

APPROVED

at IRB meeting of FEB 02 1989



Institutional Review Board
B. L. Gledhill, Chair
(Human Subjects Committee)
Lawrence Livermore National Laboratory
P.O. Box 5507
Livermore, California
Telephone: 422-6299 or 422-3883

718050

Minutes
Meeting of Institutional Review Board
November 16, 1988
Building 361, Room 1155, 1:30 p.m.

Attendees:

Committee Members:

Max Biggs
John Beatty
Alan Brautigam
Bart Gledhill
Brian Mayall
Kathleen Noonan
Jack Shearer
Vivian Shepherd
Gerry Wyman

REPOSITORY LLNL B361 Rm 940A
COLLECTION Institutional Review Board
BOX No. IRB Minutes
FOLDER Nov. 25, 1988 Human Subject Committee

Principal Investigators:

Larry Anderson/Deborah Kruchten
Bill Bigbee for Tore Straume and Ron Jensen
Dan Pinkel

Administrative Matters

1. Minutes of the IRB meeting of 9/29/88 were approved as written.
2. Discussion of PHS Policy on HIV Serostatus. This policy was handed out at the last meeting. This policy was discussed at length. LLNL does not do HIV testing. Kathleen will bring the OPRR directive to attention of Dr. Spickard, new LLNL Medical Director, in an informal way.

Protocol Reviews

1. *Whole Body Counter Calibration with Ba-133* - P.I. Larry Anderson
IRB No. 88-110, New Project

In vivo measurements of the Ba-133 deposited in the subject's body will be obtained at various body sites, using counting equipment located in the Whole Body Counter, Bldg. 253. The subject will lay in a supine position for these measurements. Radiation detectors will be placed in close proximity to various measurement sites on the body for periods of time ranging from 15 to 50 minutes. Individual is employed at AERE, Harwell, UK, and has been involved in planned and approved radioactive uptake experiments. This protocol is very similar to a procedure approved by the IRB at its March 1988 meeting.

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Note: error in second paragraph of Larry's 10/24/88 memo to the IRB. Amount of radionuclide should be 76 KBq (2.05 mCi) instead of 76 Bq (2.05 nCi).

Action: After lengthy discussion, this project was approved by majority vote of IRB members. There were dissenting votes by Shearer and Gledhill. Minority opinion will be submitted in writing for IRB records with a copy to the P.I. (copy attached).

2. *Glycophorin A-Based Somatic Mutation Analysis of Cancer Patients Being Treated with Cis-Platinum* - P.I. Ron Jensen
IRB No. 88-109, New Project

W. Bigbee represented PI Jensen. Thirty men newly diagnosed with testicular cancer and enrolled in a cis-platinum therapy will be asked to donate seven samples of blood (50 ml per sample) over a two-year period so as to perform five different biodosimetry assays on each sample (LLNL will only perform the GPA-based somatic mutation assay). Collaboration with Dr. Perera at Columbia University.

Action: One-year approval of this project was voted unanimously. Conditions: Collaborating institutions' explicitly mention LLNL as participant in study on collaborating institutions' protocols and consent forms. Also need current copies of approval documents from collaborating institutions' IRBs. The IRB will need copy of written substantiation from collaborators that this has occurred.

3. *GPA-Based Somatic Mutation Analysis of Blood Samples from Smoking and Non-Smoking Mothers and Cord Blood Samples from Their New-Born Infants* - P.I. Ron Jensen
IRB No. 88-112, New Project

Collaborative study with Dr. Manchester, The Childrens Hospital, Denver Colorado. Coded blood samples from approximately 200 mothers (smokers and non-smokers) and cord blood samples from their newborn infants will be obtained. Samples will be tested at LLNL using the glycophorin A-based *in vivo* somatic mutation assay to determine whether smoking induces an elevated frequency of somatically variant red cells in the mother's blood and/or infant's cord blood.

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4. *Protocol to Measure Cytogenetic Effects and Glycophorin Mutations in Irradiated Persons (note title change)* - P.I. Tore Straume
IRB No. 86P-103, Renewal

Collaborative studies (1) analysis of blood from radiotherapy patients treated at the University of Washington; (2) analysis of blood from radiotherapy patients treated at Stanford Medical Center; (3) analysis of blood from radiotherapy patients treated at the VA Hospital in Martinez, CA; and (4) analysis of blood from persons exposed in 1958 to the criticality accident at Oak Ridge Y-12 plant.

Title change is necessary because original title of project related specifically to radiotherapy patients at University of Washington. Since that time additional groups of people have been added who are getting additional clinical radiation exposure. Would like title to more accurately reflect the enlarged scope of the study.

Action: One-year renewal of this protocol was unanimously approved. Conditions: PI amend protocol to list procedures for collecting samples. Collaborating institutions must explicitly mention LLNL as collaborator on protocols and consent forms. Provide the IRB with current copies of approval documents from collaborating institutions' IRBs. Also, the IRB recommends that the word "irradiated" in the title be changed.

