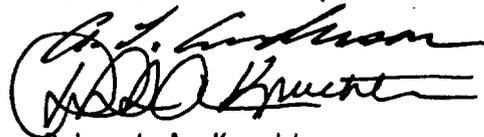
along with one other American and five British subjects were later counted at several British and American facilities, for the purpose of validating the LLNL plutonium lung counter calibration phantom which was developed at this Laboratory. In further work, 11 women (all British), were employed in another Nb-92m intercalibration program to determine the suitability of the phantom as calibration medium for females. Both of these programs produced valuable data, enabling us to perform our work more accurately and with more confidence.

The primary purpose of [REDACTED] visit to LLNL is to meet with Ron Jensen of the Biomedical Department to discuss the assessment of accumulated radiation dose on humans. Pending approval by the Institutional Review Board, we are proceeding to invite [REDACTED] to participate in measurements pertaining to his Ba-133 uptake while he is here at this Laboratory on November 17-19, 1988. Representatives from DOE-SAN have been informed of LLNL's intended measurements.

Attached for your review are the written communications with [REDACTED] to date.

With tougher standards such as ANSI N13.30 around the corner, better calibrations are needed to produce more accurate estimates of activity in the body. Taking advantage of the data provided by humans with radioactive uptakes is a means of better calibrating the radiation detectors used in various in vivo monitoring programs. If you have any questions regarding the above, please call Larry Anderson or Deborah Kruchten, on 2-5181 or 2-5199, respectively.

A. Larry Anderson
Whole Body Counting Laboratory
Hazards Control Department



Deborah A. Kruchten
Whole Body Counting Laboratory
Hazards Control Department

ALA/DAK:beb

Attachment

1122533



Lawrence Livermore National Laboratory

October 24, 1988

Mr. James Davis
U.S. Department of Energy
DOE SAN Office
1333 Broadway
Oakland, CA 94612

Subject: Visit Request and Whole Body Counting of Employee from AERE
Harwell, U.K.

Dear Mr. Davis:

Enclosed for your information are documents submitted to the LLNL Institutional Review Board regarding proposed whole body counter measurements in mid-November 1988 for [REDACTED], the Division Leader of the Environmental and Medical Sciences Division at AERE Harwell, United Kingdom. The primary purpose of [REDACTED] visit is to meet with Ron Jensen of the Biomedical Department to discuss the assessment of accumulated radiation dose in humans. [REDACTED] has volunteered to stay an extra two days to allow whole body measurements of the residual activity present in his body from Ba-133 which was administered in the United Kingdom. These measurements will be useful to LLNL and other DOE facilities as a means of calibrating our counters, since the Ba-133 activity in [REDACTED] is known quite accurately.

If you have any questions regarding the above, please call Larry Anderson or Deborah Kruchten of my staff on FTS 532-5181 or 532-5199, respectively.

Sincerely,

Thomas R. Crites
Department Head
Hazards Control Department

TRC:beb

Attachment:

cc: Bart Gledhill w/o attachments

1122534



HARWELL
UK ATOMIC ENERGY AUTHORITY

Environmental and Medical Sciences Division
B551 Harwell Laboratory
United Kingdom Atomic Energy Authority
Oxfordshire OX11 0RA

Telex: [REDACTED]
Telephone: Abingdon (0235) 24141
Extension [REDACTED]

19 September 1988

Dr A L Anderson
Body Radioactivity Measurements Section
Lawrence Livermore National Laboratory
LIVERMORE
California 94550
U S A

Dear Dr Anderson

I am a colleague of Don Newton and plan to visit the Lawrence Livermore National Laboratory in November, primarily to discuss the assessment of accumulated radiation dose in humans with Dr Mendelsohn of the Biomedical Sciences Division.

Before coming to Livermore, I will be attending a Symposium at the Inhalation Toxicology Research Institute at Albuquerque (14-16 Nov) and if possible would like to visit LLNL on 17th and 18th. The reason you may be interested, is that I have been injected with ^{133}Ba some months ago and Don thinks that by November, my body content will be ~6 KBq.

