



Lawrence Livermore National Laboratory

February 23, 1988

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Dr. Susan Rose
Human Health & Assessments Division, ER-73
Office of Health and Environmental Research
Office of Energy Research
U.S. Department of Energy
Washington, D.C. 20545

VIA

Mr. James Foster
Environmental Health and Safety
U. S. Department of Energy
San Francisco Operations Office
1333 Broadway
Oakland, CA 94612

REPOSITORY DOE-OAK
COLLECTION Env Safety Sup Div
BOX No. Central File
FOLDER 1300.3.B Human Subj Testing
1986-1987

Dear Dr. Rose:

Attached is information on research proposals approved by the LLNL Human Subjects Committee at its meetings of 11/30/87. Also attached is a copy of the meeting minutes of the 11/30/87 meeting.

<i>P.I.</i>	<i>Project Title</i>
A. L. Biermann	Transfer of Particulates to Hands
D. Moore/S. Fry (ORAU)	5-Rem Study/DOE Health and Mortality Study
D. Pinkel	Tumor Cytogenetics by Fluorescence In Situ Hybridization
Tore Straume	Chromosomal Aberration Frequencies in Patients Undergoing Radiation Therapy with X-Rays or Fast Neutrons. (Note: At its meeting of 11/30/87 the IRB fully approved LLNL collaboration with the University of Washington. All paperwork is in hand for IRB Committee approval of the supplementary collaborations with U.C. Davis (VA Hospital, Martinez) and Stanford University; formal approval for these collaborations is expected from the IRB at its next meeting. Note that LLNL approval of these latter two collaborations is essentially pro forma since the U.C. Davis and Stanford IRBs have primary responsibility for review of the use of human subjects in this project, and the respective Boards have approved the protocol.)
Paul Williams	Lipoprotein Subfractions and Heart Mortality

Sincerely,

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

BLG:gw
Attachments

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University of California



Lawrence Livermore National Laboratory

Meeting of Institutional Review Board

November 30, 1987

Building 361, Room 1155, 2:00 p.m.

Attendees:

Committee Members:

Max Biggs
Max Creamer
Lowry Dobson
Bart Gledhill (Chair)
Jack Shearer
Vivian Shepherd
Dr. Alan Brautigam (Livermore VA Hospital)
Gerry Wyman (Recording secretary)

Principal Investigators:

Art Bierman
Paul Meyer
Dan Moore
Dan Pinkel
Tore Straume
Paul Williams

Administrative Matters

1. PI Handbook status: Bart and Gerry are working with Bob Spencer and Ken Rhodie at CRO to produce an informational handbook for principal investigators on projects involving human subjects. At present, no deadline has been set for completion.
2. Meeting Minutes: A copy of the Minutes of each meeting will be distributed to each Committee member for formal approval at the next IRB meeting. Once approved, a copy of the meeting minutes will be sent to SAN for informational purposes. The meeting minutes require careful review by the IRB, as they become archival records. Committee vote on each protocol will be recorded, and if there are minority opinions, members are strongly encouraged to submit opinions in writing.
3. Larry Anderson called Gerry 11/30 a.m. regarding a proposed an intercalibration counting project for British subjects who have inhaled niobium-92m. Present plans are for the subjects to be available in February 1988. Larry was told that the next IRB meeting will be scheduled for late January 1988. Larry should be prepared to present a strong justification for LLNL participation in this study. Larry was also asked to provide as much information on this project for Committee review as soon as possible.

Reviews

1. *Lipoprotein Subfractions and Health Mortality* - Renewal - P.I. Dr. Paul Williams
IRB Approval No. 87P-101, last approval 11/25/86

This project is a follow-up study to one originally begun 30 years ago by Dr. John Gofman using LLNL employees. They are attempting to locate 2500 people who were part of Gofman's original cohort. So far, approximately 1250 questionnaires have been received. Paul is an employee of LBL; contact at LLNL has been Dr. Lawton and Dan Moore. The LBL IRB approval for this project expires in February 1988. The Committee stressed the importance of protecting the Social Security numbers and names of employees. The data that Paul receives from employees responding to his questionnaire are maintained on a Macintosh computer not linked with an external computer system,

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and stored in a locked office. The original data from Gofman's study resides on a large computer storage system.

At 11/24/86 meeting Creamer was to get approval of UC general counsel to give Paul access to medical records. Creamer contacted Fred Hatch, former Chairman of the IRB, with a verbal approval from UC General Counsel for UC system access to medical records based on the fact that the request is for medical research, and Paul works within the UC system (LBL).

There is no change in the protocol approved on 11/25/86.

Action: One-year approval of this protocol was approved by unanimous vote of the Committee. Dr. Williams will provide a copy of the new LBL IRB approval for our files.

