# UCSB OFFICE OF RESEARCH POLICY

**Research Circular No. D.2**
Revised February 1997
Distribution:
Deans, Directors, Department Heads, Principal Investigators, Administrative Personnel
Policy on the Use of Human Subjects

## 1. References

**A.** The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (GPO 887-809)

**B.** Title 45, Code of Federal Regulations, Part 46.

**C.** Federal Policy for the Protection of Human Subjects; Federal Register, Vol.56 No. 117.

**D.** University of California Policy on Protection of Human Subjects (Office of the President, September 2, 1981).

**E.** UCSB Policy on the Use of Human Subjects, Research Circular No. D.2 (Revised February 1984; *RC No 22-72 is superseded by this document).

## 2. Background

**A.** Since 1966 the United States Department of Health, Education, And Welfare (now Department of Health and Human Services, referred to herein as DHHS) has required peer group review and approval of activates involving human subjects which are supported by Department-funds and certification that such review and approval has been accomplished.

**B.** Department of Health and Human Services regulations for the protection of human subjects of research and for the protection of special populations of human subjects, as currently set forth or as subsequently modified in Title 45 Code of Federal Regulations Part 46, and University of California Policy on Protection of Human Subjects shall apply to all UCSB research except that when a research activity is not funded by DHHS and either UCSB Policies and Procedures or the policies and regulations of the funding agency conflict with 45 CFR 46 or any portion thereof, the more restrictive requirements shall prevail.

### 3. Definitions of Terms Used in this Document

**A.** Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or(2) identifiable private information.

1. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes.

2. Interaction includes communication or interpersonal contact between investigator and subject.

3. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or can readily be ascertained by the investigator or associated with the information to constitute research involving human subjects.

**B.** Information Sheets are the means by which UCSB researchers and departmental administrators are informed of policies and procedures regarding the protection of human subjects. They are published in the Office of Research and distributed to all UCSB faculty members and to the staff administrators of all academic departments and organized research units. They are also available on the Office of Research web site.

**C.** Research means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of this policy, whether or not they are considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

**D.** IRB means institutional review board. The UCSB Human Subjects Committee is an IRB.

**E.** CFR means the Code of Federal Regulations. 45 CFR 46 refers to Part 46 of Title 45 of the Code of Federal Regulations.

**F.** ORU means organized research unit.

## 4. Ethical Principles

Researchers conducting research involving the use of human subjects conducted at or sponsored by the University of California, Santa Barbara shall be guided by the Basic Ethical Principles developed for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and published in the Belmont Report which are summarized in Information Sheet #7.

## 5. Applicability

**A.** This policy applies to all research involving human subjects conducted at UCSB or by the UCSB faculty, students, or staff, whether funded or unfunded, and if funded regardless of source of funding. Except that the only parts of this policy which apply to activities defined in information Sheet #3a (Exempt research), are Sections IV.B and VI.B.(9).

**B.** Exemptions:

1. Information Sheet #3a defines those research activities which may be exempt from review by the HSC. Additional research activities may be exempt from review by the HSC when such activities have been approved for exemption by the Secretary of HHS and by the HSC and when such additional exempt activities have been disseminated through campuswide publication or notice.

2. Investigators who believe their projects should be exempt under guidelines found in Information Sheet #3a should secure confirmation of exemption, in accordance with procedures published in Information Sheet 3.

**C.** Compliance with this policy will in no way:

1. Limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state or local law.

2. Render inapplicable pertinent federal, state or local laws.

## 6. Responsibilities

**A.** The UCSB Human Subjects Committee

1. The UCSB Human Subjects Committee has been established and shall be composed in accordance with 45 CFR 46.107 and other applicable Federal regulations.

2. The responsibility for establishing and administering a policy on the protection of human subjects has been delegated by the Chancellor to the

Human Subjects Committee. The chain of authority and organizational structure of this Committee is available from the Office of Research.

3. No research involving the use of human subjects is to be undertaken unless it has been reviewed and approved by the HSC in a convened meeting except as provided in IV.C and VII.B.

4. Before approving research covered by this policy, the HSC shall determine that all of the requirements set forth in 45 CFR 46.111 are satisfied.

5. The HSC shall review and have authority to approve, require modifications in (to secure approval) or disapprove all research activities covered by this policy.

6. The HSC shall apply the expedited review policy (Information sheet 4a) when the policy is applicable to all procedures included in a protocol.