Can you please let me know whether you would be interested in measuring my radioactivity and if you are, contact Dr Mendelsohn to whom I have written already, to decide how best to utilise the time available. We have had a postal strike in U.K., so I haven't been able to write to you before. If, when you have contacted Dr Mendelsohn, you could telephone me I would be grateful. My numbers are as follows:

Office 0235 24141 [REDACTED]
Hofme 0235 [REDACTED]

With best regards.

Yours sincerely

[REDACTED]
[REDACTED] (Dr)

1122535



HARWELL
UK ATOMIC ENERGY AUTHORITY

Environmental and Medical Sciences Division
B551 Harwell Laboratory
United Kingdom Atomic Energy Authority
Oxfordshire OX11 0RA

Telex: [REDACTED]
Telephone: Abingdon (0235) 24141
Extension [REDACTED]

26 September 1988

Dr A L Anderson
Body Radioactivity Measurement Section
Lawrence Livermore National Laboratory
LIVERMORE
California 94550
USA

Dear Dr Anderson

I understand that Don Newton has contacted you regarding my visit to LLNL in November. He requested that I send you the following details:-

- Date of birth: [REDACTED]
- Place of birth: [REDACTED]
- Passport No: [REDACTED]
- Expiry date: [REDACTED]
- Home address: [REDACTED]

I have completed a U.S. DoE request for an unclassified visit to LLNL. Please will you book accommodation for me in Livermore for the nights of 16th and 17th November.

With best regards.

Yours sincerely

[REDACTED SIGNATURE]

[REDACTED]

cc Dr D Newton

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REVIEW BOARD**

STAFF IN CONFIDENCE

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Page 1 of 2

PART ITitle of Study: Metabolism of alkaline earth elementsPurpose of investigation:

To provide data relevant in the formulation of models of alkaline earth metabolism

Description of Study:Intravenous injection of ^{133}Ba in isotonic saline; measurement of ensuing radioactivity in blood, excreta and whole bodyTISAC paper (85)8Minute Reference (85)M2ARSAC Cert RPC 313-2(8)Held by Dr J C EvansRadionuclide(s) ^{133}Ba Likely No of
administrations 1

Total activity administered:

75 kBq maximum

Anticipated committed dose equivalent to organ(s):

Red marrow	1.0 mSv	Gonads	0.15 mSv
Bone surfaces	1.4 mSv	Lungs	0.16 mSv
		Adrenals	0.22 mSv
		Committed effective dose equivalent	<u>0.23 mSv</u>

Name: D NEWTONSigned: D Newton

(Investigator)

Date: 31/12/87

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STAFF IN CONFIDENCE

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Page 2 of 2

STUDY TITLE: Metabolism of alkaline earth elements

PART II

I confirm that I have explained the nature, purpose and possible hazards of this study to this volunteer.

Name: Jeffrey R. Morgan

Signed: [Signature]
(Medical Examiner)

Date: 12/1/88

PART III

The nature of the study and its possible hazards have been explained to me by Dr J.R. Morgan. I have informed the Doctor of any medication/drugs that I have recently taken, am taking or planning to take, whether prescribed or not.

I will not be referred to by name in any report describing the study, which is disclosed to a third party without my consent. I shall not claim to be entitled to restrict, in any way, the use to which the results of said study may be put.

I understand that the study may be of a confidential nature and I undertake not to divulge unnecessarily the existence of the study or its nature. I may, however, consult my GP on my participation.

It is understood that I may withdraw from this study at any time, without the need to justify my decision.

I hereby consent to take part, and to carry out the procedures outlined above.

Name: [Redacted]

Signed: [Redacted]

Date: 12/1/88

PART IV

In consideration of [Redacted] (Volunteer's name) ('The Volunteer') agreeing to participate in the study described above, the United Kingdom Atomic Energy Authority ('The UKAEA') will pay compensation to the Volunteer or his or her dependants without proof of negligence on the part of the UKAEA in the event of the volunteer suffering any injury or damage as a result of his participation in the said study provided that such compensation may be reduced to take account of any fault on the part of the volunteer which has contributed to the injury or damage.

D NEWTON

Signed: [Redacted]

Date: 12/1/88

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