2. *Tumor Cytogenetics by Fluorescence In Situ Hybridization - Renewal - P.I. Dan Pinkel*
IRB Approval No. 87G -101, last approval 11/25/86

Project is designed to begin use of new method to identify chromosomes using cell cultures and DNA probes specific to particular chromosomes with limited use of material from cancer patients. Funding for proposal began in August 1987 so limited progress has been made to date. The samples are drawn for other purposes at other institutions and some is given to LLNL for this project.

There is no change in the protocol approved on 11/25/86.

Action: One-year approval of this protocol was approved by unanimous vote of the Committee. The Committee asked for copies of the standard consent forms used for the patients at Sloan Kettering and NY University. Dan Pinkel is also to write a letter requesting permission be granted by Sloan/Kettering and NYU for LLNL to use tissues from their repositories. Samples will be identified by code number only.

3. *Protocol to Measure the Chromosomal Aberration Frequencies in Patients Undergoing Radiation Therapy with X-Rays or Fast Neutrons - Renewal - P.I. Tore Straume*
IRB Approval No. 86P-103, last approval 11/25/86

Project is now in data collection mode. Samples are from radiotherapy patients, collected under clinical setting at University of Washington. Tore receives coded samples with dosimetry and background information for each. Blood samples are drawn at beginning of treatment and also after diagnosis and after treatment is completed. This project has been approved by University of Washington IRB. A copy of the University of Washington consent form is in LLNL IRB files.

Tore seeks to broaden his experiment (and LLNL IRB approval) to include VA Hospital Martinez; and Stanford Medical Center. He is still negotiating with these institutions. Within the next few weeks he should be getting approval from VA Hospital Martinez.

Action: One-year approval of this protocol was approved by unanimous vote of the Committee, pending receipt of revised consent form from University of Washington. Before he accepts any samples, Tore will need to submit a copy of the amended consent form (U of WA) to the IRB. Tore is to provide copies of approval forms from other institutions' (VA Hospital Martinez and Stanford Medical Center) IRBs, and standard consent forms from these institutions to the IRB Secretariat, who will forward copy to Max Creamer immediately. Copies of these forms will be distributed with agenda to next IRB meeting so all members can review.

4. *Human Subjects Experiments with Air Tagged with Radioisotopes N-13 and Ar-41 - Renewal - P.I. Paul Meyer*
IRB Approval No. 80R-109, last approval 11/25/86

This project, for the U.S. Navy, is designed to obtain quantitative measures of niobium and argon gas exchange rates using radioactive tracers. Data will be used to evaluate physiological models of gas exchange and provide a database for decompression calculations necessary for safer decompression procedures of deep sea divers.. Ar-41 and niobium are mixed into normal breathing mixture. Paul now wants to enlarge database of samples taken. No data were taken in 1986 as PI at other institution was reassigned. U.S. Navy divers are the subjects. Work is done at LLNL. LLNL equipment is used. Paul mixes the radioactive gas here. Work is done at ambient pressures, not hyperbaric conditions. There is no pain to the divers involved in this experiment. Paul estimates the radiation dose (exposure) to the divers at 250 millirem per person. Paul has no time deadline at present to begin work on the next phase of this project.

Action: No vote was taken on this renewal. Committee asks Paul to resubmit project for approval, and provide to the committee (at its January meeting, if convenient for Paul) in writing, the risk-benefit evaluation and justification for LLNL to be involved in this project. In addition, Max Creamer requested a copy of the consent form that will be given to divers.

5. *Transfer of Particulates to Hands - Renewal - P.I. Art Bierman*
IRB Approval No. 87R-101, last approval 11/25/86

This DOD project will use flour as the particulate. A slight change in the protocol is needed to add the taking a hand print of each subject to get better data of area of hand. Art says a MSDS on the ink to be used for the handprint has been sent for. This ink has been widely used in the U.S. The consent form to be given to subjects will state that handprints taken will not be used for investigative purposes (this statement was suggested by LLNL Security Department).

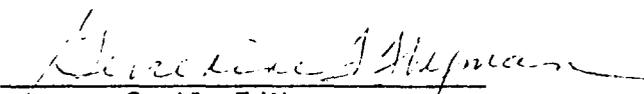
Action: One-year approval of this protocol was approved by unanimous vote of the Committee.

6. *5-Rem Study/DOE Health and Mortality Study - Renewal - P.I. Dan Moore/Shirley Fry (Oak Ridge Associated Universities)*
IRB Approval No. 87P-102, last approval 11/25/86

This is a DOE study undertaken by ORAU to obtain incidence and mortality of cancer from people in the DOE community who have received a total radiation dose of 5 rem or greater in a single year. No LLNL employee addresses are given to ORAU. ORAU provides LLNL with a list of names of present and former LLNL employees in this category, and LLNL mails ORAU information packet out to LLNL employees using home addresses from LLNL records. Dan Moore has been the LLNL contact for this study.

Action: One-year approval of this protocol was approved by unanimous vote of the Committee.

Respectfully submitted:


Geraldine F. Wyman