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UNIVERSITY OF CALIFORNIA AT BERKELEY

GENERAL INSTITUTIONAL ASSURANCE FOR COMPLIANCE WITH THE  
REGULATIONS AND POLICIES OF THE U. S. DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE PERTAINING TO THE PROTECTION OF HUMAN SUBJECTS

The University of California at Berkeley 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 interests.

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.

Official signing for the Institution

Signature S/Albert H. Bowker  
Albert H. Bowker

Title Chancellor

Date June 19, 1972

Enclosure: Implementing Guidelines, Part Two of a General Institutional Assurance.

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HUMAN SUBJECTS 1  
HISTORICAL 1972-1975

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**POLICY AND PROCEDURE OF THE UNIVERSITY OF CALIFORNIA,  
BERKELEY CAMPUS, GOVERNING THE PROTECTION OF HUMAN SUBJECTS**

(June 1, 1972)

**PURPOSE**

This document establishes the policies and procedures for the protection of human subjects under projects sponsored through the Berkeley Campus of the University of California. It also serves to implement the specific requirements of the U. S. Department of Health, Education and Welfare (USDHEW) as set forth in the USDHEW Grants Administration Manual, Chapter 1-40.

**APPLICABILITY**

The policies and procedures set forth herein apply to all activities, irrespective of fund source, which involve human subjects for which the Berkeley campus is responsible.

**BACKGROUND**

The National Advisory Health Council, after a study of the issues pertaining to clinical research and investigation involving human beings, recommended to the Surgeon General of the Public Health Service (PHS) in December 1965 that PHS adopt a policy statement pertaining to the protection of human subjects under PHS supported projects.

The present DHEW policy, published in April 1971 as Chapter 1-40 to the DHEW Grants Administration Manual, is an outgrowth of the basic principles and premises of prior U. S. Public Health Service policies issued in 1966 and 1969.

On June 25, 1970, the Office of the University President extended the USPHS policies to all activities of the University involving human subjects regardless of the funding source supporting such activities.

On March 29, 1972, the 1971 DHEW regulations were also made applicable to all University sponsored activities.

**DEFINITIONS**

1. **Subject:** This term describes any individual who may be at risk as a consequence of participation as a subject in research, development, demonstration, or other activities. This may include patients; outpatients; donors of organs, tissues, and services; informants; and normal volunteers, including students who are placed at risk during training in medical, psychological, sociological, educational, and other types of activities.

Of particular concern are those subjects in groups with limited civil freedom. These include prisoners, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline.

The unborn and the dead should be considered subjects to the extent that

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DEFINITIONS (CONT'D.)

Subject (Cont'd.) they have rights which can be exercised by their next of kin or legally authorized representatives.

2. At risk: An individual is considered to be "at risk" if he may be exposed to the possibility of any harm--physical, psychological, sociological, or other--as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs.

...Physical risks - Unusual physical activity required of a subject, or the imposition of strong aversive stimulation, or engaging him in a social situation that could involve violence, might endanger his physical well-being. It is important that an investigator foresee possibilities of physical danger and bring them to the attention of the Committee.

...Psychological risks are far more pervasive among behavioral science researchers. The right to privacy is considered relatively inalienable, and hence invasion of a subject's privacy is, ipso facto, held to be a "risk". Carelessness about the maintenance of confidentiality of protocols could increase the risk. Any procedure that may conceivably produce humiliation, embarrassment, loss of self-esteem, feelings of failure or frustration, feelings of anger toward the experimenter or others, or even acute boredom can be considered undesirable outcomes of the research experience; hence, such procedures must be considered as placing the subject at risk. Any personality change, or change in the subject's feelings or motivation that extend beyond a debriefing period, must also be considered undesirable; possibility of their occurrence constitutes risk. A subject's personal stimulus value to his fellows, such as would be represented by the term "his reputation", is something of value to him, and the possibility of its being damaged constitutes a risk also.

