



**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

**Minutes**  
**Meeting of Institutional Review Board**  
**May 15, 1989**  
**Building 361, Room 1130, 1:30 p.m.**

**Attendees:**

*Committee Members:*

Dr. John Beatty  
 Alan Brautigam  
 Max Creamer  
 Jim Johnson  
 Brian Mayall  
 Kathleen Noonan  
 Jack Shearer  
 Gerry Wyman

*Principal Investigators:*

Bill Bigbee for Ron Jensen  
 Brigitte Brandriff  
 Paul Meyer  
 Andy Wyrobek

**Administrative Matters**

1. In the absence of Chairman Barton Gledhill, Kathleen Noonan acted as chairperson for this meeting.
2. Minutes of the meeting of 3/27/89 were unanimously approved as written.

**Protocol Reviews:**

**Expedited Review**

1. *Cytogenetic Investigation of a Radiation Exposed Individual*,  
 IRB No. 89-108, P.I. A. Carrano

This project was approved by expedited review on 5/2/89. IRB unanimously concurs in this approval, subject to receipt for IRB records of a copy of the following documents for this project from Letterman

REPOSITORY LLNL B351 Rm B904A  
 COLLECTION Institutional Review Board  
 BOX NO. IRB Minutes  
 FOLDER Human Subjects Committee  
Expedited Review  
July 31, 1991

collaborator: consent form used by Letterman Army Institute, and a copy of the approval form from the Letterman Hospital IRB.

### Renewals

2. *Biological Dosimeter Using a New Cyto-Immunological Method: Glycophorin-based Flow Cytometric Analysis of Human Red Blood Cells*, IRB No. 88-105, P.I. Ron Jensen

Gerry Wyman has been working with D Warner to provide information about this project requested by DOE HQ office (Susan Rose) as the requests have been received. The same information provided to them earlier apparently has been lost.

Funding source is DOD/DNA. Original samples were handcarried by Bob Gale from UCLA. The PI is working to try to get direct communication from the USSR hospital sources. Jensen is in USSR this week. He has informed USSR of our informed consent procedures. All specimens to be used at LLNL are to be coded samples. IRB requests that Jensen obtain information from collaborators as to what their procedures are, and let them know information on the issue of informed consent.

**Action:** Unanimous approval of renewal of this project for one-year period.

3. *Chromosomal Analysis of Human Sperm Chromosomes Visualized in Hamster Eggs*, IRB No. 84P-101, P.I. Brigitte Brandriff

DOE and IR&D funding sources. This project involves using sperm samples from M.D. Anderson Hospital for the past two years. There is a maximum of six local donors (three donors from Andy Wyrobek's protocol, three that Brigitte obtains). It was noted that the approval from the M.D. Anderson IRB needs to be brought up to date, or verify that their IRB approval is current, and a copy is to be provided for IRB records.

**Action:** Unanimous approval for a one-year renewal of this project.

4. *Urine Bioassay of Metals as an Early Indicator of Occupational Exposure*, IRB No. 87-105, P.I. Kathleen Noonan

Noonan stepped aside as chairperson as she is the P.I. on this project. Max Creamer acted as chairperson.

Metal worker population at LLNL is not included in the IRB review. This portion of the project is for the control population of LLNL people who are not working with metals to establish "normal" baseline readings. This study is part of "no exposure" management policy by program. It is understood that the metabolic pathway for some of these metals may not be through urine.

**Action:** Unanimous vote to approve renewal of this project for one-year period. Noonan abstained from vote.

5. *Detection of Gene Mutations and Chromosomal Abnormalities in Human Sperm* (former title: Specific locus mutations in Human Sperm), IRB No. 86P-106, P.I. Andy Wyrobek

All subjects are internal to LLNL. Project involves sperm from anonymous donors; only P.I. knows their identity. Donors provide sperm at their convenience. Some donors have been in this program for up to 10 years. There are advantages to using same people year after year. Advantages include: (1) it has worked out, (2) have baselines, (3) people participate who are interested, and (4) develop for small number of people first. There are no disadvantages in using small number of people. Has research reached the point where any conclusions can be drawn from what they are seeing? Wyrobek's answer was NO.

**Action:** Unanimous vote to approve renewal of this project for one-year period.

6. *Human Studies of Somatic, Germinal and Heritable Genetic Damage*, IRB No. 84P-102, P.I. Andy Wyrobek

There are three parts to this project. Collaborator is at EPA. Local donors from Bill Bigbee's project are used for second part of this project. M.D. Anderson collaboration involves the use of archived sperm smears. Coded samples are received by LLNL. An interesting finding is that after end of therapy (9 months to 2 years) sperm counts and their morphology patterns recover. P.I. can't retrospectively request that people know that part of work is being done at LLNL in the case of archived sperm smears. P.I. to provide a copy of the M.D. Anderson consent form for IRB records if possible.

