

Interdepartmental letterhead

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704102

February 11, 1980

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TO: A. J. Wyrobek

SUBJECT: Human Subjects Approval - 80P-102-01

This memorandum is to confirm that at its January 18, 1980 meeting, the LLL Human Subjects Committee approved your use of human semen in your project titled, "Testicular Dysfunction in Men Occupationally Exposed to Lead".

The Committee has based its approval upon the protocol submitted to the Environmental Protection Agency on May 22, 1979 at the November 2, 1978 meeting and understands that this is a reimbursable funded project. Should you wish to change the protocol in any way, you must obtain the prior approval of the Committee. This approval is subject to the following conditions:

1. The identity of the donor must be protected through the coding of samples.
2. Any abnormal findings will be determined by Dr. Donald Wharton, clinical director of this study, and relayed to the occupational physician for transmission to the donor.
3. The donor must be given a copy of the attached Experimental Subject's Bill of Rights.
4. The donor must give his/her informed consent, using the attached consent form with the approval number 80P-102-01.
5. The donors must be given a copy of the signed LLL consent form.



University of California

LAWRENCE LIVERMORE LABORATORY

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The LLL Human Subjects Committee will be available to assist in the determination of "abnormal findings".

This approval is valid for the period of one year. If you desire to continue this work beyond January 17, 1981, you must obtain prior approval of the LLL Human Subjects Committee.



David C. Shepherd
Secretary
LLL Human Subjects Committee

DCS:VLJ

Distribution:

J. O. Beatty

M. W. Biggs

S. D. Cole

R. L. Dobson

attachments

D. B. Gordon

F. T. Hatch

J. S. Johnson

file

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UNIVERSITY OF CALIFORNIA
LAWRENCE LIVERMORE LABORATORY

Consent to Act as a Human Subject

LLL Human Subjects Committee

Approval Number 80P-102-01

Title: Testicular Dysfunction in Men Occupationally Exposed to Lead

Approval Date: January 18, 1980

Subjects Name: _____

Date: _____

1. I hereby authorize _____ and/or such assistants as he may select to obtain from me a sample of semen to be utilized for experimental purposes.
2. I understand that the medical procedures for obtaining this material are standard (not of an experimental nature) and these procedures are outlined in the attached document.
3. Since this activity does not involve medical treatment, there is no alternative procedure which might be advantageous to me.
4. At the conclusion of this procedure it is expected that I will be able to function normally immediately.
5. I understand that the purpose of performing these procedures is to obtain sperm for biochemical and biophysical tests outside the human body. Specifically, the material will be used for the following:

To study the effect of lead exposure on the production and morphology of human sperm.

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LLL Human Subjects Committee

Approval Number 80P-102-01

Title: Testicular Dysfunction in Men Occupationally Exposed to Lead

Approval Date: January 18, 1980

6. I further understand that this study may result in no direct benefit to me but it may contribute to the understanding of sperm abnormalities, possibly reducing birth defects and may, therefore, be of some benefit to individuals in the future.
7. I understand the the sample will be encoded to protect my identity and that my identity will be disclosed only to those needing that information to conduct this research.
8. I understand that Andrew J. Wyrobek and/or such assistants as he may select will answer any inquiries I may have at any time concerning the procedures and/or investigation.
9. Any publication arising from this study will be made without specific reference to my name.
10. I recognize that my participation in this experiment is entirely voluntary and I may refuse to participate or may withdraw at any time without jeopardy. Owing to the scientific nature of the study, the investigator may in his absolute discretion terminate the procedures and/or investigations at any time
11. Andrew J. Wyrobek, an employee of the University of California - Lawrence Livermore Laboratory, is responsible for the conduct of the research in which I am to participate. This research is sponsored by the Environmental Protection Agency and is being performed at the Biomedical Division of Lawrence Livermore Laboratory which is operated by the University of California under contract W-7405-ENG-48 with United States Department of Energy.

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LLL Human Subjects Committee
Approval Number - 80P-102-01
Title: Testicular Dysfunction in Men Occupationally Exposed to Lead
Approval Date: January 18, 1980

12. I understand that if I have any complaints or concerns about the procedures, I may address them to David C. Shepherd, Secretary of the Human Subjects Committee, in person, by telephone, or in writing. Mr. Shepherd can be reached at (415) 422-8406, L-446, Lawrence Livermore Laboratory, P.O. Box 808, Livermore, CA 94550.

Subject's Signature _____

Witness _____

To be completed if Subject is a minor or otherwise unable to sign:

Subject is a minor (age___) or otherwise unable to sign because:

Father

Legal Guardian

Mother

Witness

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