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PROTECTION OF HUMAN SUBJECTS: POLICIES

This policy was approved by the Academic Senate on March 24, 1994
and approved by the President on June 8, 1994.

I. PREAMBLE

California State University, Long Beach accepts an ethical responsibility for safeguarding the rights and welfare of human subjects involved in research.

The University's Institutional Review Board for the Protection of Human Subjects (IRB) believes in the value of research involving human subjects and strives to ensure the greatest opportunity for all investigators to engage in this activity. The IRB further believes that one vital safeguard of the privilege is the institutional review of all research projects to minimize the possibility of unacceptable levels of risk to the rights, welfare and dignity of human subjects.

Although federal requirements mandate the IRB review of projects seeking or receiving federal funds, we believe that review is equally appropriate and necessary for unfunded research since the extent to which a project entails risk for human subjects is a function of the actual research procedures to be employed, not whether federal funding is involved.

Whereas direct involvement in a project might shield a researcher from noticing undesirable risks to human subjects, having others from a variety of disciplines examine the proposal and procedures serves as an appropriate safeguard. To assist the individual researcher in protecting the rights of human subjects and minimize the potential legal liability of the investigator should a human being be placed at risk, the IRB acts in the spirit of an advisor and consultant, rather than as an adversary, with the researcher. Thus, if an ethical problem exists, the IRB seeks to work with the researcher and will request that the researcher revise the protocol. In this light the IRB seeks not to judge the merit or social sensitivity of the research but only the risks and benefits of the research in relationship to the protection of human subjects.

II. BACKGROUND

A. History

In 1965, the National Advisory Health Council sent the Surgeon General of the United States Public Health Service the following resolution:
"Be it resolved that the National Advisory Health Council believes that Public Health Service support of clinical research and investigation involving human beings should be provided only if the judgment of the investigator is subject to prior review by his institutional associates to assure an independent determination of the protection of the rights and welfare of the individual or individuals involved, to the appropriateness of the methods used to secure informed consent, and of the risks and potential medical benefits of the investigation."

In response, the Surgeon General in 1966 and again in 1969 established policies and procedures governing the use of human subjects for all recipients of contracts and grants from the U.S. Public Health Service.

In 1974, the National Research Act, Public Law 93-348, was signed into law and established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. This was followed by the federal requirement for the formation of Protection of Human Subjects Institutional Review Boards to insure that a code of federal regulations relating to the protection of all human subjects be followed (Code of Federal Regulations, Title 45, Part 46, Department of Health and Human Services, Protection of Human Subjects, Revised January 26, 1981).

B. California State University, Long Beach Institutional Review Board for the Protection of Human Subjects

On July 12, 1983, California State University, Long Beach (CSULB) President Stephen Horn established the CSULB Institutional Review Board for the Protection of Human Subjects (hereafter referred to as IRB). The charge to the Board is:
"(1)To act in conformity with 45 CFR 46 in the review of all grant and contract proposals prior to and as a part of institutional endorsement and acceptance by the CSULB Foundation; and

(2) To serve as the review board for all academic programs, demonstrations, and research which include the participation of individuals who may be placed 'at risk' because of their participation as human subjects or as investigators or staff to investigators when such activities and research arise from the conduct of the academic program directly, using the principles of 45 CFR 46 as the basis for such reviews. The review board shall have authority to approve, require modifications in (to secure approval), or disapprove all activities covered by these regulations. If the review board disapproves an activity, reasons for disapproval must be sent to the Vice President for Academic Affairs, and the investigator must be given an opportunity to respond."

With this as its charge, the IRB developed the following policies and procedures to be followed by all members of the academic community whenever human beings are used in any research activity which exposes them to circumstances not typically encountered in the standard and accepted instructional setting.

III. INTRODUCTION

A. Summary Statement
While the IRB values and encourages research, it also realizes the necessity to protect the welfare and rights of research participants. The ethical principles used by the IRB when reviewing proposals will be guided by the ethical principles as set forth in 45 CFR 46, and The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education and Welfare, April 18, 1979. The Belmont Report recognizes the absence in our culture of any precise decision procedure for resolving all ethical disputes. It does, however, indicate certain ideals and certain general ethical principles which may conflict with research proposals involving human subjects, and it also notes possible ways in which researchers may unknowingly place undue risk on human subjects or a class of human subjects. This document provides the basis for looking upon an independent review as a worthwhile step in designing research involving human subjects. When a conflict of basic ethical principles can occur, an articulation of competing values is called for, and having an independent review panel such as the IRB provides an appropriate forum for this important deliberation.

