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Mail Station L- 319

Ext: 32887

COLLECTION Institutional Review Board

BOX No. IRB Minutes

FOLDER Human Subjects Committee Dec. 15, 1984

April 20, 1982

M E M O R A N D U M

TO: P. Meyers

FROM: V. L. James

SUBJECT: Human Subjects Approval 80P-109-02

This memorandum is to inform you that at its December 15, 1981 meeting the LLNL Human Subjects Committee approved your use of human subjects in the project titled, "Human Subjects Experiments With Air Tagged With Radioisotopes ^{13}N and ^{41}Ar. The Committee understands that this project is being funded by the Navy.

The Committee based its approval upon the protocol reviewed at that time, and the Laboratory's Operational Safety Procedure No. 194, Supplement 29, dated April 20, 1982. Should you wish to change the protocol in any way, you must obtain the prior approval of the Committee. This approval is subject to the following conditions:

1. The identity of the participants must be protected in any publication of the results, and no medical information about the participants can be divulged publicly.

2. Any adverse reactions to this test must be promptly reported to the LLNL Medical Department.

3. All participants must be given a copy of the attached Experimental Subject's Bill of Rights.

4. The donor must give his/her informed consent, using the attached consent form with the serial number 80P-109-02.

5. The donor must be given a copy of the signed LLNL consent form.

This approval is valid for the period of one year. If you desire to continue this work beyond December 15, 1982, you must obtain prior approval of the LLNL Human Subjects Committee.

Vivian L. James

Vivian L. James
Secretary
LLNL Human Subjects
Committee

University of California
Lawrence Livermore
National Laboratory

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LAWRENCE LIVERMORE LABORATORY

UNIVERSITY OF CALIFORNIA
LAWRENCE LIVERMORE NATIONAL LABORATORY

Consent to Act as a Human Subject

LLNL Human Subjects Committee
Approval Number: 80P-109-02
Approval Date: June 13, 1980, December 15, 1981

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 titled Human Subject Experiments With Air Tagged With Radiosotopes ^{13}N and ^{41}Ar.

2. I understand that the procedures for conducting this test will involve:

   Breathing ^{13}N and ^{41}Ar labelled air for up to 120 minutes.

3. I understand that any possible risks and discomfort that may result from the procedures are considered unlikely but include:

   The discomfort from breathing through a mouthpiece for 120 minutes.

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.

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.

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LLNL Human Subjects Committee
Approval Number: 80P-109-02
Approval Date: June 13, 1980, December 15, 1981

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.

10. 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.

11. I understand that if I have any complaints or concerns about the procedures, I may address them to Vivian L. James, Secretary of the Human Subjects Committee, in person, by telephone, or in writing. Ms. James can be reached at (415) 423-2887, L-319, Lawrence Livermore National Laboratory, P.O. Box 808, Livermore, CA, 94550.

Subject's Signature_____

Witness_____

To be completed if Subject is a minor or otherwise unable to sign:

Subject is a minor (age___) or otherwise unable to sign because:

_____

_____ Father

_____ Legal Guardian

_____ Mother

_____ Witness

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LAWRENCE LIVERMORE LABORATORY

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 Secretary of that Committee, Vivian L. James, may be reached by calling, (415) 423-2887, from 8:00 a.m. until 5:00 p.m., Monday through Friday, or writing to the Human Subjects Committee, L-319, Lawrence Livermore National Laboratory, P.O. box 808, Livermore, CA 94550.

University of California

Lawrence Livermore National Laboratory

Assurance of Compliance with HHS Regulations for
Protection of Human Research Subjects

PART 1

The Lawrence Livermore National Laboratory, hereinafter known as LLNL, hereby gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended on January 26, 1981) as specified below.

I. Statement of Principles and Policies

A. Ethical Principles

1. LLNL is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research. In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) will be met for all applicable HHS-funded research.

Institutional Policy

1. Except for research in which the only involvement of human subjects is in one or more of the categories exempted or waived under 45 CFR 46.101(b)(1-5) or 46.101(e) of the HHS regulations, this policy is applicable to all research involving human subjects, and all other activities which even in part involve such research, if either:

   a. the research is sponsored by LLNL, or
   b. the research is conducted by or under the direction of any employee or agent of LLNL in connection with his or her institutional responsibilties, or
   c. the research is conducted by or under the direction of any employee or agent of LLNL using any property or facility of LLNL, or
   d. the research involves the use of LLNL's nonpublic information to identify or contact human research subjects or prospective subjects.

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2. LLNL acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this policy.

3. LLNL assures that before human subjects are involved in research covered by this policy, proper consideration will be given to:

   a. the risks to the subjects,
   b. the anticipated benefits to the subjects and others,
   c. the importance of the knowledge that may reasonably be expected to result, and
   d. the informed consent process to be employed.

