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Records Series Title	<u>LBL Life Sciences Division</u>
	<u>R & D Administrative Files</u>
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File Code No.	<u>13-11-26</u>
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UNIVERSITY OF CALIFORNIA, BERKELEY

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SANTA BARBARA • SANTA CRUZ

DONNER LABORATORY AND DONNER PAVILION
JAMES L. BORN, M.D., DIRECTOR

BERKELEY, CALIFORNIA 94720

August 13, 1970

INSTITUTIONAL ASSURANCE
ON RESEARCH INVOLVING
HUMAN SUBJECTS

The Donner Laboratory, Lawrence Radiation Laboratory, University of California, Berkeley will comply with the principles of the Public Health Service policy with regard to research involving human subjects which requires a review independent of the investigator or director to safeguard the rights and welfare of those subjects. It assures that it will establish and maintain advisory groups competent to review research plans involving human subjects, prior to the initiation of this research, in order to insure adequate safeguards. Group reviews and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved, (2) the appropriateness of the methods used to obtain informed consent, and (3) the risks and potential benefits of the proposed research.

The institution agrees to a continuing exchange of information and advice between the review group and the investigator or director, particularly to deal with proposed changes in research design, and with emergent problems which may alter the investigational situation with regard to the criteria cited above. The institution will assure itself that its policies and the advice of its review groups are followed. It will also provide whatever professional attention or facilities are required to safeguard the rights and welfare of human subjects involved in research. Records of group review and decision on the use of human subjects and of informed consent will be developed and kept by the institution.

Signed James L. Born, M.D.
Title Director, Donner Laboratory
Date Aug 13, 1970

Enclosures (Implementing Guidelines)

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HUMAN SUBJECTS I
HISTORICAL 1972-1975

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Statement of Principles Concerning the Treatment of Human Subjects:

The Donner Laboratory has adopted the Declaration of Helsinki as the guiding principle for review of research involving human subjects.

Description of Review Committee:

A Review Committee has existed at this laboratory for many years for the purpose of evaluating proposed studies involving the administration of radioactive isotopes to humans. This committee now broadens the scope of its duties to include all research involving humans. The composition of the Committee is given below:

Chairman: B.A. Chemistry, Bucknell University, 1954; M.D. Hahnemann Medical College, 1958; Ph.D. Biophysics, University of California, Berkeley, 1962. Member American Federation for Clinical Research, New York Academy of Sciences. Eight years experience as research investigator with principal interest in Hematology and Metabolism.

Members: 1. B.S., Chemistry, Regis College, 1954; M.S. Oceanography, University of Washington, Seattle, 1957; M.D. University of Colorado, 1964. Member American Association for Advancement of Science, Sigma Xi, New York Academy of Science. Two years experience as physicist in research on use of large computers for development of information systems in medicine and Biology; three years as industrial physician, Lawrence Radiation Laboratory, Berkeley, and research investigator with special interests in election microscopy, the use of scintillation scanners in diagnosis, therapy, and research, biological effects of radiation.

2. B.A. Chemistry and Zoology, University of California, Los Angeles, 1937; M.A. Physiology, University of California, Berkeley, 1939; Ph.D. Physiology and Biochemistry, University of California, Berkeley, 1944. Professor of Medical Physics and Physiology, U.C. Berkeley. Former Chairman Graduate Group in Biophysics and Medical Physics, U.C. Berkeley. Thirty years research experience. Has conducted research on physiology of circulation, gas exchange, decomposition sickness, lipid metabolism, radiation exposure limits, cancer biology, aging, changes in health patterns (by demographic methods). Current Research Interests: Quantitative evaluation of information relating to mammalian disease, experimental induction of cancer, factors affecting life span, impact of science on society.

3. B.S. Physics, University of Chicago, 1941; Graduate Study in Physics, University of Chicago and University of California, Berkeley. Member American Physical Society, American Association for the Advancement of Science. Deputy leader and Scientific Director, U.S. Mt. Everest Expedition. Twenty-five years research experience; principal interests: Measurement of body volume, composition and other physiologic parameters by indirect physical methods; Red blood cell metabolism, biological effects of radiation.

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4. B.A. Political Science, Ohio State University, 1936; L.L.B., University of Wisconsin School of Law, 1940; M.D., University of Wisconsin, 1948. Four years legal experience, twenty years experience as research physician and research administrator. Principal research interests: hematology, endocrinology, medical applications of radioactive isotopes, and heavy particle beams.

Description of the Initial and Continuing Review Procedures:

Timing: Investigators who propose a new project involving human subjects, or who contemplate a change in an existing study, must submit a protocol to the Committee sufficiently in advance of the starting date for Committee evaluation and decision.

Adequacy of Protection of Rights and Welfare of Subjects:

Guided by the Helsinki Declaration, the Committee will insure that the means used by the investigator to obtain informal consent are appropriate to the Balance of Benefit/Risk to the subject. It will bear in mind that certain studies entail neither risk nor benefit to normal controls, e.g., measurement of naturally occurring radioactive potassium with a whole-body counter; some have only miniscule theoretical risk (withdrawing small blood samples), while others may pose a greater hazard if proper precautions are not followed.

As a matter of laboratory policy, minors are not utilized as normal controls; their only involvement is with diagnostic and therapeutic procedures directly related to their disease. Nor are female subjects used where the procedure could have any degree of risk to pregnancy (present or future).

Methods Used for Obtaining Consent:

Free and informed consent shall be obtained from patients and research subjects, either in oral or written form, depending on the study involved. In addition, as noted above, the committee will specifically state to the investigator those circumstances requiring more than the ordinary explanation and completion of the consent form, and specify the additional measures required.

Notification of Committee Decision:

As prescribed in the Public Health Service regulations, the Committee will indicate to the investigator any modifications in the protocol required for Committee approval. It will keep in its records an indication of the reasons for required changes and the investigators compliance with same.

Continuing Review:

As an integral part of its operation, the Committee will periodically review ongoing projects for possible revisions in its requirements for involvement of human subjects. All investigators are advised of the requirement for Committee approval of modifications in their protocol.

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Facilities Available:

The Donner Laboratory has a large staff of physicians, an outpatient clinic staffed with a nurse and licensed clinical technologists, and an inpatient unit at Cowell Memorial Hospital having special facilities and trained medical personnel to deal with radiation injuries.

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