IV. POLICY

A. Definitions
"Research" is defined in the new federal rules (Title 45, code of Federal Regulations, Part 46) as "a systematic investigation, including research development, testing and evaluation, 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 conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

"Human subject" is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the person, or (2) identifiable private information."

B. Application of Policy*
This policy applies to all faculty, all staff, all administrators, and all students whenever they are supervising or conducting any research activity involving human subjects, regardless of whether the participants are members of the University community. Non-University personnel also come under the purview of this policy when their research or related activities utilize members of this University community. Both funded and non-funded research activities are included in this policy.

The University does not bear responsibility for research conducted by the above groups of investigators while they are functioning in another capacity, e.g., while functioning as an entrepreneur or as employee of a firm.

Research activities which involve investigators from other institutions are to be managed in the following manner:
1. If the subjects, in whole or part, are to be drawn from the University, the CSULB investigator is responsible for submitting the proposal to the IRB for review and approval.

2. If the subjects are not drawn from the University, then:
a. The principal investigator submits the proposal to the appropriate reviewing agency; except that;
b. If there is no identified principal investigator, or if the principal investigator's institution does not have an IRB approval by the U.S. Department of Health and Human Services, the CSULB investigator is responsible for submitting the proposal to the IRB for review and approval.

*Note: Also see Section VI for policy concerning instructional demonstrations and activities for which no research product is intended.

C. Responsibilities
Final responsibility for the protection of human subjects and adherence to ethical standards rests with the University; however, the primary responsibilities for the protection of human subjects and adherence to ethical standards remain with all persons (faculty, students and staff) involved in these activities.

Consequently, it is required that all persons at CSULB involved in activities involving human subjects be familiar and comply with the provisions of this document.

It is the responsibility of heads of units (Department Chairpersons, Directors and Deans) to bring to the attention of their faculty, staff and students the existence of this policy. It is the responsibility of the principal investigator to submit in a timely manner a protocol and consent form for review to the IRB.

V. UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

A. Institutional Review Board Membership
The IRB shall have members with varying backgrounds to promote complete and adequate review of research activities. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB may not consist entirely of men or entirely of women, or primarily of members of one discipline.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall, therefore, include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

The membership of the CSULB Institutional Review Board for the Protection of Human Subjects shall be:
At least one non-University representative conversant with general principles of research involving human subject participation, selected by the President;

One tenured member of the University faculty at the rank of full or associate professor conversant with ethics and ethical systems, selected by the Academic Senate;

Two tenured members of the University faculty with significant experience in research, selected by the Academic Senate;

Four tenured members of the University faculty with significant expertise in human subjects research, at least one with expertise in such medically relevant issues as physically invasive

procedures, physical therapy and pharmacology, and at least one with expertise in survey research and assessment, selected by the Academic Senate; The Chair of the Scholarly and Creative Activity committee; The Director of University Research; and, The Vice President for Academic Affairs (or designee).

The period of service for the non-University representative and for members appointed by the Academic Senate shall be for single, staggered two-year terms. A member will be eligible for reappointment after one year of absence.

The Director of University Research shall maintain the roster of membership, insuring that the Vice President for Academic Affairs is made aware of resignations or other reasons for nonparticipation.

B. Institutional Review Board Responsibilities

1. The IRB shall consider only the risks and benefits of the research in relationship to possible harm of the human subjects involved. Research merit, and social sensitivity, or other socio- political considerations shall not enter into judgments concerning a protocol. Issues and concerns about research which arise in the IRB but which go beyond or are unrelated to protection of human subjects are to be referred to the Scholarly and Creative Activity Committee for its consideration, if appropriate, or for forwarding via the Academic Senate Executive Committee to the appropriate body.

2. The responsibility and authority for promulgating, implementing and administering a policy that will protect the dignity, rights and welfare of human subjects shall be delegated to the IRB.