4. LLNL acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this policy.

5. LLNL bears full responsibility for complying with federal, state or local laws as they may relate to research covered by this policy.

6. LLNL encourages and promotes constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

7. LLNL will exercise appropriate administrative overview carried out at least annually to insure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

8. LLNL will consider additional safeguards in research when that research involves prisoners, fetuses, pregnant women, children, individuals institutionalized as mentally disabled, other potentially vulnerable groups and human in vitro fertilization.

9. LLNL shall provide each individual at the institution conducting or reviewing human subject research (e.g. research investigators, department heads, research administrators, research reviewers) with a copy of this statement of ethical principles and policy (Part 1, I.A. & B.).

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PART 2

In regard to the project entitled Human Subjects Experiments With Air Tagged With Radioisotopes ^{13}N and ^{41}Ar, submitted on behalf of Paul Meyer, the Lawrence Livermore National Laboratory has complied and will continue to comply with the requirements of 45 CFR 46 as specified below.

I. IRB Review

A. The convened IRB reviewed and approved the above project.

B. The IRB has determined, in accordance with the criteria found at 45 CFR 46.111, that human research subjects' protections are adequate.

C. The IRB has determined that legally effective informed consent (copy of document attached) will be obtained in a manner and method which meets the requirements of 45 CFR 46.116 and 46.117.

D. The IRB shall review, and have the authority to approve, require modification in, or disapprove changes proposed in this reaearch activity.

E. The next scheduled meeting of the IRB for review of this activity will be December 14, 1982. The IRB may be called into an interim review session by the Chairperson at the request of any member, an institutional official, or the project director to consider any matter concerned with the rights and welfare of any subject.

F. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 45 CFR 46.115.

G. The IRB shall report promptly to institutional officials and the Office for Protection from Research Risks (OPRR):

1. any serious or continuing noncompliance by investigators with the requirements of the IRB, and
2. any suspension or termination of IRB approval.

H. The IRB shall report promptly to institutional officials any information received concerning:

1. injuries to human subjects, and
2. unanticipated problems involving risks to subjects or others.
3. any changes in this research activity which are reviewed and approved by the IRB.

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II. Research Investigator Reporting Responsibilities

A. Research Investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

B. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

III. Institutional Responsibilities

A. LLNL has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and recordkeeping duties.

B. LLNL shall report promptly to the OPRR:

1. injuries to human subjects,
2. unanticipated problems involving risks to subjects or others, and
3. any changes in this research activity which are reviewed and approved by the IRB and LLNL.

C. In addition to the review and approval of the IRB, LLNL has reviewed and sponsors the project entitled Somatic Point Mutation Monitoring in Rabbits and Humans.

D. The following IRB members participated in the review and approval of the above project, in full compliance with Part 46, Title 45 of the Code of Federal Regulations:

John O. Beatty, M.D.
Physician, Medical Department
LLNL Representative

Max W. Biggs, M.D.
Physician, Medical Department
LLNL Representative

Samuel D. Cole, J.D.
Attorney, Office of Laboratory Counsel
LLNL Representative

R. Lowry Dobson, M.D.
Research Scientist, Biomedical Sciences Division
LLNL Representative

Frederick T. Hatch, M. D.
Research Scientist, Biomedical Sciences Division
LLNL Representative

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James S. Johnson, M.S.
Certified Industrial Hygienist, Hazards Control Department
LLNL Representative

David C. Shepherd, B. A.
Manager, Business Services
Department
LLNL Representative

PART 3

Institutional endorsement of the project titled Human Subajects Experiments With Air Tagged With Radioisotopes ^{13}N and ^{41}Ar.

I. I certify that the above project was reviewed and approved by the Lawrence Livermore National Laboratory IRB in accordance with the requirements of Part 46, Title 45 of the Code of Federal Regulations and this assurance of compliance on March 4, 1982.

IRB Chairperson

Signature: Max W. Biggs Date:_____
Name: Max W. Biggs, M.D.
Address: Medical Department
L-423
Lawrence Livermore National Laboratory
P. O. Box 808
Livermore, CA 94550
Phone: (415) 422-4759

II. I certify that this institution endorses the above project and abides by the principles, policies, and procedures of PARTS 1 and 2 of this assurance of compliance.

Authorized Institutional Official (primary contact)

Signature: Roger E. Batzel Date:_____
Name: Roger E. Batzel
Title: Director
Address: L-1
Lawrence Livermore National Laboratory
P. O. Box 808
Livermore, CA 94550
Phone: (415) 422-7401

III. All parts of this assurance are in compliance with the requirements of Part 46, Title 45 of the Code of Federal Regulations.

HHS Approving Official
Signature:_____ Date:_____
Name:_____
Title:_____
Address:_____
Phone:_____

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