



**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

**APPROVED**

at IRB meeting of MAR 27 1989

717999

**Minutes**  
**Meeting of Institutional Review Board**  
**February 2, 1989**  
**Building 361, Room 1130, 9 a.m.**

**Attendees:**

*Committee Members:*

Alan Brautigam  
Max Creamer  
Bart Gledhill  
Jim Johnson  
Brian Mayall  
Kathleen Noonan  
Vivian Shepherd  
Gerry Wyman

REPOSITORY LLNL B361 Rm 940A  
COLLECTION Institutional Review Board  
BOX No. IRB Minutes  
FOLDER FEB 2, 1989 Institutional  
Review Board Mtg

*Principal Investigators:*

Marty Vanderlaan/Jim Tucker

**Administrative Matters**

1. Minutes of the IRB meeting of 11/16/88 were approved as written.
2. Tentative meeting schedule for 1989 was discussed. Specific dates will be determined by the availability of a quorum of IRB members.

**Protocol Reviews**

1. Cytogenetic Studies, P.I. A. Carrano  
IRB No. 88-111

Bart informed the IRB that he had approved an expedited review for this project on 12/22/88.

1122392

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

Protocol approval expired on 1/26/89. P.I. Anderson fulfilled his responsibility and submitted protocol in time for review at 1/89 meeting. He offered to have Don Newton, AERE Harwell and a PI for this project, who is visiting LLNL Feb. 16-21, meet with the IRB to answer any questions or concerns they may have about the project. Because the majority of the IRB had approved this protocol at the time of its last review and in order for the IRB to consider information to be provided at meeting with Don Newton, the protocol expiration date was extended by Gledhill to 2/22/89.

**Action:** IRB approved conditional extension of this protocol to 2/22 (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-1130 for the IRB to meet with Anderson and Newton. Also, at that time the IRB will address renewal of protocol 88-101.

3. *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

This project will use autopsy tissue from UCLA. This is surgical material removed for diagnostic purposes. The human tissues will be used to make baseline measurements for TCE. There is no evidence the people have been exposed to TCE. LLNL IRB file needs documentation that the UCLA human subjects committee reviewed and exempted this project from their review.

**Action:** Vote to approve this new project was unanimous, with the following conditions: Vanderlaan contact collaborators with LLNL IRB requests: (1) UCLA mention LLNL as collaborator in this project, and (2) documentation of UCLA IRB exemption of this project.

4. *Biochemical Measures of Exposure to Dietary Carcinogens* - P.I. M Vanderlaan  
IRB No. 88-100

Changes to protocol from last year: expand dietary restriction to add vegetarian diet 4 days on either end of beef diet. Added procedure to obtain third data curve--micronucleus assay. Will also obtain microliter amounts of blood from each volunteer, using finger prick on a daily basis, during course of volunteers' participation.

**Action:** Unanimous approval of one-year renewal of this protocol.

5. *Protective Breathing Equipment (Respirators) Testing* - P.I. R Da Roza  
IRB No. 89-101

*Effect of Face Shape and Exercise on Respirator Performance* - P.I. R. Da Roza  
IRB No. 88-102

*Performance of a "Portacount" and Other Respirator Fit Measuring Methods -  
P.I. R. Da Roza  
IRB No. 88-102A*

There are presently 3 ongoing respirator testing projects which involve human subjects. These projects all involve using the same test but with different respirators.

Portacount (IRB #88-102A)--no change to protocol reviewed by IRB 8/88. This approval is still valid until 8/89.

**Action:** For IRB recordkeeping purposes, Bob will resubmit the information on these protocols, combining the three active projects into 1 general protocol, with subsets for different medical surveillance criteria and populations. IRB #88-102 will be used. This revised protocol will be reviewed at the 3/27 IRB meeting.

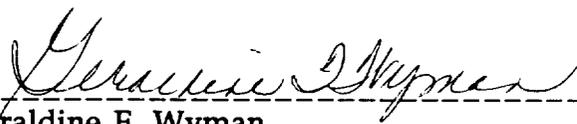
6. *Total Encapsulating Suit Leakage Rate - P.I. J. Johnson  
IRB No. 82P-103*

Although there are some similarities, this protocol is separate from Da Roza's. Changes from last review: introduction of two additional new test agents. Tests are run on people who would be expected to use these suits. General population volunteers are not used.

