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University of California



Lawrence Livermore National Laboratory

**Meeting of Institutional Review Board
January 26, 1988
Building 361, Room 1155, 2:00 p.m.**

Attendees:

Committee Members:

Max Biggs
Alan Brautigam¹
Max Creamer
Lowry Dobson
Bart Gledhill (Chair)
Jack Shearer
Vivian Shepherd
Gerry Wyman²

Principal Investigators:

A. Larry Anderson (with Deborah Kruchten and
Tom Crites)
Robert da Roza
James Felton
Paul Meyer
Martin Vanderlaan

REPOSITORY LLNL B361 Rm 910A
COLLECTION Institutional Review Board
BOX No. IRB Minutes
FOLDER Mar. 14, 1988 Institutional
Review Board Mtg

Administrative Matters

1. Minutes of the Committee meeting of 11/30/87 were approved with amendments.

Protocol Reviews

1. *Lung Counter Calibration with Inhaled Nb-92m as a "Mock Plutonium"* - P.I. A.Larry Anderson
IRB No. 88-101 - new project.

Approval is requested from the LLL Institutional Review Board for LLNL to participate in radioactivity measurements on up to eight male subjects involved in a United Kingdom project sponsored and funded by British Nuclear Fuels and the UK Central Electricity Generating Board. The subjects will inhale particles labeled with Nb-92m in a repeat of an experiment performed in 1979-82 to determine *in vivo* the influence of spacial distribution on calibration factors for the internal measurement of inhaled plutonium. In the current experiment 1 micron particles will be used rather than the 5 micron particles which were used in the earlier study.

Larry Anderson provided detailed background information on this proposal.

Action: The vote to approve this protocol as submitted was 6 in favor and 1 abstention.

¹non-LLNL representative (Livermore Veterans Administration Hospital)

²Secretary, non-voting

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

This project, for the U.S. Navy, measures the uptake and clearance of niobium from parts of the body. Ar-41 and niobium are mixed into normal breathing mixture. The knee is the most common site for decompression problems. Paul now wants to enlarge database of samples taken. No data were taken in 1986 as PI at other institution was reassigned. Some physics problems occurred in 1985 in that carbon-11 contamination of sample taking apparatus occurred, so no samples were taken. U.S. Navy divers are the subjects. Work is done at LLNL. The divers come to LLNL for one week at a time. 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, only data is extracted.

Request for renewal of this project was submitted to the IRB at its last meeting. Meyer provided information on the risk/benefit aspects of this study to Committee members as requested at the last meeting.

Action: Vote on this project was tabled until Paul submits additional information to (1) clarify why the experiment is being done; (2) clarify dose calculations; (3) clarify information provided by Meyer's collaborator; U.S. Navy interest in this project; and (5) provide documentation on why this research should involve LLNL people (our expertise, equipment, etc.) Also, Paul was asked to provide statistics on decompression sickness risks. Paul should provide this information in letter form addressed to Bart Gledhill and submitted through Gerry Wyman.

3. *Effect of Beard Growth on Respirator Performance* - P.I. Robert da Roza
IRB No. 85P-101, last renewal 3/17/87

Effect of Face Shape and Exercise on Respirator Performance - P.I. Robert da Roza
IRB No. 88-102, new project

Bob would like the Committee approval to renew this project (85P-101) for one year. He will use sulfur hexafluoride or freon-12 gas in addition to an aerosol to determine protection provided by respirators under working conditions. He would also like to widen the scope of this experiment to allow female subjects. Exercise ECG's while participants wear SCBAs will be done only for subjects being tested with SCBAs. A variety of respirators are to be tested on how well they function (as a function of work rate). Have female health & safety technicians, guards, etc. at LLNL. The FAA wants a particular mask to be tested on female. All funding for this project is from the outside, but wide interest at LLNL.

After Committee discussion, it was decided to treat these requests as two separate experiments ongoing simultaneously. One project will be titled "Effect of Face Shape and Exercise on Respirator Performance." The other will continue to be titled "Effect of Beard Growth on Respirator Performance."

Action: One-year approval of the protocol titled "Effect of Face Shape and Exercise on Respirator Performance" (88-102) was voted unanimously.

One-year renewal of approval of the project titled "Effect of Beard Growth on Respirator Performance" (85P-101) was approved by unanimous vote.

4. *Biochemical Measures of Exposure to Dietary Carcinogens* - P.I. Martin Vanderlaan/James Felton
IRB No. 88-100 - New project

Previous experiments have identified formation of series of compounds that are highly mutagenic. This proposal is to extend studies to humans. This proposal has been submitted to NIH in response to their specific request. For a specified time, volunteers will eat meat cooked at LLNL in a certain way, and urine and blood samples will be drawn to measure compounds. Applicants will be screened before their participation for cholesterol levels, non-smoking, etc. It was requested that they ask for LLNL medical department physical before they begin the project.

Action: One year approval of the protocol was unanimously approved. The P.I. will make minor modification of the consent form and submit it to the Chairman for approval.

Respectfully submitted:

Geraldine F. Wyman