94-00
May 16, 1994

PROTECTION OF HUMAN SUBJECTS: POLICIES

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.

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 protecti6(ri)(t)4(3 year.)-4( )]TJ0 Tc 0 conas4(m)3(a)4(t)My0.0036 Tc 90.0018 Tw 0 -1.26.5 0.[(deni) th rem

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

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 researche

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,

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

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.

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

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:

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

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:

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)