

APPROVED

at IRB meeting of FEB 02 1989



Institutional Review Board
B. L. Gledhill, Chair
(Human Subjects Committee)
Lawrence Livermore National Laboratory
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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 946A
COLLECTION Institutional Review Board
BOX No. IRB Minutes
FOLDER FEB 2, 1989 Institutional
Review Board Mtg

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.

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

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
IRB No. 87G-101, Renewal

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.

Action: One-year renewal of this protocol was unanimously approved. Conditions: As possible, collaborating institutions explicitly mention LLNL as collaborator on protocols and consent forms. Provide the IRB with copies of current approval documents from collaborating institutions' IRBs.

6. *Relationship of Lipoprotein Subfractions to Coronary Disease in Men and Women* - P.I. Paul Williams
IRB No. 87P-101, Renewal

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