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713733

BERKELEY: DONNER LABORATORY AND DONNER PAVILION

October 15, 1974

J. L. Born  
T. F. Budinger  
J. McRae  
H. H. Stauffer

Gentlemen:

At the suggestion of Dr. Stauffer, I have secured and enclose herewith a copy of the UCSF General Assurance.

\_\_\_\_\_  
Baird Whaley

BW:b  
Enclosure

1090123

HUMAN SUBJECTS II  
UCSF 1974-1975

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UCSF  
General Assurances

F VICK  
WOOD  
126-1307

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GENERAL ASSURANCE OF COMPLIANCE WITH DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

PROTECTION OF HUMAN SUBJECTS

PART ONE

The University of California, San Francisco will comply with the policy for the protection of human subjects participating in activities supported directly or indirectly by grants or contracts from the Department of Health, Education, and Welfare. In fulfillment of its assurance:

This institution will establish and maintain a committee competent to review projects and activities that involve human subjects. The committee will be assigned responsibility to determine for each activity as planned and conducted that:

The rights and welfare of subjects are adequately protected.

The risks to subjects are outweighed by potential benefits.

The informed consent of subjects will be obtained by methods that are adequate and appropriate.

This institution will provide for committee reviews to be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from reviews of projects or activities in which they have an active role or a conflict of interest.

This institution will encourage continuing constructive communication between the committee and the project directors as a means of safeguarding the rights and welfare of subjects.

This institution will provide for the facilities and professional attention required for subjects who may suffer physical, psychological, or other injury as a result of participation in an activity.

This institution will maintain appropriate and informative records of committee reviews of applications and active projects, of documentation of informed consent, and of other documentation that may pertain to the selection, participation, and protection of subjects and to reviews of circumstances that adversely affect the rights or welfare of individual subjects.

This institution will periodically reassure itself through appropriate administrative overview that the practices and procedures designed for the protection of the rights and welfare of subjects are being effectively applied and are consistent with its assurance as accepted by the Department of Health, Education, and Welfare.

*Leslie L. Bennett*  
 \_\_\_\_\_  
 Leslie L. Bennett  
 Vice Chancellor, Academic Affairs  
 July 27, 1973

Enclosure: Implementing Guidelines, Part Two of a General Institutional

1090125

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PART TWO

IMPLEMENTING GUIDELINES

STATEMENT OF PRINCIPLES

Preamble

The Committee on Human Experimentation accepts the Declaration of Helsinki as a guiding principle. Inasmuch as that document is limited to clinical research, it is further understood that such principles will not supersede Department of Health, Education, and Welfare policy or the institutional assurances derived from it which apply to human subjects participating in activities that place their rights or welfare at risk beyond established and accepted practices.

Experimentation in Medical Research development, demonstration, or other similar activities often culminates in experimentation on human beings, for they are the very subjects of medical care. Three aspects of care characterize experimentation on human beings: (1) no permanent harm to the experimental subject should be intended or anticipated, (2) it is the irrevocable right of every individual to accept or reject participation in the experimentation without prejudice, and (3) experimental subjects and experimenters are fellow beings equal in human dignity. These facts of experimentation on human beings are second to none other. No gain in knowledge can compensate for the odium of their betrayal.

In experiments done for the well-being of the patient, ethical responsibilities rest, as in the usual pursuit of medical care, on the experimenter's professional judgment and conscience. In experiments done for the advancement of knowledge (whether on sick or healthy persons), ethical obligations ordinarily are fulfilled best when the experimenter himself participates as the first subject of the experiment.

From the legal point of view, "Fear of sanctions respecting a carefully performed experiment may be considered academic when the following circumstances prevail:

- (a) The experiment enjoys the consensus of confirmed medical opinion as to its legitimacy, and is not in violation of statute;
- (b) the subject, a competent adult person, knowingly and voluntarily consents, after full explanation;
- (c) there has been adequate preparation by animal experimentation.\*

Statement of Policy

1. This policy applies to any and all research, demonstration, and teaching activities that are not determined to be established and accepted practices that would expose an individual to the possibility of harm--physical, psychological, sociological, or other--as a consequence of his or her participation as a subject.

\*Ref: Louisell, D.W., Archives of Environmental Health, 6:98, 1965.

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3.

2. All persons who are involved in initiating, approving, or conducting a particular research project share a responsibility for the welfare of any individual who may serve as a subject in that project.
3. The nature and degree of risk or stress to the human subject must be defined as accurately as possible and the project designed to minimize the possible risks to the subject. Furthermore, the project director and his co-workers and staff must work within the limits of the statutes without consciously exposing a human subject to unreasonable risk of any kind.
4. The decision to utilize a human subject during an experiment must be based on the necessity for observing the unique reaction of the human species. The fullest practicable knowledge of the reactions of suitable animals to similar conditions is a prerequisite to making such a decision.
5. Medical supervision appropriate to the procedures in question shall be provided in selecting suitable subjects for observing them and continued during the course of the project or activity as may be necessary to protect their welfare.
6. Regardless of the nature of the project, subject participation must be voluntary and the informed consent of the individual must be obtained. The Committee on Human Experimentation will require that a copy of the proposed consent form be submitted for review and approved with the protocol. As a minimum, the consent must follow:
  - (a) A fair explanation of the procedures to be followed, including an identification of those which are experimental;
  - (b) a description of the attendant discomforts and risks;
  - (c) a description of the benefits to be expected;
  - (d) a disclosure of appropriate alternative procedures that would be advantageous for the subject;
  - (e) an offer to answer any inquiries concerning the procedures;
  - (f) an instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

In addition, the agreement, which may be signed by either the subject or his authorized representative, may not include any exculpatory language, through which the subject is made to waive, or to appear to waive, any of his or her legal rights, or to release the institution or its agents for negligence.
7. Remuneration may be offered to an individual for his participation in a study provided the Committee is satisfied that under the circumstances the remuneration is not so large as to constitute an improper inducement.
8. At any time, and for any reason, a subject may request that his participation in an experiment be terminated and his request will be honored promptly and without prejudice.

