

6-12

Paul
 the IRB has received
 copies of the
 updated OSP.

still needed for our
 files is a copy of the
 Navy Review Board's
 current approval covering
 this specific program
 (item II of approval).

thank you -
 gerry wyman

REPOSITORY LLNL B361 Rm. B940A
 COLLECTION Institutional Review Board
 BOX No. IRB Protocol File
 FOLDER Meyer, P. IRB No. 80P-109

1121902

Decompression Sickness Studies
 With Radioactive Gases

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, 5/15/89

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 _____

1121903

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: _____



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.