3. The IRB will evaluate all research activities involving human subjects. The IRB will evaluate the protocol and informed consent form for the purpose of establishing compliance with the provisions of this document. In this light, the IRB shall evaluate a protocol to determine whether:

a. The protocol is complete;

b. The documentation of the potential risks to the dignity, rights and welfare of the subjects is adequate;

c. The proposed safeguards against the risks are adequate;

d. The objectives could be achieved with less potential risk;

e. The procedures to obtain informed consent are appropriate and the forms used are complete, clear and non-coercive;

f. For research which involves more than minimal risks, the benefits to the subjects shall outweigh those risks.

4. On the basis of its review, the IRB has the authority to require modifications of a protocol and the project itself and to give ultimate approval or denial to the project. When the IRB approves or disapproves a protocol, it will furnish a written statement to the investigator. The decision to approve a protocol requires a majority of the quorum at the time of the vote.

5. The IRB shall meet at least once a month throughout the academic year. Meeting times and dates shall be established and published for the year at the beginning of each academic year.

6. The IRB shall monitor and conduct reviews (if needed) of approved research activities involving human subjects in order to assure compliance with these regulations.

7. The IRB shall report to the Vice President for Academic Affairs annually as required by the enacting Executive Order of July 12, 1983.

8. The Director of University Research shall:

a. Maintain a complete and accurate record of the proceedings of all meetings of the IRB and shall annually report these activities to the Vice President for Academic Affairs.

b. Insure that the IRB is provided full and accurate information on the regulations governing protection of human subjects; that at least one copy of the complete regulations be available at all meetings of the Board; and that the assurances required by regulation or, in cases of internal activities, the assurances directly paralleling those which would have been required by regulation, are properly prepared, signed, and delivered to the responsible authority; and,

c. Call meetings of the Board as required in the normal conduct of business or at the request of the Vice President for Academic Affairs or the Associate Vice President for Academic Affairs--Instructional Programs.

C. Institutional Review Board Action

The IRB when reviewing a protocol will take one of the following actions:

1. Approve the protocol as exempt;
2. Approve the protocol as submitted;
3. Approve the protocol as contingent on minor revisions;
4. Request outside review of the protocol and then reconsider;
5. Require significant modification of the protocol before approval;
6. Request the investigator to discuss problems with the IRB;
7. Reject the protocol.

VI. INSTRUCTIONAL DEMONSTRATIONS AND ACTIVITIES

A. Often a faculty member will wish to give an instructional demonstration or activity within or outside the classroom which involves the use of human subjects, typically including for example, the students in the class. All courses other than independent study or independent research or thesis research that involve human subjects are intended to be included in this section.

B. The responsibilities for proper conduct of these instructional demonstrations or activities are to be borne by the individual faculty member and are not subject to review by the IRB. The instructor shall be aware of the potential risks to the dignity, rights or welfare of subjects, make them known to the potential subjects, and, if more than minimal risk is involved, inform the subjects of their rights as embodied in this document. (See CSULB Faculty Handbook, Appendix C, Documents on Professional Standards and Ethics and Related Documents.)

C. The responsibility for informing students of the potential risks in such non-standard instructional activities lies with the instructor. Students shall be informed in writing during the first week of class of the potential risks involved in such activities and should be encouraged to pursue possible alternatives with the instructor if the risks appear excessive.

D. The responsibility for providing properly maintained and supervised equipment rests with the department or service offering the courses. This responsibility includes availability of personnel properly trained to operate such equipment as well as any emergency equipment necessary in the case of an accident. It is expected that all departments will have emergency procedures established at all times. (Also see University Administrative Policies and Procedures Handbook, Section 8. Safety).

VII. REGULATIONS

The University adopts the specific procedural regulations of the United States Department of Health and Human Services where applicable. In the case of conflict between DHHS and some other set of relevant regulations, the more restrictive of those applicable shall be employed.

VIII. APPEAL OF IRB DECISIONS

If a protocol is disapproved by the IRB, the reason(s) for disapproval shall be provided in writing to the investigator. The investigator may appeal the decision on procedural matters only to the Vice President for Academic Affairs. The investigator has twenty (20) instructional days following written notification by the IRB to appeal in writing to the Vice President for Academic Affairs. Upon receipt of the written appeal, the Vice President for Academic Affairs has twenty (20) instructional days to review the appeal and confer with the IRB. However, the ultimate decision for approval of a protocol rests with the IRB.

