



LAWRENCE LIVERMORE LABORATORY

CERTIFICATION OF REVIEW

704100

AND

SPECIAL IMPLEMENTATION OF INSTITUTIONAL ASSURANCE

REPOSITORY DOE-FORRESTAL

COLLECTION MARKET FILES

BOX No. 2 OF 6

FOLDER CONSENTS FILED REPORTS

The reimbursable activity titled, Testicular Dysfunction in Men Occupationally Exposed to Lead submitted on behalf of Andrew J. Wyrobek on May 22, 1979 to the Environmental Protection Agency, has been reviewed by the assembled members of the Committee whose signatures appear below in accordance with the requirements of the DOE regulations on the Protection of Human Subjects.

A. This Committee has determined that the subjects in this activity are at risk. The risks are:

- 1. Invasion of privacy resulting from the disclosure of the donor's identity and/or the release of any medical information pertaining to the donor.

B. This Committee has determined to its satisfaction that the following safeguards against the specified risks are adequate:

All work involving human subjects under this activity will be performed by the University of California Lawrence Livermore Laboratory whose Human Subjects Committee has reviewed and approved the use of human semen in this activity. A copy of the approval from this Committee is attached.

C. The Committee has determined to its satisfaction that the risks to the subjects are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept the risks. This determination is based upon the following benefits or reasons:

The aim of the research done under this reimbursable activity is to determine the correlation of and effect on sperm production and morphology as a result of long term exposure to lead.

While there may be no direct benefit to the subject, there is the potential benefit to large numbers of people in the future in the area of birth defects. The risks are minimal.

- D. This Committee has determined to its satisfaction that legally effective informed consent is to be obtained and properly documented in accordance with the requirements specified in the regulation 10 CFR 745 (a). The informational statement to be given or read to each prospective subject before his participation in the activity is attached.

- E. This Committee agrees to arrange for the continuing exchange of information and advice between itself and the activity director on any matters affecting the rights and welfare of human subjects who participate in the activity. The specific instructions, advice, counsel, and conditions imposed by the Committee for the conduct of the activity are:

The LLL Human Subjects Committee has advised Dr. Wyrobek that the Committee must approve any changes in the protocol. Also, any abnormal findings must be reported to the occupational physician for transmission to the donor's private physician.

The next scheduled meeting of the Committee for review of this activity is January 17, 1981. The Committee may be called into an interim review session by the Chairman at the request of any member, an institutional official or the project director to consider any matter concerned with the rights and welfare of any subject.

- F. This Committee has determined to its satisfaction that this institution will have available the professional attention and facilities that may be needed for subjects who may suffer physical, psychological, or other injury as a result of participation in the activity.

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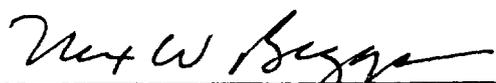
Signature Requirements

The members of the Committee are listed below. None of the signatories has a vested professional interest in this activity that conflicts with the principle of independent, objective review.

I certify that this review was carried out in accordance with the requirements of Part 745 Protection of Human Subjects of Title 10 of the Code of Federal Regulations.

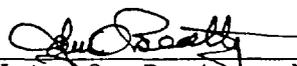


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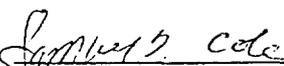
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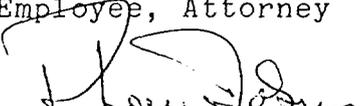
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