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**Committee on Human Experimentation**

The following members constitute the Committee appointed by Chancellor Francis A. Sooy to conduct reviews for experiments involving human subjects.

- Julien I.E. Hoffman, Chairman
- Thomas B. Bradley
- James R. Nielsen
- Morton Weinstein
- William B. Atchley
- William K. Ehrenfeld
- Otto Guttentag
- Albert Jonsen, S.J.
- Theodore Phillips
- Violette Sutherland
- Doris Wellenkamp

Dr. James R. Nielsen, besides his University appointment as Lecturer, conducts a private law practice in San Francisco and holds a part-time appointment at the Hastings Law School.

Dr. Albert Jonsen, formerly president of the University of San Francisco is a member of the Jesuit Order. Since 1972, he has held the title of Visiting Professor of Medical Ethics. He continues to hold the title of Associate Professor of Theology and Philosophy at the University of San Francisco.

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#### Procedure for Review of Proposals Involving Human Subjects

1. All proposals are reviewed by the appropriate administrative official to determine if human beings are involved as subjects. Action then follows to advise:
  - (a) the Principal Investigator of the need to have the protocol approved by the Committee on Human Experimentation, and
  - (b) the Committee on Human Experimentation that it should be prepared to review the protocol.
2. The Chairman or Vice Chairman of the Committee on Human Experimentation
  - (a) reviews for completeness;
  - (b) contacts Principal Investigator if necessary,
  - (c) determines if proposal may be released to supporting agency "pending" review and if so, advises the Contracts and Grants Office, and
  - (d) docket for consideration by the Committee at next weekly meeting.
3. The Committee on Human Experimentation initiates consideration as
  - (a) Committee of Whole, or
  - (b) requests assistance by referring to panel of experts.
4. The Committee acts on basis of report of panel of experts and on its own deliberations. Action may result in
  - (a) request for additional information, clarification or modification;
  - (b) denial;
  - (c) approval; or
  - (d) establishment of continuing review dates.
5. Principal Investigator and Contracts and Grants Office are advised of
  - (a) Committee action,
  - (b) date of next review for those proposals receiving approval, and
  - (c) any conditions imposed.
6. The Chancellor has the option of reviewing Committee action. He is the Appeals Officer both for Principal Investigators and for subjects either directly or through their authorized representatives. The Chancellor may override a favorable decision by the Committee; he may request reconsideration by

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the Committee of an unfavorable decision by the Committee. A final decision on appeal of an unfavorable decision will be made by the Committee as a whole. The Grants Manual asks that we specify:

"The procedures which the Committee will follow to provide advice and counsel to project and program directors with regard to the Committee actions as well as the requirements for reporting to the Committee any emergent problems or proposed procedural changes."

Item 4 of the procedure outlined above incorporates a mechanism for providing advice and counsel to the project director. The advice is forwarded in the form of

- (a) quotations from the comments of the panel of experts;
- (b) requests for additional information;
- (c) statements that the procedure will be denied unless specific changes are made or specific conditions are established. The latter may include the requirement that the consent of the subject shall be obtained in a specific manner or in specific words.

The Committee on Human Experimentation is in continuous communication with the Vice Chancellor, Academic Affairs and with the Committee on Research of the San Francisco Division of the Academic Senate. Both of these receive Minutes of the weekly meetings. The Minutes contain listings of projects under review at various stages of review, including notice of final action. When it appears from the Minutes, from discussion with the Committee or its officers, or from other indications that a change in the organization or membership of the Committee is desirable or needed in order to expedite its work, the Vice Chancellor, Academic Affairs in consultation with the Committee on Research will effect such change. Any change in the personnel of the Committee will be made by the Chancellor.

Items 5 and 6 above provide for implementation of recommendations of the Committee. Execution of approval of proposals or protocols involves administrative action by the Chancellor or his designee for that purpose, including the administrator of the Office of Contracts and Grants.

7. As a means of effecting continuing review, upon notice of the approval of the Committee on Human Experimentation, each Principal Investigator will be advised that it will be incumbent on him or her to immediately notify the Committee of any deviation from the approved protocol. At that time the Committee will review its approval to the same extent as if it were a newly received protocol. Its decision will be similarly announced. If no change is reported, each Principal Investigator will be required to reaffirm this fact at intervals of not more than one year. Protocols will also be re-reviewed on the occasion of filing supplemental applications, extensions of time (with or without additional funds), continuations or renewals. Finally, a complete review of the original approval will be conducted by the Committee at least once in every four years, if there has been no other Committee action in the interim. The Committee initiates follow up on any question or expression of concern from any source.

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8. A quorum of the Committee, regardless of its size, shall be six members of whom at least one shall be from other than the health professions. In addition, in the case of review of a protocol involving investigative new drug studies, the composition of a quorum must satisfy the requirements of the Food and Drug Administration for investigative new drug studies, namely at least two members who are licensed to administer drugs and one member who is not so licensed.
  
9. Members of the Committee on Human Experimentation may not be involved in the review or continuing review of any activity in which he or she has a professional responsibility or conflict of interest except to provide information requested by the Committee.
  
10. Promulgation of the principles and procedures, including sample consent forms, copies of the Department of Health, Education, and Welfare guidelines, the Declaration of Helsinki, the membership of the Committee on Human Experimentation, and other related documents will be accomplished by frequent communiques from the Chairman, the campus Chancellor or the University President addressed to Deans, Department Chairmen, Principal Investigators, Administrative Officers, and the campus library.