IX. LEGAL ASSURANCES

A. Legal Liability of the University for Acts of Committee Members
Duly appointed committee members who, while acting in the course and scope of their committee assignments, carry out their obligations in good faith and exercise good judgment, are to be provided defense by the University in the event of legal action, and coverage under the State of California liability policy in the event of an adverse decision.

B. Legal Liability of the University for Acts of Principal Investigators
Employees or former employees may request the University to defend them against any claim or action against them for injury due to negligence within the scope of their employment. Employees,

who, while acting in the course and scope of their employment, carry out their obligations in good faith and exercise good judgment, will be provided defense by the University in the event of legal action, and coverage under the state of California liability policies in the event of an adverse decision. However, the University will not defend an employee if it is determined that the action or omission involved was not within the employee's scope of employment, that it was based upon actual fraud, corruption or actual malice, or that the providing of such defense would involve a conflict of interest. Therefore, in order to minimize the risk of incurring unnecessary liability, all employees are expected to adhere to all University policies and procedures. Failure to do so may result in the State of California electing not to defend or indemnify.

Specifically, faculty members may find that the University is more clearly committed to their defense in connection with research that has been approved by the IRB than for that which has not. This principle applies to research in any of the three categories. Standard, Expedited, or Exempt. Therefore, researchers who judge their research to be "exempt" would nonetheless be well advised to obtain IRB approval of that judgment, as required by this document. Doing so assures researchers that they are in full compliance, as well as protect their human subjects.

C. Submission to General Counsel
If any reviewing body believes that the proposed activity violates any law, may possibly violate any law, or may otherwise contain some significant legal issue, the protocol shall be submitted to the Vice President for Academic Affairs for forwarding to the Office of General counsel for evaluation. Other criteria for judging the need to submit a protocol to General Counsel may include:
1. The involvement of minors.
2. The involvement of adults whose competence to give consent may be subject to question.
3. The necessity for the investigator to perform acts requiring license under provisions of the law.

X. ENFORCEMENT

The Vice President for Academic Affairs shall be responsible for the enforcement of decisions of the IRB.

XI. REFERENCES

For guidance, concerned parties should consult:

A. "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education and Welfare, April 18, 1979;

B. The American Psychological Association, Ethical Principles in the Conduct of Research with Human Participants, 1982, and;

C. Code of Federal Regulations, Title 45, Part 46, Department of Health and Human Services, Protection of Human Subjects, Revised June 18, 1991.

Copies of these references are on file in the Office of University Research.

PROTECTION OF HUMAN SUBJECTS:

PROCEDURES

GENERAL INFORMATION

Research involving human subjects may not begin until approval is obtained from the CSULB Institutional Review Board for the Protection of Human Subjects (IRB).

APPLICATION FOR IRB APPROVAL OF RESEARCH PROTOCOL

An Application with the required number of copies must be submitted to the IRB through the Office of University Research. This Application is to include the information described below. All materials must be typed. Incomplete Applications will not be evaluated.

Get actual form from Office of Research Foundation Building, Ste. 310 (985 5314)

I. THE APPLICATION

A. The basis for review and approval of research involving human subjects will be an Application submitted by the researcher to the IRB.

B. The following numbers of copies of the Application must be submitted: Twelve (12) copies for research in the "Standard Review" category; six (6) copies for research in the "Expedited Review" category, or; one (1) copy for research in the "Exempt Review" category. Applications and all copies are submitted to the IRB through the Office of University Research [Foundation Building, (310) 985-5314]. Communication with potential human subjects may not begin until approval of the Application has been obtained through the Office of University Research. Therefore, researchers would be well advised to wait for IRB approval before purchasing/duplicating the final sets of materials needed in conducting the study.

C. Changes or supplemental information added to the Application which are initiated by the researcher after the Application is in review may necessitate withdrawal of the original Application and submission of a new one.

