APPROVED

at IRB meeting of JUN 0 2 1988

University of California

Lawrence Livermore National Laboratory

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Meeting of Institutional Review Board
March 14, 1988
Building 361, Room 1155, 1:30 p.m.

REPOSITORY LLNL B361 Rm 9401A
COLLECTION Institutional Review Board
BOX No. IRB Minutes
FOLDER Mar 14, 1988 Institutional Review Board Mtg

Attendees:

Committee Members:

John Beatty
Max Biggs
Alan Brautigam
Max Creamer
Lowry Dobson
Bart Gledhill
Jim Johnson
Jack Shearer
Gerry Wyman

Principal Investigators:

Dan Moore (for Dr. David Discher)
Irene Jones
Ron Jensen
Harvey Mohrenweiser (for T. Carrano)

Administrative Matters

1. Minutes of the Committee meeting of 1/26/88 were approved with no additions or corrections.

2. Jack Shearer presented to the Committee a memorandum with comments on Paul Meyer's proposed experiment using Navy Divers (IRB No. 80P-109, last approval 11/25/86). A copy of Shearer's memo will be sent to Paul Meyer. **(Note: copy sent 3/23/88).** This project has been under Committee review at its last two meetings. Prior to this meeting, copies of a memorandum from Max Creamer on this subject were sent to IRB members. Paul Meyer indicated he plans to attend the next IRB meeting for further discussion of this project.

3. P.I.'s will be sent a reminder stating that **new and renewal projects** submitted for Board review will not be considered unless the P.I. or a member of the scientific team is available during the meeting to answer questions.

4. The next IRB meeting will be held on May 16 at 1:30 p.m. in Building 361, Room 1155. A written confirmation of this date will be sent to Committee members, and a notice will be sent to P.I.'s who have active projects with renewals expiring in May and June 1988.

Protocol Reviews:

1. *Workplace Investigation for Melanoma Risk Factors*
   P.I. Dr. David Discher
   IRB No. 86P-101 - last approval 11/25/86

   The interview protocol will be the same as the one approved by the IRB on November 25, 1986. This study consists of two phases. In phase I, which has been completed, melanoma cases were interviewed. Review of the results of these eleven interviews is in progress. A summary of the findings of phase I will be presented to the LLNL Melanoma Investigation Task Group for a decision as to whether phase II, interview of matched controls, will be necessary. Matched controls have been selected. In addition, consent will be obtained to

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procure medical records for radiation treatment received by one already-interviewed subject as a youth. Records of the workplace investigation project are protected and confidentiality of the records will be maintained.

Action: One-year renewal of approval of this project was voted unanimously.

2. *Molecular Analysis of the Spectra of Mutations in the Human hprt Gene*
P.I. Irene Jones
IRB No. 88-104 - new project

Blood lymphocytes are cultured in the laboratory under conditions that allow only cells with mutated (altered) hprt genes. These cells then supply DNA and RNA for biochemical/molecular analysis of the specific alteration in the DNA that is responsible for the mutation. By studying many (50-100) different mutants per person, one learns the spectrum of mutations characteristic of that gene in that person. In Phase 1 (first year) normal unexposed people will be studied to learn about spontaneously occurring mutations. Phase 2 - next year - will involve samples recovered from NIEHS of exposed people. NIEHS human subjects approval will be submitted before then.

LLNL local donors will be used. Donors will not be chosen by random selection. A small number of donors will be required (8). 50 ml of blood will be drawn from each volunteer, who will be paid $10.00. Donors will be people not normally in the cell culture facility or who are involved in this research. The Board asked Irene to provide, for committee records, a copy of the questionnaire which will be used to screen volunteers. The Board also asked that minor additions be made to the form now on file with the IRB.

Action: One-year approval of this project was voted unanimously. Minor changes to the protocol form will be made. A copy of the questionnaire will be submitted to the IRB.

3. *Protocol to Measure the Chromosomal Aberration Frequencies in Patients Undergoing Radiation Therapy with X-Rays or Fast Neutrons*
P.I. Tore Straume
IRB No. 86P-103 - last approval 11/30/87

P.I. was not present. This protocol was approved for one year by the IRB at its meeting of 11/30/87 for the collaboration with the University of Washington. As requested by the IRB at that meeting, Tore provided for IRB records, information regarding his collaborations planned with the Stanford Medical Center and the VA Hospital in Martinez/UC Davis.