5. *Tumor Cytogenetics by Fluorescence In Situ Hybridization* - P.I. Dan Pinkel
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Samples of peripheral blood and bone marrow obtained for standard medical procedures will be used. A small amount will be fixed and deposited on microscope slides. These will be coded and sent to LLNL. Material from solid tumors, cultures and tissue sections, will be available either from fixed archival specimens or from new material remaining after medically required procedures are completed. Collaborations with NYU and Sloan Kettering.

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6. *Relationship of Lipoprotein Subfractions to Coronary Disease in Men and Women* - P.I. Paul Williams
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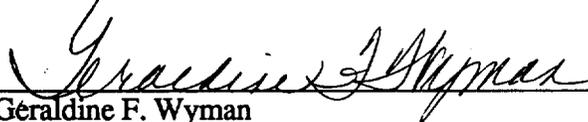
This is a follow-up study of 2518 apparently healthy men and women who were employed at LLNL 1954-1957 who had lipoprotein concentrations and other risk factors measured by Dr. Gofman. Collaboration with UC Berkeley.

The PI was on travel and unable to appear before the IRB. The IRB had no questions that needed to be directed to the PI. IRB was satisfied with paperwork submitted for the meeting.

Action: One-year renewal of this protocol was unanimously approved. Kathleen Noonan abstained from voting as she was unfamiliar with details of this project.

Meeting adjourned at 4:00 p.m.

Respectfully submitted:


Geraldine F. Wyman
Secretary to the Institutional Review Board

Interdepartmental letterhead

L-1/452

Ext. 3-0837/2-6299

November 29, 1988

TO: Institutional Review Board

FROM: Jack Shearer/Bart Gledhill

SUBJECT: Minority Opinion, IRB Protocol 88-110, "Whole Body Counter Calibration with Ba-133," P.I. Larry Anderson, approved at 11/26/88 IRB meeting

We believe that LLNL should not participate with another organization in an experiment involving human subjects unless, in principle, we would be willing to do the entire experiment here at LLNL using LLNL employees as the experimental subjects.

We are unwilling to approve this protocol because it has no obvious thought-through experimental design. It may be possible that the use of human subjects is unnecessary or at least premature.

Specifically regarding the protocol, we have never been told how many individual people have to inhale radiation, or how much total person-rem exposure is necessary, before the necessary data are collected. In fact, it has never been made clear to us exactly what problem is being addressed. Is it to discover how asymmetric might be the distribution of inhaled radioactivity within individual people? From one person to another? Is it to help develop a measurement system that, given some unknown but probably asymmetric distribution, does a more accurate job of determining total burden in the body?

Elements of all of these appear during discussion with the experimenters, but there is never a clear statement of the basic purpose. This being the case, we have no way of deciding whether we should approve the deliberate exposure of human subjects. We cannot get a clear fix on how many people, or how much exposure, or whether humans need to be involved at all.

xc: Larry Anderson

Jack Shearer
Bart Gledhill

University of California



Lawrence Livermore National Laboratory

1122639

Meeting on 11/16 (1:30 p.m., B-361, R-1155)

Attendees:

Committee Members:

Max Biggs
John Beatty
Alan Brautigam
Bart Gledhill
Brian Mayall
Kathleen Noonan
Jack Shearer
Vivian Shepherd
Gerry Wyman

Principal Investigators:

Larry Anderson/Deborah Kruchten
Bill Bigbee for Tore Straume and Ron Jensen
Dan Pinkel

Administrative Matters

1. Minutes of the IRB meeting of 9/29/88 were approved as written.
2. Discussion of PHS Policy on HIV Serostatus. This policy was handed out at the last meeting. It may affect how the LLNL IRB does business. Comments: Medical does not do HIV testing, period! Will need specific directive from Director's Office to do HIV testing. Testing without tying it to a specific person. If testing is useful in protecting our employees against infection, we should find way to do so without getting specific (HIV, hepatitis issues, etc.). Operationally, should treat all blood as though it were HIV positive. If LLNL sets policy about HIV testing we can implement in light of OPRR regulations. LLNL can't fulfill counseling requirement, particularly in our collaborations with other institutions. Action: Kathleen will bring the OPRR directive to attention of Dr. Spickard, new LLNL Medical Director, in an informal way.

Protocol Reviews:

1. ~~Whole Body Counter Calibration with Ba-133~~ - P.I. Larry Anderson
IRB No. 88-110, New Project

In-vivo measurements of the Ba-133 deposited in the subject's body will be obtained at various body sites, using counting equipment located in the Whole Body Counter, Bldg. 253. The subject will lay in a supine position for these measurements. Radiation detectors will be placed in close proximity to various measurement sites on the body for periods of time ranging from 15 to 50 minutes. Individual is employed at AERE, Harwell, UK, and has been involved in planned and approved radioactive uptake experiments.