D. The Application is to include the following information and documentation:

1. Principal Researcher (Name):

   Position (professor, M.A. thesis student, etc.):

   Department:

   Address :

   Daytime Telephone Number:

2. (If student,) Thesis Advisor/ Faculty Supervisor (name):

   Faculty University Telephone Number:

3. Title of proposed research study:

4. Describe the purpose(s) of the study (including research hypotheses, if applicable).

5. Describe the characteristics of the sample of human subjects:

   a. Approximate number of each sex;

b. State age(s): Will any children be involved? If not, state "No Minor Subjects." If yes, what is the legal parent/ guardianship status?

c. Developmental disabilities? mental illness? adults having legal guardians?

d. Other subject characteristics relevant to the study.

6. How will subjects be selected? From what source(s), such as hospital, institution, school, class, shopping mall, etc.? Attach letters of approval from all participating organizations on their official letterhead.

7. When and where will the activities involving human subjects take place? Be specific, give exact locations.

Note: The beginning date must be after approval by the IRB. (Allow a minimum of 3 instructional days for Exempt Review; 7 instructional days for Expedited Review, and refer to the schedule of monthly IRB meeting dates for Standard Review.) IRB approval normally covers a twelve-month period, even if the anticipated time-span of participation by human subjects is less than twelve months. If the anticipated participation will take more than twelve months, please so state, and approval will be granted for that longer span.

8. What will you do with the human subjects? Describe the details of research methods and procedures that involve the subjects.

9. Identify and attach any copyrighted tests, questionnaires, or other materials to be used. If security or copyright prohibits attaching, explain. If none, state "No copyrighted materials."

10. Identify and attach any specially designed tests, questionnaires, or other materials to be used. If none, state "No special tests or questionnaires designed especially for this research."

11. What risks, if any, does this research present to the dignity, rights, health, welfare, or well-being of the subjects? Describe the safeguards for protection against or minimization of risks:

12. Describe any benefits to the subjects which may reasonably be expected from the research, including summary of research findings where appropriate (as for professionals, students in the discipline, and participating organizations). Describe benefits, if any, to others.

13. Describe the procedures you will use to obtain Informed Consent. Attach your proposed consent form(s). Include the text of oral explanations, if applicable, and any additional Informed Consent forms required by the participating organizations. Instruct potential subjects to both print and sign their names.

14. If applicable, describe the nature of any debriefing of subjects:. If not, state "No debriefing."

15. Briefly describe the training and experience that qualifies you to carry out the proposed research.

16. Student thesis research, independent study, or independent research require completion of the Faculty Supervisor Form.

II. INFORMED CONSENT

A. Definition.

1. Three major ethical concerns underlie the requirements for Informed Consent. All three must be dealt with in the documentation and process of obtaining Informed Consent from individuals or their legally authorized representatives. Informed Consent is necessary whether the research is designed primarily for the direct benefit of research participants or for the advancement of knowledge.

a. One concern is to respect the ability and desire of individuals to decide whether they want to participate in research. Adequate information about the research must be provided. Individuals who are to be subjects of research or experimentation must understand as completely as possible what will be done to or asked of them.

b. A second concern requires that individuals or their representatives understand the nature and extent of potential benefits and risks to themselves.

c. The third concern is that Informed Consent must be given freely, without pressure or inappropriate inducement. In other words, possible participants must be able to exercise free power of choice without unethical inducements or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

B. Consent Form.

1. The informed consent of subjects is ordinarily to be documented by a signed consent form. See Special Circumstances, below, for exceptions.

2. The consent form must be written so that it is comprehensible to the subjects in their preferred language. The exact wording should be appropriate to the particular research situation as well as to the level of understanding of the subjects. Their age, maturity, status, and condition must be taken into account.

