



Institutional Review Board
(Human Subjects Committee)
Lawrence Livermore National Laboratory
P.O. Box 5507
Livermore, California

REPOSITORY LLNL B361 Rm. B940A 717870
COLLECTION Institutional Review Board
BOX No. IRB Protocol File
FOLDER Meyer, P. IRB No. 80P-109
Decompression Sickness Studies
With Radioactive Gases

NOTIFICATION OF APPROVAL

Principal Investigator: Paul Meyer
Mail Code: 280

Department: Physics
Phone Number: 2-9678

Project Title: Pulmonary Gas Rates in Man

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: 80P-109

APPROVAL DATE: 6/2/88

Full Board Review

EXPIRATION DATE: 6/1/89

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

CONDITIONS OF APPROVAL:

1. A very thorough and complete file on this experiment, including dosimetric data must be maintained
2. The applicable OSP must be updated and approved.
3. The identity of the participants must be protected in any publication of the results, and no medical information about the participants can be publicly divulged.
4. Any adverse reactions to this test must be promptly reported to the LLNL Medical Department.
5. The donor must give his/her informed consent, using the attached consent form with the serial number 80P-109.
6. The donor must be given a copy of the signed LLNL consent form.
7. All participants must be given a copy of the attached Experimental Subject's Bill of Rights.
8. The consent form must state that none of the participants are current smokers.
9. The U.S. Navy Human Subjects Protection Committee must approve the project and a copy of that approval must be on file with the LLNL IRB.
10. Provide to the LLNL IRB the total number of human subjects to be involved in this study.

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, M.D.
Chairman, Institutional Review Board



Date

UNIVERSITY OF CALIFORNIA
LAWRENCE LIVERMORE NATIONAL LABORATORY

Consent to Act as a Human Subject

LLNL Institutional Review Board

Approval Number: 80P-109

Approval Dates: 6/13/80, 12/15/81, 10/11/84, 11/19/85, 11/25/86, 6/2/88

Pulmonary Gas Rates In Man

Subject's Name: _____

Date: _____

1. I hereby consent to act as a test subject in the joint Naval Medical Research and Development Command/Lawrence Livermore National Laboratory study entitled Pulmonary Gas Rates in Man (Human Subjects Experiments with Air Tagged with Radioisotopes ^{13}N and ^{41}Ar).
2. I understand that the procedures for conducting this test will involve:
 - Breathing ^{13}N and ^{41}Ar labeled air for up to 120 minutes.
3. I understand that any possible risks and discomforts that may result from the procedure(s) are considered unlikely but include:
 - a. The discomfort from breathing through a mouthpiece for up to two hours.
 - b. Any exposure to ionizing radiation carries a risk of causing cancer--in this case potentially of the lung or upper air passages where the most significant part of the radiation dose is delivered. The best estimate of the risk of lung cancer from this procedure lies between one chance in 100,000 and one chance in 10,000. The radiation exposure to the lung and air passages in this procedure will be less than 0.4 rem. This amount is slightly below the Federal exposure limit for annual exposure of the general population; is one tenth of the permissible annual exposure of radiation workers; and is approximately three to four times the radiation received by the public in most geographical areas of the United States from natural sources and average usage for medical and dental purposes.
4. Since this activity does not involve medical treatment, there is no alternative procedure which might be advantageous to me.
5. At the conclusion of this procedure it is expected that I will be able to function normally immediately.
6. I further understand that this study may result in no direct benefit to me but it may contribute to the understanding of nitrogen uptake and elimination in the body and may therefore, aid in the understanding of decompression sickness and may therefore, be of some benefit to individuals in the future.

Subject's Initials _____

LLNL Institutional Review Board

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- 7. I understand that _____ 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. I am not currently a smoker.
- 9. Any publication arising from this study will be made without specific reference to my name.
- 10. 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.
- 11. I acknowledge the receipt of a signed copy of this consent form and the LLNL Human Subjects Bill of Rights.
- 12. Paul Meyer, 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 Naval Medical Research and Development Command; and Lawrence Livermore National Laboratory is providing support.
- 13. 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.