...Social risks are related in the main to procedures that may place the reputation or status of a social group or an institution in jeopardy. Procedures designed to measure the characteristics of easily defined sub-groups of a culture may entail risk if the qualities measured are ones which have positive or negative value in the eyes of the group. Even when research does not impinge directly on it, a group may be derogated or its reputation injured. Likewise, an institution, such as a church, a university, or a prison, must be guarded against derogation, for many people may be affiliated with, or employed by, the institution, and pejorative information about it would injure their reputations and self-esteem. In evaluating social risk, an investigator should ask himself how the findings will appear to persons belonging to any identifiable group -- or affiliated with an institution -- studied and reported upon. These cautions are as equally warranted in the case of anthropological field research in distant cultures as in studies performed in domestic settings.

3. Informed consent: This is an appropriate agreement obtained from a

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**DEFINITIONS (CONT'D)**

Informed consent (Cont'd.) subject, or from his authorized representative, to the subject's participation in a project or activity. The basic elements of informed consent are:

- (1) a fair explanation of the procedures to be followed, including an identification of those which are experimental;
- (2) a description of the attendant discomforts and risks;
- (3) a description of the benefits to be expected;
- (4) a disclosure of appropriate alternative procedures that would be advantageous for the subject;
- (5) an offer to answer any inquiries concerning the procedure; and
- (6) 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, written or oral, entered into by the subject, may not include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights or to release the institution or its agents from liability for negligence.

**STATEMENT OF ETHICAL PRINCIPLES**

1. The University of California at Berkeley, accepts as basic principles that:
  - (a) no human being is to be exposed to unreasonable risk to health or well being,
  - (b) the rights and welfare of all subjects involved in research, training, demonstration, development and other activities who are subject to risk shall be adequately protected,
  - (c) that the risks to an individual must be outweighed by the potential benefit to him or by the importance of the knowledge to be gained, and
  - (d) that adequate and appropriate informed consent is to be obtained without duress or deception in those cases where human beings will be or are likely to be "at risk".
2. All persons involved in initiating, approving, conducting, or supervising activities involving human subjects must be aware of their joint responsibility for the welfare of the individuals who serve as subjects.
3. It shall be the responsibility of the individual investigator to decide when he does not have adequate knowledge of the possible consequences of his research or of research done under his direction. When he is in doubt, he must obtain the advice of others who do have the requisite or relevant knowledge.
4. Any possible hazard to health resulting from procedures utilizing human subjects must be first investigated through animal research, whenever such be possible and relevant.
5. Whenever medications, operative procedures, or exposures to hazardous

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STATEMENT OF ETHICAL PRINCIPLES (CONT'D.)

environmental conditions are used (or occur), the activity must be performed under medical protection and supervision.

6. The nature of the activity, the procedures to be followed, and the possible risks involved must be carefully and fully explained to the subject, parent, or guardian, as appropriate. The explanation must have been fully understood and informed consent obtained as appropriate.
7. The subject's personal privacy and the confidentiality of information received from him must be protected.
8. Any subject may request termination of his participation in an experiment at any time, and this request will be honored promptly and without prejudice.
9. Remuneration may be offered to a subject as recompense for his time provided that such remuneration is not so large as to constitute an improper inducement.
10. If participation as a subject is part of the academic work of a student, it must not be a coercive requirement and, as appropriate, informed consent must be obtained.
11. The University will provide, at no cost to the subject, adequate medical treatment for hospitalization as required during or as a direct result of an experiment. Such individual care shall be provided without the necessity for establishing legal liability on the part of the University. The subject's right to compensation for damages must, however, be established on the basis of legal liability, e.g., negligence or wrongdoing, on the part of the University.

COMMITTEE FOR PROTECTION OF HUMAN SUBJECTS (a Subcommittee of the Graduate Council)

Background: In 1966, an advisory committee was appointed by the Dean of the Graduate Division, to review research proposals contemplating use of human subjects, as required by USPHS regulations then in effect and as later revised in 1969. With the extension of the USPHS requirements to all University activities, as required by the 1970 and 1972 University directives, the status of the advisory committee was reconstituted as an administrative subcommittee of the Graduate Council.