**Action:** One-year renewal of this protocol was approved by unanimous vote (J. Johnson abstained).

Meeting adjourned at 11:20 a.m.

Respectfully submitted:

  
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Geraldine F. Wyman  
Secretary to the Institutional Review Board



**Institutional Review Board**  
**B. L. Gledhill, Chair**  
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*Principal Investigators:*

Marty Vanderlaan/Jim Tucker

**Administrative Matters**

1. Minutes of the IRB meeting of 11/16/88 were approved as written.
2. Tentative meeting schedule for 1989 was discussed. Specific dates will be determined by the availability of a quorum of IRB members.

**Protocol Reviews**

1. Cytogenetic Studies, P.I. A. Carrano  
IRB No. 88-111

Bart informed the IRB that he had approved an expedited review for this project on 12/22/88.

1122395

2. *Lung Counter Calibration with Inhaled Nb-92m as a "Mock Plutonium"* -  
P.I. Larry Anderson  
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**Action:** IRB approved conditional extension of this protocol to 2/22 (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-1130 for the IRB to meet with Anderson and Newton. Also, at that time the IRB will address renewal of protocol 88-101.

3. *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

This project will use autopsy tissue from UCLA. This is surgical material removed for diagnostic purposes. The human tissues will be used to make baseline measurements for TCE. There is no evidence the people have been exposed to TCE. LLNL IRB file needs documentation that the UCLA human subjects committee reviewed and exempted this project from their review.

**Action:** Vote to approve this new project was unanimous, with the following conditions: Vanderlaan contact collaborators with LLNL IRB requests: (1) UCLA mention LLNL as collaborator in this project, and (2) documentation of UCLA IRB exemption of this project.

4. *Biochemical Measures of Exposure to Dietary Carcinogens* - P.I. M Vanderlaan  
IRB No. 88-100

Changes to protocol from last year: expand dietary restriction to add vegetarian diet 4 days on either end of beef diet. Added procedure to obtain third data curve--micronucleus assay. Will also obtain microliter amounts of blood from each volunteer, using finger prick on a daily basis, during course of volunteers' participation.

**Action:** Unanimous approval of one-year renewal of this protocol.

5. *Protective Breathing Equipment (Respirators) Testing* - P.I. R Da Roza  
IRB No. 89-101

*Effect of Face Shape and Exercise on Respirator Performance* - P.I. R. Da Roza  
IRB No. 88-102

*Performance of a "Portacount" and Other Respirator Fit Measuring Methods -  
P.I. R. Da Roza  
IRB No. 88-102A*

There are presently 3 ongoing respirator testing projects which involve human subjects. These projects all involve using the same test but with different respirators.

Portacount (IRB #88-102A)--no change to protocol reviewed by IRB 8/88. This approval is still valid until 8/89.

**Action:** For IRB recordkeeping purposes, Bob will resubmit the information on these protocols, combining the three active projects into 1 general protocol, with subsets for different medical surveillance criteria and populations. IRB #88-102 will be used. This revised protocol will be reviewed at the 3/27 IRB meeting.

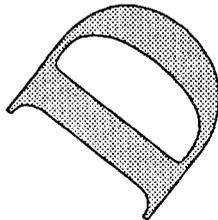
6. *Total Encapsulating Suit Leakage Rate - P.I. J. Johnson  
IRB No. 82P-103*

Although there are some similarities, this protocol is separate from Da Roza's. Changes from last review: introduction of two additional new test agents. Tests are run on people who would be expected to use these suits. General population volunteers are not used.

**Action:** One-year renewal of this protocol was approved by unanimous vote (J. Johnson abstained).

Meeting adjourned at 11:20 a.m.

Respectfully submitted:



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Geraldine F. Wyman  
Secretary to the Institutional Review Board

**Meeting on 2/2 (9 a.m., B-361, R-1130)**

**Attendees:**

*Committee Members:*

Alan Brautigam  
Max Creamer  
Bart Gledhill  
Jim Johnson  
Brian Mayall  
Kathleen Noonan  
Vivian Shepherd  
Gerry Wyman

*Principal Investigators:*

Marty Vanderlaan/Jim Tucker

**Administrative Matters**

1. Minutes of the IRB meeting of 11/16/88 were approved as written.
2. Tentative meeting schedule for 1989 was discussed. Specific dates will be determined by the availability of a quorum of IRB members.
3. Delete from generic consent form the signature block for minor/person unable to sign. This can be added to individual statement of conditions of protocol approval and consent form for specific projects as needed.