7. The HSC shall require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116. The HSC may require that information in addition to that specifically mentioned in 45 CFR 46.116 be given to the subject when in the judgment of the Committee the information would meaningfully add to the protection of the rights and welfare of subjects.

8. The HSC shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117.

9. The HSC shall notify investigators of its decision to approve or disapprove the proposed research activity, or to require modifications before approving the activity. And also provide such information to the appropriate representative of The Chancellor.

10. If the HSC disapproves a research activity, it shall include in its written notification to the investigator a statement of the reasons for its decision, and the investigator shall have an opportunity to respond in accordance with procedures delineated in Information Sheet #5.

11. The HSC shall review all ongoing research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. When review intervals of less than one year are required, the HSC's notification of approval to the investigator shall specify the review interval.

12. The HSC shall have the authority to observe or have a third party observe the consent process and the research. Procedures shall be established by which such authority may be exercised on a case by case basis.

13. The HSC shall report immediately to the Vice Chancellor for Research any serious and unanticipated problems involving risks to subjects or others which have been reported to the HSC by investigators or others. If such unanticipated problems occur in a research activity funded by HHS, the Vice Chancellor for Research shall be responsible for reporting them to the Secretary, DHHS.

14. The HSC shall be responsible for reporting to the Vice Chancellor for Research any serious or continuing noncompliance by investigators with the requirements and determinations of the HSC when such incidents become known to the HSC. If such noncompliance involves an investigator whose research is funded by HHS, the Vice Chancellor for Research shall be responsible for reporting it to the Secretary, DHHS.

15. The HSC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the HSC's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall a statement of the reasons for the HSC's action and shall be reported promptly to the investigator and to the Vice Chancellor for Research. If the project for which approval is suspended or terminated is funded by DHHS, the Vice Chancellor for Research shall be responsible for reporting the suspension or termination to the Secretary, DHHS.

**B.** Investigators

1. The ultimate responsibility for assuring human subject protection rests with the investigator.

2. Prior to an involvement of human subjects in research which is not included in Information Sheet #3a, the investigator must submit to the HSC, in accordance with published procedures, an application for review and approval of the use of human subjects in the research. If the research will be supported by extramural funds, such application should be submitted prior to or simultaneously with the funding proposal according to the policy of the Office of Research Awarded funds will not be released until the use of human subjects is approved by the HSC.

3. The investigator is responsible for obtaining HSC approval when it is proposed to use human subjects in a research activity for which there were previously no plans or only indefinite plans for the involvement of human subjects. If such activity is extramurally funded, involvement of human subjects may not be initiated until certification of HSC approval (where required) has been submitted to the funding agency--,. If the activity is funded by DHHS and had been undertaken without the intention of involving human

subjects, final approval must be given to the proposed change by DHHS before human subjects are involved.

4. The investigator is responsible for reporting to the HSC proposed changes in a research activity, and for ensuring that changes in approved research, during the -period for which HSC approval has already been given, will not be initiated without HSC review and approval except where necessary to eliminate apparent immediate hazards to the subject.

5. The investigator shall report immediately to HSC any unanticipated problems involving risks to subjects or others.

6. The investigator is responsible for submitting to the HSC application for renewal of approval of ongoing research at a time early enough so that the HSC may have adequate opportunity to review the application before the expiration date of the approval.

7. The investigator is responsible for securing informed consent of subjects using procedures approved by HSC in accordance with 45 CFR 46.116 (Information Sheets #2 and #2a) except when the requirement to obtain consent is waived by the HSC in accordance with 45 CFR 46.116(c) or 45 CFR 46.116(d)

8. The investigator is responsible for documenting consent using procedures approved by HSC in accordance with 45 CFR 46.117 (Information Sheets #2b and #2c) except when the requirement for documentation is waived by the HSC in accordance with 45 CFR 46.117(c).

9. The investigator is responsible for obtaining confirmation of a claim of exemption from the requirements of this policy.

10. The investigator is responsible for complying with HSC decisions, conditions and requirements

**C.** The Departments

1. Department heads and research investigators within each department shall be responsible for ensuring that all research to which this policy is applicable is submitted to the HSC.

2. Each academic department and organized research unit in which there are investigators who use human subjects in research shall be responsible for maintaining files of originally signed consent forms.

3. Each academic department and organized research unit shall be responsible for protecting signed consent forms from unauthorized access to the extent possible under applicable law.

4. Signed consent forms shall be retained for a minimum of five years after completion of the research project; where minors are involved, the forms shall be retained for five years after the subject has reached the age of majority (18).