Organization of the Committee: The Committee, in its present form, must consist of at least five members, one of whom is to be the Director of the Student Health Service. Other members must possess varying qualifications, backgrounds, and experience which will assure complete and adequate review of projects and activities commonly administered or sponsored by the campus. No less than two members of the Committee shall be licensed to practice the healing arts, and at least one member shall not be so licensed but shall be competent in other relevant areas.

Appointment of the chairman and members of the Committee shall be made by the Graduate Council and the term of service shall be at the pleasure of the Graduate

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COMMITTEE FOR PROTECTION OF HUMAN SUBJECTS (CONT'D.)

Organization of the Committee (Cont'd.) Council. Committee membership as of June 1, 1972, is set forth in Appendix A.

The Committee may establish subcommittees as deemed necessary by workload or other considerations. Such subcommittees, constituted within teaching or research units, are normally chaired by a member of the Committee. The functioning of such departmental subcommittees is informal and their main role is to provide a focus of expertise within a specific unit for the rendering of advice and assistance and preliminary review of the adequacy of protocols. In accordance with DHEW requirements, only the Committee or a quorum thereof may finally review a project involving human subjects and issue a certification that the requirements of the institutional assurance and USDHEW policy have been satisfied.

Functions of the Committee: The Committee has two responsible functions which must be given equal priority: (1) to determine and certify that all campus sponsored activities utilizing human subjects conform to the regulations and policies of the USDHEW and University concerning the safety, welfare, health, rights and privileges of human subjects; and (2) to facilitate, within the limits of applicable regulations, policies and procedures, accomplishment of project or program objectives by those whose work involves the use of human subjects.

The policies and procedures set forth herein concern mostly the first function. The second function, though of equal importance, is not easily set forth in formal statements. However, the Committee and the campus administration recognize the importance of the second function and desire, at all times, to be of service to members of the campus community and consultation with the Committee, or individual committee members in project planning is strongly encouraged. The Committee is not an authoritarian 'watchdog', but rather serves to benefit the University, the scientific community, and the public, through the facilitation of activities which will extend the boundaries of human knowledge to the ultimate good of all mankind.

PROCEDURES FOR OBTAINING COMMITTEE REVIEW

Initial Review: The following procedures are prescribed for the initial review of proposals and activities to insure compliance with University and USDHEW requirements for the protection of human subjects:

1.0 Projects Supported from Solicited Extramural Funds:

- 1.1 The Approval Form for Extramural Support Proposal, accompanying all applications for funding submitted to the Campus Research Office for institutional endorsement, shall contain an appropriate entry or entries on the prospective use of human subjects.
- 1.2 If human subjects are to be used, the following procedures must be followed:

A protocol, in sufficient detail, must be submitted to the Campus Research Office with the proposal. As a minimum, the protocol

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**PROCEDURES FOR OBTAINING COMMITTEE REVIEW (CONT'D.)**

Initial Review (Cont'd.) should contain the following information:

- 1.2.1 A statement of the significance and benefits of the proposed project or activity,
- 1.2.2 A statement whether the project involves:
  - 1.2.2a Research on the nature and effects of marijuana and hallucinatory drugs. 1/
  - 1.2.2b Drug abuse. 2/
  - 1.2.2c Investigation of new drugs. 3/
- 1.2.3 An evaluation of the need or desirability for the utilization of subjects.
- 1.2.4 A statement as to whether any subjects will be minors (under age 18 per California law) or University of California students.
- 1.2.5 The precise way in which subjects will be utilized,
- 1.2.6 An analysis of the possible physical, psychological, emotional, and socially deleterious effects upon the subjects.
- 1.2.7 A description of the means to be taken to minimize each such deleterious effect including the means by which the subject's personal privacy is to be protected and confidentiality of information received maintained.
- 1.2.8 A statement concerning the method to be employed in documenting informed consent:
  - 1.2.8a Written consent agreement (regular form) in format of Appendix B (include completed copy), or
  - 1.2.8b Written consent agreement (short form) with written script of oral presentation to be made to the subjects (Appendix C).