3. The information in the consent form must be consistent with the corresponding items in the Application.

4. The consent form should contain all of the following information. If it does not, the IRB is to be provided with an explanation as to why specific parts are missing:

a. A statement that the study involves research, and an explanation of the purpose of the research;

b. A description of the procedures to be followed; a description of the expected duration of the subject's participation; and identification of any procedures which are experimental;

c. A description of any reasonably foreseeable risks or discomforts to the subjects;

d. A description of any benefits to the subject or to others which may reasonably be expected from the research;

e. A statement describing the extent to which anonymity (subject identity not known) and/or confidentiality (subject identity known only to researcher) of participation and records will be maintained;

f. A statement to the effect that participation is voluntary, and that the individuals should not feel pressured in any way to participate by the researcher or anyone else. Furthermore, if they agree to participate, subjects are completely free to discontinue participation at any time. Indicate that agreeing or refusing to participate will have no effect on their usual position, status, or role in the setting from which they were recruited. If appropriate, indicate that there will be no gain or loss of benefits to which they would otherwise be entitled in that setting.

g. A statement of whom to contact for answers to pertinent questions about the research and about the rights of participants in research. That is: researcher and faculty member for questions regarding the study; CSULB Office of University Research for questions regarding the rights of research participants.
Where applicable, the consent form should also include:

h. An explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of , or where further information may be obtained.

i. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

C. Special Circumstances.

1. Types of special circumstances

a. Oral presentation with short written version. In some circumstances, the elements of

Informed Consent have to be presented orally (as in cases of illiteracy or visual impairment). A short version of the consent document should be substituted for the usual version, indicating that all of the elements of informed consent have been presented orally to subjects or their legally authorized representatives. The short version is to be signed by the subject or representative and by a witness to the oral presentation. (The proposed short version and the written verbatim script of the oral presentation must be part of the Application in order to receive IRB approval.)

b. No Prior Consent. Circumstances occasionally arise (especially in observational studies in the social sciences) in which obtaining prior written consent would defeat the purpose of the research, or in which participants would have no reasonable expectation of privacy.

c. Consent-Related Risk. In some cases in which the regular written Informed Consent form is used, signing the form would put the subject at risk (for reasons not directly related to the research).

d. Purpose not Revealed. In some special circumstances, revealing the purposes of the research can render it useless. For such research, indicate on the consent form that there is information about the research which the subjects will receive at its completion. It should be particularly noted that this refers to the informed consent requirements concerning explanation of the purpose of the research (item 4.a., above). It is not an exception to the rule that all subjects must be informed about the research procedures that involve them directly. For example, the researcher studying people's behavior when they are startled must inform the subjects that they will be startled and by what means, but that (if it is the case) the startling events will occur at unexpected times.

2. Modified Procedures. In any of the above special circumstances, modified procedures may be proposed in the Application, if and only if all four of the following conditions exist. (A complete explanation must be included in the Application.)

a. The research involves no more than minimal risk to the subjects; and

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

c. The research could not practicably be carried out without the waiver or alteration; and

d. Whenever appropriate, subjects will be provided with additional pertinent information (debriefing) after participation.

D. Additional protections for all children, and for adults who are under legal guardianship or otherwise require special concern (for example, for those who are developmentally disabled, or mentally ill.)

1. Children (and adults described above) may not participate without prior informed consent of parent/guardian. However, parental consent while necessary is not sufficient. All children, and such adults, must themselves be given the opportunity freely to assent or to decline to participate in the research. Mere failure to object should not be construed as assent. Researchers are cautioned to be sensitive to the possible implied pressure of parental consent and/or the subject's relationship and rapport with the researcher.

2. In accordance with federal regulations (45 CFR 46, Subpart D- Additional Protection for Children Involved as Subjects in Research) the IRB may determine that the research is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, (for example, neglected or abused children). In such cases the IRB may choose to waive the consent requirements. However, an appropriate mechanism for protecting the subjects must be used and the researcher must document to the IRB that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the research, the risk and anticipated benefit to the research subjects, and their age, maturity, status and condition.

E. Retention of Records. Researchers must keep the signed Informed Consent forms for all subjects for three years to protect themselves in the event that future problems may arise with any research participants.

III. PERMISSION OF PARTICIPATING AGENCIES

Prior to submitting your IRB application, you must obtain written permission from any agency, school, clinic, or other organizational entity whose cooperation is required in obtaining access to subjects and conducting the study. Such permission must be presented on printed agency letterhead and must be signed by an agency official. The letter of permission must indicate that the official approves of agency involvement as described in the IRB application. Include this letter of permission with your IRB application materials.

PROTOCOL CATEGORIES

There are three categories for review by the IRB under which researchers must choose to submit their application. These categories relate to the expediency of the review process and the nature and the level of potential risk to the subject. Any protocol deemed inappropriate for a given category will be transferred by the Director of University Research to the appropriate category.

