



LAWRENCE LIVERMORE LABORATORY

CERTIFICATION OF REVIEW

704112

AND

SPECIAL IMPLEMENTATION OF INSTITUTIONAL ASSURANCE

The programmatic activity titled, The Effects of Flagyl (Metronidazole) on Sperm Morphology and Biochemistry submitted on behalf of Barton L. Gledhill on January 18, 1980 to the United States Department of Energy, 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 study will be performed by the University of California San Francisco, Medical Center under a formal collaborative arrangement. This Committee bases its approval of this activity on the approval of the U.C. San Francisco Medical Center Committee on Human Research. A copy of this approval and the consent form are attached. U. C. San Francisco holds a General Assurance with the Department of Health, Education, and Welfare.

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 programmatic activity is to determine the effects of Flagyl on sperm morphology or sperm protein. This study may show an increase of sperm with abnormal sperm antibodies and an increase of y chromosome due to non-disjunction. This information may be of importance to the medical profession and to patients contemplating pregnancy. The risks are minimal.

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- 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 U.C. San Francisco Medical Center Committee on Human Research has advised Dr. Simon Henderson that the Committee must approve changes in the protocol and must be notified in the event of complications. The LLL Committee is requesting the U. C. Committee to notify LLL should either of the above events occur.

The next scheduled meeting of the Committee for review of this activity is January 17, 1980. 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.

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.

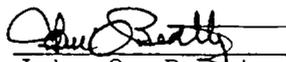


Roger E. Batzel
Director
Lawrence Livermore Laboratory

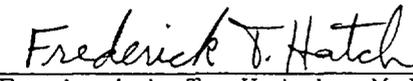


Max W. Biggs, M.D., Chairman
Director, Medical Department
Lawrence Livermore Laboratory
Licensed State of California
Employee, Practitioner

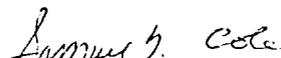
David B. Gordon, Ph.D.
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Past Member & Chairman,
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ASSURANCE OF COMPLIANCE WITH DOE
REGULATIONS ON PROTECTION OF HUMAN SUBJECTS

1. The University of California Lawrence Livermore Laboratory (LLL) will comply with the Department of Energy regulations on Protection of Human Subjects (10 CFR 745 as amended), accordingly.
2. LLL has established and will maintain an institutional review board, titled Human Subjects Committee, competent to review projects and activities that involve human subjects. The Committee shall determine for each activity as planned and conducted whether subjects will be placed at risk, and if risk is involved, whether:
 - (a) The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
 - (b) the rights and welfare of any such subjects will be adequately protected;
 - (c) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provision of the regulation;
 - (d) the conduct of the activity will be reviewed at timely intervals.
3. LLL will provide for Committee reviews to be conducted with objectivity and in a manner to insure the exercise of independent judgment of the members. Members will be excluded from review of projects or activities in which they have an active role or conflict of interest.
4. LLL will encourage continuing constructive communication between the Committee and the activity director as a means of safeguarding the rights and welfare of the subjects.
5. LLL will have available the facilities and professional attention required for subjects who may suffer physical, psychological, or other injury as a result of participation in an activity.
6. LLL acknowledges that it will bear full responsibility for the proper performance of all work and services including the use of human subjects under any grant or contract covered by this assurance, including continuing compliance with pertinent state or local laws, particularly those concerned with informed consent.

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7. LLL will maintain appropriate and informative records of the Board's review of applications and activities, of documentation that may pertain to the selection, participation, and protection of subjects and to the review of circumstances that adversely affect the rights or welfare of individual subjects.
8. LLL will at least annually reassure itself through appropriate administrative overview that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are consistent with the regulation and with the implementation of this assurance as accepted by the Department of Energy.
9. This special assurance of compliance applies specifically to the proposal, project, or activity entitled Variability in Repeated Semen Samples of the Same Individual submitted by the University of California, Lawrence Livermore Laboratory on behalf of Barton L. Gledhill on January 18, 1980 to the United States Department of Energy.



Roger E. Batzel
Director
Lawrence Livermore Laboratory