**Protocol Reviews:**

**Expedited Review**

1. Cytogenetic Studies, P.I. A. Carrano  
IRB No. 88-111

Bart informed the IRB that he had approved an expedited review for this project. Tucker had submitted this project to do cytogenetic and related analyses to the IRB and had appeared before the IRB to answer questions at its meeting in November 1988. Creamer reviewed documents submitted to IRB, Tucker made additions, explanations per Creamer's recommendations. Reviewed protocol was submitted to IRB, Gledhill approved it by expedited review on December 22, 1988 under exemption category 4.

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

Don Newton 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 Don Newton 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

IRB No. 88-100

General discussion same as for Vanderlaan's new protocol above. Changes to protocol from last year: will add vegetarian diet, add few days on either end of eating beef. Diet controls, not rigid # of blood samples. Add procedure to obtain third data curve: micronucleus assay. Want to get microliter amounts of blood, using finger prick, on a daily basis during course of study, beginning with vegetarian stages through the end vegetarian stages. For finger pricks, Kathleen Noonan said to clean area with alcohol first, do finger stick. Very minor risk potential for infection. Give people option of doing stick themselves.

4 days	4 days	4 days
- - -	- - -	- - -
veg. diet	beef diet	veg. diet

Want to find out individual metabolism. Approximately 6 subjects to measure individual variability.

Consent form: add under 5c, "to examine micronuclides...." add statement "These urine samples will not be used for drug detection." (per Max Creamer)

Statement to prospective participants: add statement (words per Max Creamer): "These urine samples will not be used for drug detection."

Disqualification statement (a) and (b)--delete explanation why--doesn't have to explain.

Action: Unanimous approval of one-year renewal of this protocol.

4. *Protective Breathing Equipment (Respirators) Testing* - P.I. R Da Roza  
IRB No. 89-101

*Effect of Face Shape and Exercise on Respirator Performance* - P.I. R. Da Roza  
IRB No. 88-102

*Performance of a "Portacount" and Other Respirator Fit Measuring Methods* -  
P.I. R. Da Roza  
IRB No. 88-102A

Background: Have done respirator testing for over 10 years. Began with standard fit test for respirators (standard tests). Then expanded study to include effect of face hair growth (this project is now inactive), and the effect of face shape and exercise on respirator fit. Bob has funding from DuPont to test some other types of respirators. There are presently 3 ongoing projects. These involve using the same test but with different respirators.

General protocol: Measuring performance of testing equipment. Subsets differ in terms of (1) medical procedures, and (2) proscribed volunteers. The IRB is not concerned with funding sources in its review, but needs to know funding sources for certain funding application procedures.

Portacount (88-102A)--no change to protocol. Reviewed by IRB 8/88. This approval is still valid until 8/89.

For IRB recordkeeping purposes, these projects will be administratively reorganized (IRB numbers, review schedule, etc.) Bob will resubmit the information on these procedures, etc., combining the three active projects into 1 general umbrella protocol, with subsets for different medical surveillance and population. This will be reviewed at the IRB 3/27 meeting. Bob was asked to submit paperwork to Gerry by 3/13--one week is required for IRB review before the meeting, one week to allow duplication and distribution.

**Note to Gerry: memo to PI's regarding 3/27 meeting. Which of their protocols expire, and which do they want to renew.**

5. *Total Encapsulating Suit Leakage Rate* - P.I. J. Johnson  
IRB No. 82P-103

Although similar in some ways, this project is separate from Da Roza's. Changes from last review: introducing two additional new test agents. Tests are run on people who would be expected to use these suits. General population volunteers are not used. General issues for approval of this project: ammonia test, 6 people. As hazardous material response people, firefighters must perform these tests under Federal law. Jim could do these tests including firefighters rather than firefighters building their own test facility.

Consent form: add: check for allergies to ammonia, list test agents.

Action: One-year renewal of this protocol was approved by unanimous vote (J. Johnson abstained).

Meeting adjourned at 11:20 a.m.