**Action:** Unanimous vote to approve renewal of this project for one-year period conditional on receipt by IRB of M.D. Anderson approval form update; and P.I. make renewed effort to get a copy of the consent form M.D. Anderson uses.

7. *Decompression Sickness Studies with Radioactive Gases*, IRB No. 80-P-109, P.I. Paul Meyer

No changes from last year. Maximum radiation dose: 400 mrem; average dose approx. 250 mrem. IRB directed PI to insure individual calculated exposures are documented in detail. Maximum number of divers to be studied: 8. The possibility exists that pregnant women might volunteer for this study. If any female divers are included in this study, the IRB requires a special consultation with the subject, Kathleen Noonan and the Health Services Department, and the responsible Navy M.D. before acceptance into

study. This study must be approved by the Navy IRB; copy of their approval document must be on file with LLNL IRB.

Information as to why it is necessary to use human beings exclusively to obtain this information was submitted by the P.I. in earlier memoranda, and copies are in IRB records.

**Action:** Vote to renew approval for this protocol for a one year period.

Yes: Brautigam  
Creamer  
Mayall  
Johnson  
Noonan  
Beatty  
No: Shearer

Shearer was requested to provide written minority opinion for IRB records.

Approval conditions:

- (1) Must have on file with the IRB, updated, recently reviewed
  - (a) LLNL OSP;
  - (b) Navy review board's current approval covering this specific program.
- (2) LLNL IRB approval for maximum of 8 divers.
- (3) Before any irradiation involving female divers, a consultation must be held with LLNL Health Services Department and Navy doctor to explain our concerns about potential exposure to fetus. There will be written documentation that this has been done.
- (4) Human subjects in this study must be non-smokers.

Meeting adjourned at approximately 3:15 p.m.

Respectfully submitted,

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Geraldine Wyman, Secretary

**Meeting on 5/15 /89 (1:30 p.m., B-361, R-1130)**

**Attendees:**

*Committee Members:*

Dr. John Beatty  
Alan Brautigam  
Max Creamer  
Jim Johnson  
Brian Mayall  
Kathleen Noonan  
Jack Shearer  
Gerry Wyman

*Principal Investigators:*

Bill Bigbee for Ron Jensen  
Brigitte Brandriff  
Paul Meyer  
Andy Wyrobek

**Administrative Matters**

1. In the absence of Chairman Barton Gledhill, Kathleen Noonan acted as chairperson for this meeting.
2. Minutes of the meeting of 3/27/89 were unanimously approved as written.

**Protocol Reviews:**

**Expedited Review**

1. *Cytogenetic Investigation of a Radiation Exposed Individual*, IRB No. 89-108, P.I. A. Carrano

This project was approved by expedited review on 5/2/89. IRB unanimously concurs in this approval, subject to receipt for IRB records of a copy of the following documents for this project from Letterman collaborator: consent form used by Letterman Army Institute, and a copy of the approval form from the Letterman Hospital IRB.

**Renewal of Protocols**

2. *Biological Dosimeter Using a New Cyto-Immunological Method: Glycophorin-based Flow Cytometric Analysis of Human Red Blood Cells*, IRB No. 88-105, P.I. Ron Jensen

Gerry Wyman has been working with D Warner to provide information about this project requested by DOE HQ office (Susan Rose) as the requests

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

██████████ will be counted while at LLNL in February. Protocol expires on 1/26/89. P.I. Anderson fulfilled his responsibilities and submitted protocol in time for review at 1/89 meeting. He offered to have ██████████ meet with the IRB to answer any questions or concerns they may have about the project. In light of the fact that it had been voted on and the majority of the IRB had approved it at its last review, the protocol expiration date was extended by Gledhill to 2/22.

Action: Vote of IRB to approve conditional extension of this protocol to 2/22 was approved by the IRB (all voting in favor except for abstention by Creamer). There will be a meeting of the IRB on 2/21 at 1:30 p.m. in B-361, R-1155 for the IRB to meet with Anderson and Newton. Also, at that time the IRB will vote on renewal of protocol 88-101.

Note to Gerry: Send copy of minority opinion on Paul Meyer experiment renewal to IRB members.