I. "STANDARD REVIEW" CATEGORY

A. Research is required to be submitted under the Standard Review category if one (or more) of the following conditions is involved:

1. More than minimal legal, physical, or psychological risk, or

2. Children under the age of 18, and adults who are under legal guardianship or otherwise require special concern (for example, developmentally disabled, mentally ill), or

3. The identity of subjects can be linked to information provided by them, by others, or by way of the research procedures.

B. Research under Standard Review will be reviewed by the IRB at its regularly scheduled monthly meeting. Twelve copies of an Application under Standard Review must be submitted to the Office of University Research two weeks prior to the meeting.

C. The IRB may request the researcher to discuss problems at a meeting; request an outside review of the application; and/or require significant modifications before approval is given.

II. "EXPEDITED REVIEW" CATEGORY

A. Research which does not require a Standard Review, but which may involve minimal risk, should be submitted under the Expedited Review category. Examples of activities appropriate for Expedited Review are the following:
1. Surveys, interviews, and questionnaires in which the participant's identity and responses are confidential.
2. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. The use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amount of energy into the subject or an invasion of the subject's privacy.
3. Weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. Not including exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves);
4. Voice recordings made to study speech/language disorders;
5. Moderate exercise by healthy volunteers;
6. The study of existing data, documents, records, pathological specimens, or diagnostic specimens, in which the identities of subjects are kept confidential, but in which subjects are not anonymous.
7. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

B. Research under Expedited Review will be reviewed by a subcommittee of the IRB within seven instructional days after receipt of six copies of a complete Application in the Office of University Research.

III. "EXEMPT REVIEW" CATEGORY

A. Research which does not require either a Standard Review or an Expedited Review is reviewed by the IRB under the Exempt Review category. All research involving survey or interview is exempt without exception when the respondents are elected or appointed public officials or candidates for public office. In compliance with 45 CFR 46, Protection of Human Subjects, January 26, 1981 (revised, 46.101 [1] - [5]), Exempt Review is appropriate for research activities in which the only involvement of human subjects will be in any of the following:

1. Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is made available to the researchers in such a manner that human subjects cannot be identified, directly or through identifiers linked to them.

2. Established or commonly accepted educational settings, involving normal pedagogical practices, such as:

a. Regular and special education instructional strategies,

b. Comparisons among instructional techniques, curricula, or classroom management methods.

3. The use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, unless the research entails any one of the following:

a. Information is made available to the researchers in such a manner that human subjects can be identified directly or through identifiers linked to them. If confidentiality cannot be assured, submit for Standard Review; if confidentiality is assured, submit for Expedited Review; or

b. Any disclosures of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing or employability (Standard Review required); or

c. Sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol (Standard or Expedited Review required, depending on the degree of risk); or

d. The human subjects are children, or developmentally disabled or mentally ill adults who have legal guardians (Standard Review required);

4. Observation, including participant observation of adults, of public behavior in settings where the subjects have no reasonable expectation of privacy, unless the subjects are children, or adults who must be given Standard Review. Even for adult subjects, however, observational research must be reviewed under Standard or Expedited Review (depending on the degree of risk) if all the following exist:

a. Observations are recorded in such a manner that the subjects can be identified, directly or through identifiers linked to them; and

b. Observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and

c. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

B. Research under Exempt Review will be reviewed by the Director of Research on behalf of the IRB, and will be approved or referred to a more appropriate category, normally within three instructional days after receipt of one copy of a complete Application in the Office of University Research.

APPLICATION
FOR IRB APPROVAL OF RESEARCH PROTOCOL

Type information on this form. Or, if you prefer, follow the format using a computer text editor.
Do not underline answers, but differentiate them from the questions.
Form available on diskette (bring formatted diskette to Office of Research

Circle one: **Standard Review (12 copies)** **Expedited Review (6 copies)** **Exempt Review (1 copy)**

(see Protocol Categories on pp. 15-17.)