This protocol is very similar to a procedure approved by the IRB at its March 1988 meeting. The individual to be counted is visiting someone at LLNL and contacted Anderson to see if he would be interested in counting him. Counting people helps with calibration of detectors.

Note: error in second paragraph of Larry's 10/24/88 memo to the IRB. Amount of radionuclide should be 76 KBq (2.05 mCi) instead of 76 Bq (2.05 nCi).

Needs chest measurements to correct counters for bone mass in order to measure true amount of radionuclide in lungs. had abnormal distribution in skull (counted at Battelle)--not true of others counted. Subject is knowledgeable person. Medical sends Larry people and asks him to count them--need best estimate of dose. Anderson is individual to get the best possible results. Shearer: thinks could do this with properly-loaded phantoms and properly constructed counters without using human subjects. Beatty: biologic systems are vastly different from physics experiments. Per Larry: LLNL was not consulted when this study was done. Did not find out until 1987 that study had been done. British would have done experiment anyway (without LLNL participation). Noonan: Vast potential benefit in counting this individual. Shepherd: Agree with Noonan. This is an informed person who knows what he is doing. Doesn't think we can pass this up. Gledhill: Does this research need to be done? Purposeful dosing of people with radioactivity. We are not a full blown co-investigator. Balance this vs need to do this work. Is this an appropriate experiment involving humans? Would we as a Committee approve dosing this individual for this use? Dose calculation: 125 mSv is what got. Dose to target organ (bone) = 140 mrem.

Action: This project was approved by majority vote of IRB members. There were dissenting votes by Shearer and Gledhill. Minority opinion will be submitted in writing for IRB records with a copy to the P.I. (Copy attached)

2. *Glycophorin A-Based Somatic Mutation Analysis of Cancer Patients Being Treated with Cis-Platinum* - P.I. Ron Jensen
IRB No. 88-109, New Project

W. Bigbee represented PI Jensen. 30 men newly diagnosed with testicular cancer and enrolled in a cis-platinum therapy will be asked to donate seven samples of blood (50 ml per sample) over a two-year period so as to perform five different biodosimetry assays on each sample (LLNL will only perform the GPA-based somatic mutation assay). Collaboration with Dr. Perera at Columbia University.

Fairly large study in terms of number of biological end points detailed on these patients. Testicular cancer patients receiving chemotherapy. Several investigators have done lots of work in this area. Would be very useful on both sides to add glycophorin A somatic mutation analysis endpoint to the other endpoints. Expect positive results with this compound based on past experience. Use standard glycophorin A assay. Studies will be done at beginning, middle and end of therapy.

This study will be done whether or not LLNL participates. There is a NIH grant to fund gathering other endpoints. LLNL will pay for our part of the study.

Action: One-year approval of this project was voted unanimously. Conditions: Collaborating institutions' explicitly mention LLNL as participant in study on collaborating institutions' protocols and consent forms. Also need current copies of approval documents from collaborating institutions' IRBs. The IRB will need copy of written substantiation from collaborators that this has occurred. Strongly urge that we participate very actively in analysis of clinical data to understand all confounding issues for patients.

3. *GPA-Based Somatic Mutation Analysis of Blood Samples from Smoking and Non-Smoking Mothers and Cord Blood Samples from Their New-Born Infants* - P.I. Ron Jensen
IRB No. 88-112, New Project

Collaborative study with Dr. Manchester, The Childrens Hospital, Denver Colorado. Coded blood samples from approximately 200 mothers (smokers and non-smokers) and cord blood

samples from their newborn infants will be obtained. Samples will be tested at LLNL using the glycophorin A-based in vivo somatic mutatin assay to determine whether smoking induces an elevated frequency of somatically variant red cells in the mother's blood and/or infant's cord blood.

New NIH grant. (1) Study of effects of this assay began with smokers and nonsmokers. This collaboration will supply large numbers of blood samples from smokers and non-smokers. (2) Fetal bloods, Manchester interest. Study indirect effects in cord blood in babies. Segregate metabolites in DNA of placenta. Steady rate of somatic mutations in mothers blood and placenta cord blood. Cord blood is collected at delivery from placenta. Manchester: questionnaire work.

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Collaborative studies (1) analysis of blood from radiotherapy patients treated at the University of Washington; (2) analysis of blood from radiotherapy patients treated at Stanford Medical Center; (3) analysis of blood from radiotherapy patients treated at the VA Hospital in Martinez, CA; and (4) analysis of blood from persons exposed in 1958 to the criticality accident at Oak Ridge Y-12 plant.

Title change is necessary because original title of project related specifically to radiotherapy patients at University of Washington. Since that time additional groups of people have been added who are getting additional clinical radiation exposure. Would like title to more accurately reflect the enlarged scope of the study.

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Trying to develop new techniques for cytogenetic analysis for tumor cells. The first year of the project was spent mostly on probe development; received limited number (approx. 10) of samples. In the second year, the number of samples is expected to increase.

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Jack Shearer
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Secretary to the Institutional Review Board

Interdepartmental letterhead

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University of California



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