2. *Adaption of a Monoclonal Antibody Immunoassay for the Detection of Dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin)* - P.I. M. Vanderlaan  
IRB No. 89-100

General discussion of this project is also valid for Vanderlaan's renewal project. Use of human materials, autopsy tissue material from UCLA. Surgical material removed for diagnostic purposes. Material is left over and available to Vanderlaan. Take baseline measurements for TCE. No evidence the people have been exposed to TCE. People have not been previously exposed. Vanderlaan provided documentation from UCLA that the material is exempt from review of the UCLA IRB. Creamer wants documented in our IRB file that UCLA human subjects committee has looked at this and decided it is not appropriate for review. We have a statement of exemption on file, category 5 pathological specimens, but it is not clear that the Chairman of the UCLA IRB has signed it off. Vanderlaan will write a letter stating that the LLNL IRB requests (1) UCLA mention LLNL as collaborator in this project, and (2) letter stating that UCLA IRB has exempted this (rather than Departmental Chairman). Our concern: has UCLA IRB looked at this and exempted it? Has UCLA IRB authorized department chairman to sign exemption?

Action: Vote to approve this new project for one year was unanimous, with conditions: Vanderlaan write letter stating that the LLNL IRB requests (1) UCLA mention LLNL as collaborator in this project, and (2) letter stating that UCLA IRB has exempted this (rather than Departmental Chairman).

3. *Biochemical Measures of Exposure to Dietary Carcinogens* - P.I. M Vanderlaan

4. *Detection of Gene Mutations and Chromosomal Abnormalities in Human Sperm* (former title: Specific locus mutations in Human Sperm), IRB No. 86P-106, P.I. Andy Wyrobek

Goal of research: take human sperm, develop methods for detecting mutations directly. Two methods still under development. All subjects are internal to LLNL. Project involves sperm from anonymous donors. Andy is only one who knows their identity. Donors provide sperm at their convenience. Some donors have been in this program for up to 10 years. There are advantages to using same people year after year. Advantages include: (1) it has worked out!, (2) have baselines, (3) people participate who are interested, and (4) develop for small number of people first. There are no disadvantages in using small number of people.

Directed by IRB to record in minutes: has research reached the point where any conclusions can be drawn from what they are seeing? Wyrobek's answer was NO.

**Action:** Unanimous vote to approve renewal of this project for one-year period.

5. *Human Studies of Somatic, Germinal and Heritable Genetic Damage*, IRB No. 84P-102, P.I. Andy Wyrobek

There are three parts to this project. Collaborator is at EPA. Using existing local donors from Bill Bigbee's project for second part of this project. M.D. Anderson collaboration in part b of this project involves the use of archive sperm smears. Coded samples are received by LLNL. An interesting finding is that after end of therapy 9 mos/2 years, sperm counts and their morphology patterns recover. P.I. can't retrospectively request that people know that part of work is being done at LLNL in the case of archive sperm smears. P.I. to provide a copy of the M.D. Anderson consent form for IRB records if possible. Andy: get me a copy of your letter to M.D. Anderson collaborator.

**Action:** Unanimous vote to approve renewal of this project for one-year period conditional on receipt by IRB of M.D. Anderson approval form update; and P.I. make renewed effort to get a copy of the consent form M.D. Anderson uses.

6. *Decompression Sickness Studies with Radioactive Gases*, IRB No. 80-P-109, P.I. Paul Meyer

No changes from last year. Maximum radiation dose: 400 mrem; average dose approx. 250 mrem. Creamer told Meyer to document exposures to individuals. Written in detail, calculated dose for each individual. Maximum number of divers to be studied: 8. Kathleen: will any pregnant women be a part of this study? Max: important because of sensitivity of

fetus during 1st trimester. Per Max: if they do have a female diver, must have a special consult---notify Kathleen and Health Services, and Navy M.D. on site. Navy Dr. to tell their people. Question was asked if we get statement from Navy MDs certifying subjects are in good health? Paul No, we have not in past. Divers are actively assigned at LLNL Navy IRB has to approve of this protocol. Copy must be on file with LLNL IRB.

Information as to why it is necessary to use human beings exclusively to obtain this information was submitted by the P.I. in earlier memoranda, and copy is in IRB records.

**Action:** Vote to renew approval for this protocol for a one year period.

Yes: Brautigam  
Creamer  
Mayall  
Johnson  
Noonan  
Beatty

No: Shearer

Shearer was requested to provide written minority opinion for IRB records.

Approval conditions:

- (1) Must have on file with the IRB, updated, recently reviewed
  - (a) LLNL OSP;
  - (b) Navy review board's current approval (includes within last year Navy's IRB) covering this specific program;
- (2) LLNL IRB approval for maximum of 8 divers.
- (3) Before any irradiation involving female divers, a consultation must be held with LLNL Health Services Department and Navy doctor to explain our concerns about potential exposure to fetus. There will be written documentation that this has been done.
- (4) Human subjects in this study must be non-smokers.

Meeting adjourned at approximately 3:15 p.m.

Respectfully submitted,

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Geraldine Wyman, Secretary