1. Principal Researcher (Name):

   Position (professor, M.A. thesis student, etc.):

   Department:

   Address :

   Daytime Telephone Number:

2. (If student,) Thesis Advisor / Faculty Supervisor(name):

   Faculty University Telephone Number:

3. Title of proposed research study:

4. Describe the purpose(s) of the study (including research hypotheses, if applicable):

5. Describe the characteristics of the sample of human subjects:

   a. Approximate number of each sex:

   b. Age(s):

Will any children be involved? If not, state "No Minor Subjects." If yes, what is the legal parent/ guardianship status?

c. Developmental disabilities? mental illness? adults having legal guardians?

State "None" or explain:

d. Other subject characteristics relevant to the study.

6. How will subjects be selected? From what source(s), such as hospital, institution, school, class, shopping mall, etc.? Attach letters of approval from all participating organizations on their official letterhead.

7. When and where will the activities involving human subjects take place?

Note: The beginning date must be after approval by the IRB. (Allow a minimum of 3 instructional days for Exempt Review; 7 instructional days for Expedited Review, and refer to the schedule of monthly IRB meeting dates for Standard Review.) IRB approval normally covers a twelve-month period, even if the anticipated time-span of participation by human subjects is less than twelve months. If the anticipated participation will take more than twelve months, please so state, and approval will be granted for that longer span.

Begins on: Ends on:

Location(s):

8. What will you do with the human subjects? Describe the details of research methods and procedures that involve the subjects.

9. Identify and attach any copyrighted tests, questionnaires, or other materials to be used. If security or copyright prohibits attaching, explain. If none, state "No copyrighted tests or questionnaires."

10. Identify and attach any specially designed tests, questionnaires, or other materials to be used. If none, state "No tests or questionnaires designed specially for this research."

11. (a) What risks, if any, does this research present to the dignity, rights, health, welfare, or well-being of the subjects?

(b) Describe the safeguards to protect against or to minimize risks:

12. Describe any benefits to the subject(s) which may reasonably be expected from the research, including summary of research findings where appropriate (as for professionals and participating organizations.) Describe benefits, if any, to others.

13. Describe the procedures you will use to obtain Informed Consent. Attach your proposed consent form(s) and include the text of oral explanations, if applicable, and any additional Informed Consent forms required by the participating organizations.

14. If applicable, describe the nature of any debriefing of subjects:. If not, state "No debriefing."

15. Briefly describe the training and experience that qualifies you to carry out the proposed research .

16. Student thesis research, independent/directed study, or independent/directed research require completion of the Faculty Supervisor Form.

Submit Application packet to the Office of University Research, University Foundation Building, Suite 310. Telephone (310) 985- 5314; FAX (310) 985-8665.

FACULTY SUPERVISOR FORM
California State University, Long Beach

TO: Institutional Review Board for the Protection of Human Subjects

FROM: Faculty Supervisor: _____

Department of: _____

Telephone Extension: _____

NAME OF STUDENT: _____

TITLE OF THESIS OR PROJECT: _____

IF MASTERS THESIS: _____

My signature below certifies that the Thesis Committee has formally approved the Thesis Proposal, and that the Application to the IRB has also been approved.

_____

Thesis Chair Signature Date

IF DIRECTED RESEARCH/INDEPENDENT STUDY:

My signature below certifies that I, as Faculty Supervisor, have approved the proposed research and the Application for Protocol.

_____

Faculty Supervisor Signature Date

(1/24/94)

RENEWAL APPLICATION FOR CHANGE OF RESEARCH DATES
California State University, Long Beach

TO: Institutional Review Board for the Protection of Human Subjects

FROM: (name)_____

(department) _____

(telephone) _____

TITLE OF RESEARCH: _____

_____

PREVIOUSLY ASSIGNED PROTOCOL NUMBER: _____

REVIEW TYPE: (Circle one) Standard Expedited Exempt

PREVIOUS DURATION (DATES) OF ACTIVITY: Begin_____ End _____

PROPOSED DURATION (DATES) OF ACTIVITY: Begin_____ End_____

BRIEF EXPLANATION OF REQUEST: _____

_____

_____ _____
signature of researcher date

IRB USE:

Approval Granted for the Period:_____ New Protocol Number: _____

Approval Denied for the Reason:_____

_____

_____ _____
Director, Office of University Research date

(1/24/94)