



**Institutional Review Board**  
 B. L. Gledhill, Chair  
 (Human Subjects Committee)  
 Lawrence Livermore National Laboratory  
 P.O. Box 5507  
 Livermore, California  
 Telephone: 422-6299 or 422-3883

REPOSITORY LLNL B361 Rm 940A  
 COLLECTION Institutional Review Board  
 BOX No. IRB Protocol File  
 FOLDER Anderson 88-110 Whole Body Counter  
Calibration with BA-133

### NOTIFICATION OF APPROVAL

**Principal Investigator:** A. L. Anderson  
**Mail Code:** L-383

**Department:** Hazards Control  
**Phone Number:** 2-5181

**Project Title:** Whole Body Counter Calibration with Ba-133

The LLNL Institutional Review Board (Department of Health and Human Services assurance #M-1415) has approved the above request to involve humans as research subjects.

**IRB PROJECT NUMBER:** 88-110

**APPROVAL DATE:** 11/16/88

Full Board Review

**EXPIRATION DATE:** 11/15/89

*If the project is to continue, it must be renewed by the expiration date.*

### CONDITIONS OF APPROVAL:

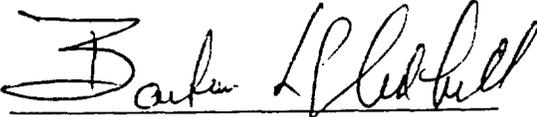
1. The Board based its approval upon the protocol reviewed at that meeting. This project will involve in vivo measurements of Ba-133 deposited in the subjects body at various body sites, using counting equipment located in the Whole Body Counter, Bldg. 253.
2. At the IRB meeting you brought to the Board's attention an error in the second paragraph of your 10/24/88 memo. The amount of radionuclide administered to the subject is 76 KBq (2.05 mCi), not 76 Bq (2.05 nCi).
3. This project has been approved by AERE Tracer and Irradiation Studies Approval Committee (their ethics committee similar to the IRB). A copy of the current approval document is on file with the LLNL IRB.
4. DOE/SAN has been informed that LLNL plans to participate in this study.
5. The identity of the participant must be protected.
6. The participant must give his informed consent, using the attached consent form with the approval number 88-110.
7. The participant must be given a copy of the signed LLNL consent form, and the attached Experimental Subjects' Bill of Rights.

Notification of Approval  
IRB 88-110  
12/7/88

**MODIFICATIONS:** *All protocol changes involving subjects must have prior IRB approval.*

**QUESTIONS:** Please contact the Institutional Review Board office at Ext. 2-3883, L-452.

**APPROVAL FOR THE BOARD**

  
Barton L. Gledhill, V.M.D.  
Chairman, Institutional Review Board

19 Jan 1989  
Date

UNIVERSITY OF CALIFORNIA  
LAWRENCE LIVERMORE NATIONAL LABORATORY

Consent to Act as a Human Subject

LLNL Institutional Review Board  
Approval Number: 88-110  
Approval Date: 11/16/88

Whole Body Counter Calibration with Ba-133

Subject's Name: \_\_\_\_\_  
Date: \_\_\_\_\_

1. I hereby authorize A. L. Anderson and/or such assistants as may be selected by him, using LLNL counting equipment, to obtain from me *in vivo* measurements of Ba-133 particles, said measurements to be utilized for experimental purposes.
2. I understand that the medical procedures for obtaining this material 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 deposition of Ba-133 in humans, and may be of some benefit to individuals in the future.
6. I understand that A. L. Anderson will disclose my name only to the individuals performing associated research.
7. I understand that A.L. Anderson and/or such assistance 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 \_\_\_\_\_

10. I acknowledge the receipt of a signed copy of this consent form and the LLNL Experimental Subjects Bill of Rights.
11. A. 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 U.S. Department of Energy 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: \_\_\_\_\_

*(To be completed if Subject is a minor or otherwise unable to sign)*

Subject is a minor, age \_\_\_\_\_.

Subject is not a minor but is otherwise unable to sign because:

\_\_\_\_\_

\_\_\_\_\_

Father's Signature \_\_\_\_\_ Date: \_\_\_\_\_

Mother's Signature \_\_\_\_\_ Date: \_\_\_\_\_

Legal Guardian'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 Institutional Review Board 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.