



Institutional Review Board
B. L. Gledhill, Chair
 (Human Subjects Committee)
 Lawrence Livermore National Laboratory
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APPROVED

at IRB meeting of **NOV 28 1989**

*with addition
as noted by*

717962

Minutes
Meeting of Institutional Review Board
October 2, 1989
Building 361, Room 1130, 1:30 p.m.

Attendees:

Committee Members:

Max Biggs
 Max Creamer
 Bart Gledhill (chairman)
 Jim Johnson
 Rev. Bill Nebo
 Jack Shearer
 Gerry Wyman

Principal Investigator:
 Joe Gray

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

Administrative Matters

1. New IRB member Rev. Bill Nebo was introduced. Rev. Nebo is the pastor of the First Presbyterian Church in Livermore.
2. Minutes of the meeting of May 15, 1989 were unanimously approved subject to the addition of the following:

Protocol review, item 7: Decompression Sickness Studies with Radioactive Gases, IRB No. 80-P-109, P.I. Paul Meyer. Add note that "subsequent action occurred; please see IRB meeting minutes of 10/2/89." (See item 3 following)

3. Project approved at 5/15/89 meeting titled "Decompression Sickness Studies with Radioactive Gases," IRB No. 80-P-109, P.I. Paul Meyer. Shearer's written minority opinion was filed after the 5/15/89 meeting; it asked questions which were answered. Shearer changed his vote to "yes" for renewal of this experiment. (See Jack Shearer memo of 6/9/89)

4. Next meeting date is tentatively set for Monday, November 13 at 1:30 p.m. Max Biggs will chair this meeting as Bart will be on travel. A new calendar for 1990 meetings will be available.

Protocol Reviews:

Expedited Review

1. *Cytogenetic studies on splenectomized individuals*,
IRB No. 89-110, P.I. Tony Carrano

This project was approved by expedited review on 9/11/89. IRB unanimously concurs in this approval.

2. *Biodosimetry for low levels of ionizing radiation*,
IRB No. 89-111, P.I. Ron Jensen

This project was approved by expedited review on 9/21/89. IRB unanimously concurs in this approval with following change:

Add to bottom of project approval form: " Upon review at its 10/3/89 meeting the IRB instructs PI to ensure that the records and identity of the donors will be kept secure and confidential." *"Question was raised: do we need or want to follow this up?" IRB asked the chairman to follow this up with the P.I. [added at 11/28/89 meeting]*

Renewals

1. Flow karyotyping: optimization and clinical evaluation
IRB No. 82G-101, P.I. Joe Gray

Renewal of ongoing project. Project end is improved prenatal diagnosis. Cooperation with UCSF prenatal diagnostics unit. Two parts to this study: (1) number of samples to be processed in future. Coded samples to be received. All discarded material. Amniocentesis--draw sample from around fetus. (2) drawing blood samples from women. Fetal cells in maternal circulation. Women carrying male fetus, looking for leucocytes (fetal membrane cells that invade to maternal circulation). In 1st trimester. UCSF take blood samples as part of workup. Part of medical workup of mother who is in clinic to be tested. Blood would be drawn if LLNL did not participate. Mothers are not told the results of Gray's test as it is still experimental procedure. Clinicians are being told results. Human subjects know that leftover blood is being used for experimental purposes. UCSF does not inform human subjects of site specific collaborations. Gray: will not check Joe's findings against any aborted material. Not getting any medically useful information out of this at this time.

Creamer: What is CSF position as to residual aborted human material? In context of this study, it is considered to be discarded material and fair game for use. Nebo: LLNL not charged for this material? Gray: no, nobody is paid for this material. Shearer: Are some people at UCSF counseling people as to whether or not to be aborted? Are people doing research? Gray: No, material comes from surrounding material. UCSF collaborates with abortion clinics. Per Joe Gray, this particular program is NIH conceived and funded project. Once material gets into UC system it becomes unidentifiable.

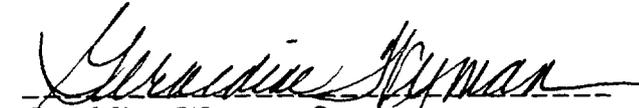
For notes: As a result of phone call from Joe Gray to Susan at approx. 2:20 p.m., cells that are obtained from them are *placental*, not fetal. NIH position is that this is different material; therefore it is acceptable to be used without any consent. NIH considers this to be a case that justifies expedited review.

Action: Unanimous approval voted to renew this project for one-year period. Memo will be prepared for file stating that this study involves use of aborted human placental material. As discussed with Susan Fisher and with the IRB the residual human material was *placental*, not fetal. This memo to be signed by Gledhill and Gray.

Gray question to IRB: Likely to happen by next review period: we are probably going to mount a national large clinical trial. Requests from one-half dozen large clinical areas. How does this get done with international colleagues? Creamer: Here are the rules I am asked to live with. Send it to potential collaborators. This sort of procedure is to be followed. Give PI some indication that human subjects have some type of informed consent. Gray: If this stuff works at all, they may stop doing conventional cytogenetic studies and use this new procedure as standard. We will supply them with reagents that will do tests and interpret results (technology transfer). We will only supply reagents. First part of study will be validation they will participate in. At beginning, LLNL major voice in how clinical trial is set up. Need to show good faith efforts in our collaborations.

Meeting adjourned at approximately 4:00 p.m.

Respectfully submitted,


Geraldine Wyman, Secretary