Action: The receipt of the above information completes IRB requirements for collaboration with the Stanford Medical Center and the VA Hospital/Martinez. Based on IRB action of 11/30/87 and 3/14/88, unanimous approval of collaborations with these two institutions, effective 3/14/88, was voted, with an expiration date of 11/29/88.

4. *Somatic Cell Mutations Using Glycophorin A*
P.I. Ron Jensen
IRB No. 80G-102 - last approval 3/17/87

This approval covers a number of projects going on for the past several years. Approval of new collaborators who furnish blood samples is requested. Two approvals are requested: (1) standard blood samples at LLNL Health Services Department (Livermore volunteers) for glycophorin analysis. No variations from last year's approval. (2) new collaborations with

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Flinders Medical Center, University of South Australia; University of Minnesota; Stanford University.

Collaborations: Documentation of the collaborating institutions current IRB approval, protocol and consent forms must be on file with the LLNL IRB. No analyses are to be done until the institutions' IRB's have approved. University of Minnesota--no approval form from them yet, but Ron knows U of M has NIH grant and their work has been going on for a year. The Stanford collaboration is more preliminary than University of Minnesota. Other places are collecting for biodosimetric analysis for other institution's purposes.

Action: Unanimous vote of approval of renewal for one year, pending receipt of supporting documentation from collaborative institutions' IRB.

5. *Detection of Aneuploid Sperm by DNA Probes*
P.I. Andy Wyrobek
IRB No. 87-109 - last approval 3/17/87

Sperm will be collected from local donors and from men receiving cancer chemotherapy (in collaboration with the M.D. Anderson Hospital, Texas). Sperm will be prepared for analysis with fluorescent chromosome specific DNA probes. There are no changes in protocol for human subjects from most recent review.

Action: Unanimous vote to approve one-year renewal of this project, pending receipt of supporting documentation from collaborating institutions' IRB.

6. *Effects of PCE on Male Reproduction*
P.I. Andy Wyrobek
IRB No. 87-107 - last approval 3/17/87

Action: No action was taken on this project as P.I. was not available to answer questions. P.I. is to provide documentation from each collaborating institution's IRB.

7. *Human Studies of Somatic Germinal and Heritable Genetic Damage*
P.I. Andy Wyrobek
IRB No. 84P-102 - last approval 3/17/87

Action: No action was taken on this project. as P.I. was not available to answer questions. P.I. is to provide additional information on item B.8 of the checklist.

8. *Specific Locus Mutations in Human Sperm*
P.I. Andy Wyrobek
IRB No. 86P-106 - last approval 3/17/87

Action: No action was taken on this project as P.I. was not available to answer questions. IRB will review this project when P.I. is available to answer questions.

9. *Chromosome Specific - Physical Mapping*
P.I. Tony Carrano
IRB No. 88-103 - new project

DNA samples derived from white blood cells of volunteers will be utilized to establish the order of genes on chromosome 19. For a limited number of individuals, lymphoblastoid cell lines will be established in order to establish a DNA resource for future needs. The establishment of a physical map will facilitate the identification of disease genes and also markers which will be useful for counseling regarding genetic diseases. 30-50 cc of blood will be drawn, with no dietary control or fasting required. In a limited number of cases when warranted by the initial data, samples may be requested for family members. As necessary, in the event that blood samples must be drawn from family members (adults) at other locations, such samples will be drawn by the family physician. The maximum number of volunteers will be 24 adults (no children involved).

Action: Unanimous approval of this protocol for one year, with minor modifications of protocol and consent form as specified by IRB.

10. *Radiobiological Techniques in Human Cancer Therapy*
P.I. Joe Gray
IRB No. 86G-102 - last approval 4/1/87

Joe Gray was not available for the IRB meeting, but had briefed the Chairman on this project.

Patients with leukemia and lymphoma will be involved in these studies. In one study, bone marrow samples taken for diagnostic purposes will be labeled with BrdUrd in vitro before and after treatment with ara-C. Flow cytometry will be used to screen for ara-C resistant cells. In the other study, patients will be given BrdUrd in vitro and bone marrow samples will be taken periodically thereafter for assessment of cell proliferation characteristics. Information will be held in confidence by attending physicians. Patient ID will not be available at LLNL.

Collaboration will continue with UCSF. Project approved by USCF IRB on 10/23/87. New collaboration with M.D. Anderson Hospital & Tumor Institute. Appropriate documentation from that institution's IRB must be on file with LLNL IRB.

Action: Vote unanimous approval of project with collaboration at UCSF; collaboration with M.D. Anderson contingent on getting documentation (IRB approval, consent form).

Respectfully submitted:

Geraldine F. Wyman

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