**D.** Office of Research

1. The Office of Research provides support staff to assist the HSC in complying with applicable laws, regulations, and policies.

2. The support staff shall serve as liaison between the HSC and investigators.

3. The support staff shall be responsible for complying with administrative and clerical procedures required by 45 CFR 46 and by other relevant policy or regulations.

4. The support staff shall provide orientation to new HSC members.

5. The support staff shall furnish available informational materials to HSC members to assist them in maintaining an up to date knowledge of matters pertaining to the protection of human subjects.

6. Support staff shall prepare for each HSC meeting an agenda which shall include a list of all projects approved by expedited review since the previous agenda was prepared.

7. For all research involving human subjects that requires certification, the support staff shall file DHHS form 596 with the agency or institution requiring certification. Form 596 shall serve as certification of the Human Subjects Committee's approval of the use of human subjects and any new drugs or devices involved in the research with the human subjects as required by 45 CFR 46.121.

8. Support staff shall prepare minutes of HSC meetings and distribute them to HSC members and to the appropriate representative of the Chancellor.

9. Requests for information or assistance on matters pertaining to the use of human subjects may be directed to the support staff of the HSC or to the Chairperson of the Committee or to any Committee member.

10. The Office Of Research shall be responsible for obtaining suitable space for HSC meetings.

11. The office of Research shall maintain adequate documentation of HSC activities as required by 45 CFR 46.115. The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the DHHS at reasonable times and in a reasonable manner.

**7. Review Process**

**A.** The HSC shall review research to which this policy applies in accordance with 45 CFR 46 and, when appropriate, with other applicable policy and regulations.

**B.** The HSC chairperson, or a member of the HSC who has served for at least 6 months on the Committee and who has been designated by the chairperson, may approve some projects through expedited review procedures.

1. The projects which may be approved through expedited review Procedures are:

   - Research appearing on the list in Information Sheet #4a if the research involves no more than minimal risk;

   - Minor changes in previously approved research during the period for which approval is authorized.

2. In reviewing the research, the expediting reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure.

**C.** When a member has a conflicting interest in a project undergoing initial or continuing review by HSC, that member shall report the conflicting interest to the HSC, and shall not participate in the initial or continuing review of such project, except to provide information requested by HSC.

**D.** The HSC, at its discretion, may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the HSC. These individuals will not vote with the HSC.

**E.** The HSC or an investigator may request legal opinion from the office of the General Counsel if there is any reason to believe an activity may violate any law or may otherwise contain some significant legal issue.

**F.** The HSC shall determine which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

## 8. Committee Meetings

**A.** The frequency of Committee meetings shall be determined by the HSC, taking into account all salient factors, including but not limited to:

1. The necessity to ensure that research will not be unduly delayed;

2. The availability of HSC members, especially during summer months;

3. The number of applications received.

**B.** The quorum required to consider approval of research involving the use of human subjects shall be determined by the HSC but shall be no less than a majority of the members of the HSC and shall include one member whose primary concerns are in non-scientific areas.

**C.** The quorum required to conduct other business shall be determined by the HSC.

**D.** The HSC shall determine the number of favorable votes required for its decisions, but for approval of a research activity, the number shall be no less than a majority of the members present at a meeting.

## 9. Cooperative Research

**A.** When a research project in which human subjects will be used involves institutions in addition to UCSB, but UCSB is primarily responsible for the research (for example, because it is the grantee or prime contractor for extramurally funded research), then the research must be approved by the HSC or by expedited review or by confirmation of exemption as set forth in this policy.

**B.** When a research project in which human subjects will be used involves institutions in addition to UCSB, UCSB is not primarily responsible for the research and the research has been reviewed by a qualified IRB of the other institution(s), then the HSC Chairperson will determine whether HSC review and approval will also be required, taking into consideration such factors as:

1. Whether the subjects will include UCSB students, staff, or faculty;

2. Whether portions of the research involving subjects will be conducted at UCSB;

3. Whether the other institutions are located in California and subject to the same or similar state and local regulations as UCSB.

**10. Revision of Policy**

**A.** This policy shall be subjected to continued revision by the HSC in its aim to develop a greater recognition of the legal and moral obligations incurred by those who study humankind or as required by federal legislation.

**B.** If the HSC is asked to approve a research project which it believes should be approved but which cannot be approved under this policy, it will assist the investigator in an attempt to obtain an exception to policy from the appropriate officials.