- 
- 1/ Must be reviewed by the State Research Advisory Panel before such projects may be legally conducted.
  - 2/ Must be reported to the UCSF Dept. of Pharmacology.
  - 3/ Regulations of Food and Drug Administration (21 CFR 130) governing consent must be adhered to.

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PROCEDURES FOR OBTAINING COMMITTEE REVIEW (CONT'D.)

Initial Review (Cont'd.)

1.2.8c Modification of either of the two primary procedures.

If a modified procedure is proposed, the protocol must include a detailed explanation of the deviation and the reasons and justification for the proposed deviation.

Substantive changes in wording in either of the regular or short form may require approval of University Counsel.

1.2.8d Waiver of prior written informed consent must be approved by the Committee. The Committee must have full justification to establish that the risk to the subject is minimum and that use of either written consent procedure would invalidate objectives of considerable immediate importance, and that any reasonable alternative means for attaining these objectives would be less advantageous to the subject.

Some situations where a waiver of prior written informed consent might be granted include anthropological field studies of illiterate culture, or studies involving deception.

Deception creates a particularly difficult problem in behavioral science research. Some experiments cannot be done if the subject is fully informed of, and the reasons for, the procedures. In most instances deception does lead to risks. Deception like the invasion of privacy is to be considered ipso facto a producer of "risk". Every effort should be made to avoid the use of deception in the research design.

When deception must be used, special emphasis should be laid on clarifying for the subject what consequences he may expect. Whether or not there are discomforting outcomes, as in the arousal of annoyance, for example, and a full explanation of the procedure which was followed is to be given the subject in a debriefing session following the experiment.

1.3 The nature of the use of human subjects and therefore the risks to the subjects may not be definable at the time the protocol is submitted to the Committee. For example, with a proposal for a training grant, the nature of the research to be undertaken by the participating students may not be known until after the student trainees are selected and they have had an opportunity to define their individual projects. In such a case it is sufficient if the training grant director submits a protocol to the Committee stating why it is not possible to satisfy the specific requirements at the time the proposal is submitted to the sponsoring agency, but agreeing to take the responsibility for seeing that each individual recipient of the funds

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### PROCEDURES FOR OBTAINING COMMITTEE REVIEW (CONT'D.)

Initial Review (Cont'd.) submits to the Committee an Individual protocol, when the individual's project has been defined insofar as use of human subjects are concerned and before such use is undertaken.

- 1.4 The protocol must be signed by the principal investigator or project/program director and responsible administrator (e.g., head of unit exercising immediate jurisdiction over the activity).
- 1.5 The Campus Research Office is responsible for referring protocols for Committee action.
- 1.6 The Committee may approve the project without condition if it is satisfied that the risks are justified and that all reasonable means will be used to reduce such risks and that the legal and ethical requirements of informed consent have been met. If the Committee is not so satisfied, it may: (a) approve the project with conditions imposed which, when satisfied, will cause the project to meet minimum ethical and legal standards and hence be approved, or (b) disapprove the project without prejudice for resubmission. The reasons for disapproval shall be recorded in the Committee minutes and shall be conveyed to the originator.
- 1.7 All decisions of the Committee shall be conveyed to the originator of the protocol by the Campus Research Office.

### 2.0 Projects Supported by Unsolicited Extramural Funds (Private Gifts and Grants):

If human subjects are to be used, the procedures outlined under paragraph 1 infra shall be followed. The award shall not be accepted by the Campus Research Office until the Committee has approved the use of human subjects.

### 3.0 Projects Supported by Extramural Funds or Intramural Funds

Awarded by the Institution (Committee on Research Grants, General Research Support Grant (School of Public Health), Biomedical Sciences Support Grant, University Patent Fund Grants, Special Intramural Funding, Cancer Research awards, etc.)

- 3.1 Those campus officials responsible for approval of allocations, shall require as part of the application process a statement from the requestor as to whether or not the use of human subjects is contemplated.
- 3.2 If the use of human subjects is contemplated, a protocol shall be obtained and said protocol with project description shall be forwarded to the Campus Research Office for referral to the Committee.
- 3.3 An award may not be made until receipt of notification from the Campus Research Office that Committee approval has been granted.

