

LAWRENCE LIVERMORE LABORATORY

CERTIFICATION OF REVIEW

AND

704092

SPECIAL IMPLEMENTATION OF INSTITUTIONAL ASSURANCE

The programmatic activity titled, Sperm Protamine Evaluation in Normal and Infertile Men 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. LLL will receive only coded samples.

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 whether electrophoretic profiles of sperm protein are different in infertile men compared with those in fertile men. This may lead to practical screening techniques to determine the reproduction capacity of men and the effects of environmental pollution on this reproductivity.

REPOSITORY DOE-FORESTAL



COLLECTION MARKEY FILES

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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, 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.

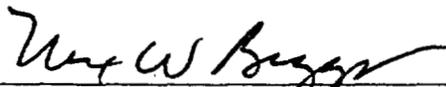
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Signature Requirements

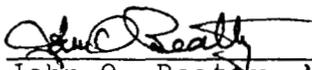
The members of the Committee are listed below. None of the signatories has a vested professional interest in this activity that conflicts with the principle of independent, objective review.

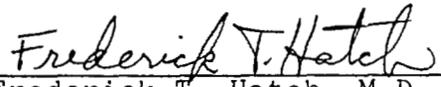
I certify that this review was carried out in accordance with the requirements of Part 745 Protection of Human Subjects of Title 10 of the Code of Federal Regulations.

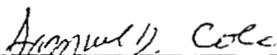

Roger E. Batzel
Director
Lawrence Livermore Laboratory

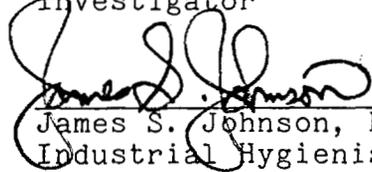

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