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PROCEDURES FOR OBTAINING COMMITTEE REVIEW (CONT'D.)

Initial Review (Cont'd.)

- 4.0 Projects, Programs or Activities Supported from Budgeted University Funds Including Endowment Income (Research Programs of an Organized Research Unit Supported from 1990 Funds, Classes Wherein Students Conduct Experimentation on Each Other, etc.):

It shall be the responsibility of the Department Chairman, responsible unit Director, and Instructor-In-Charge to see that a description of the program and protocol is furnished the Committee and that Committee approval is obtained prior to the use of human subjects.

5.0 Clinical Activities

(School of Optometry Eye Clinic, Cowell Hospital Clinics, Clinical Psychology Clinic, and other activities wherein services may be provided by student "trainees" under supervision):

A program description and protocol shall be submitted for Committee approval by the unit head at the beginning of each academic year.

- 6.0 Student Projects and Activities Supported Through Traineeships, Fellowships, Special Grants or Institutional Student Aid or Unsupported

Whenever human subjects are used by graduate or undergraduate students as part of their academic work the policies and procedures governing the protection of human subjects apply in all particulars. This is required regardless of whether the student is receiving research fellowship, or other funds. It is the responsibility of supervising faculty members, as well as department chairmen, to ensure that students who utilize human subjects be informed of, and comply with, these requirements.

In the instance of undergraduate students who, as part of their class work, use human subjects for research, experimentation, testing, observation, interviews or other purposes, adherence to these policies and procedures is also required. However, it may be more practical in connection with undergraduate academic activities for the instructor, rather than the individual student, to assume responsibility for such use of human subjects. Each instructor who requires or permits his students to use human subjects in connection with academic work should prepare a protocol, whenever feasible, for the combined activity of all of his students. In such a protocol, the instructor may describe in general terms the activities of his students which use human subjects and the means by which he ensures compliance with the DHEW and UCB requirements. Particular attention should be paid to the activities of students who are engaged in field studies.

It is expected that graduate students who use human subjects in connection with their dissertations or other academic work will ordinarily prepare their own, individual protocols, requesting approval by the

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#### PROCEDURES FOR OBTAINING COMMITTEE REVIEW (CONT'D.)

Initial Review (Cont'd.) Committee for Protection of Human Subjects. However, in certain graduate courses where use of human subjects is regularly a part of the academic work, and the use of the subjects and the risks attending such use are similar for each student in the class, it may be useful for the instructor to prepare a general protocol to cover the activities of all of the students in that class, as suggested above for undergraduate courses.

#### Continuing Review

All projects involving human subjects and approved by the Committee shall be reviewed annually by the Committee. Such review, as a minimum, will require the originator of the protocol to certify that the actual use of human subjects has been or is being conducted in accordance with the approved protocol and conditions (if any) imposed by the Committee.

Projects involving high risk may be subjected to more frequent review and/or special reviews including the review of progress reports and briefing by the project director before the Committee. The Committee may at its discretion designate an ad hoc committee to conduct project site visits.

#### RESPONSIBILITIES OF THE CAMPUS RESEARCH OFFICE

The Campus Research Office shall serve as the secretariat and Administrative Office of the Committee and for the implementation of this policy. As such, the following range of responsibilities are assigned:

1. reviews of all extramural support proposals for possible use of human subjects and requests protocols if not furnished,
2. reviews protocols for procedural compliance,
3. renders advice and assistance to campus community on human subject policy and implementing procedures,
4. develops appropriate educational campaigns concerning human subject policy, utilizing available house organs and media; arranges workshops to discuss human subject policies,
5. serves as coordinative interface between DHEW, the Committee, General Counsel, Office of the Chancellor, and Principal Investigators,
6. conducts a continuing review of active projects and programs to ascertain: (a) the currency of approved protocols, (b) compliance with protocols containing conditions, and (c) whether human subjects are in fact being used on projects for which no protocol is on file; advises Committee of results of these reviews,
7. provides logistic support for Committee meetings, including scheduling, notification of members, agenda and minutes.
8. maintains necessary records and files.

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Campus Policy

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