00-03
January 28, 2000

Protection of Human Subjects

(This policy supercedes Policy Statement 94-00 and the executive order issued by President Stephen Horn on July 12, 1983.)

This policy was recommended by the Academic Senate on December 2, 1999 and approved by the President on December 15, 1999.

1000 Introduction.

1100 California State University, Long Beach has a moral and legal responsibility to safeguard the rights, welfare, and dignity of human subjects involved in research. The University is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). The basic ethical principles outlined in the Belmont Report are respect for persons, beneficence, and justice.

1110 Respect for persons dictates that researchers must obtain informed consent from all human subjects invited to participate in research. In order to respect subject autonomy, the consent process includes giving subjects full and comprehensible information about the research and providing a clear assurance of the subjects' voluntary participation.

1120 Beneficence is the essence of concern for the well-being of subjects, and requires that the risk of harm to subjects is the least possible, and that the sum of benefits to the subject and the importance of the knowledge to be gained so outweigh any remaining harm as to justify a decision to allow this risk.

1130 Justice requires that the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition as children, prisoners, patients, or impoverished persons places them in a vulnerable or dependent position. [Language on principles adopted directly from UCLA policy]

1200 The University affirms its commitment to the importance of research involving human subjects and strives to ensure the widest opportunity for its faculty and students to engage in this essential activity. A vital safeguard of the privilege of conducting such research, however, is the institutional review of all research projects to minimize the possibility of unacceptable or unnecessary levels of risk to the rights, welfare, and dignity of human subjects. Careful review of this type also enhances the likelihood that any given research project will yield results that are accepted as valid by the scholarly community.

1300 Toward this end, and to comply with the requirements of federal law, the University has created an Institutional Review Board for the Protection of Human Subjects (IRB). To assist the individual researcher in protecting the rights of human subjects and to minimize the potential legal liability of the investigator and the University should a human being be placed at risk, the IRB is instructed to review all research projects involving human subjects where there may be an element of risk but to do so in the spirit of an advisor and consultant, rather than as an adversary of the researcher. Thus, if an ethical problem exists, the IRB will make every

reasonable effort to work with the researcher in revising the protocol. In this light the IRB will seek to judge not 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.

2000 Background

2100 The Public Health Service has had a rule since 1966 that "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."

2200 Congress provided a statutory basis for this rule in Title II of the National Research Act of 1974 (Public Law 93-348), which also established a National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, charged with the responsibility of identifying "the basic ethical principles which should underlie the conduct" of such research and developing guidelines that researchers must follow. Today the Office for Protection from Research Risks, an agency of the U.S. Department of Health and Human Services, is charged with the enforcement of these principles. The regulations issued by the Department of Health and Human Services are codified in the Code of Federal Regulations at Title 45, Part 46 (commonly cited as 45 CFR 46).

2300 Researchers working with human subjects at CSULB are not eligible to apply for support from any federal agency unless the University provides a written assurance that must include, among other things, "a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation," and the designation of an IRB "established in accordance with the requirements of this policy," that is, 45 CFR 46.103. This policy statement constitutes the required statement of principles.

3000 Institutional Review Board for the Protection of Human Subjects

The University shall have an Institutional Review Board for the Protection of Human Subjects (IRB) which shall have the responsibility of administering this policy to protect the dignity, rights, and welfare of human subjects involved in research.

3100 Definitions

3110 Research means 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. [45 CFR 46.102 (d)]

3120 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 person, or (2) identifiable private information. [45 CFR 46.102 (f)]

3130 Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102 (i)]

3200 Application of Policy

3210 This policy applies to all faculty, staff, and students whenever they are supervising or conducting research activity involving human subjects, regardless of whether the subjects are members of the University community. Non-University personnel may also come under the purview of this policy when their research or related activities utilize members of the University community. Both funded and non-funded research activities are covered by this policy. [45 CFR 46.103 (b)(1)]

3220 No research involving human subjects may be conducted by University faculty, staff, or students, or by non-University personnel in instances where members of the University community are serving as the subjects, prior to approval being granted under the appropriate provisions of this policy. This restriction applies equally to all three categories of review: standard, expedited, and exempt. No contact of any kind may be made for purposes of research with actual or prospective subjects until after the appropriate informed-consent form has been reviewed and approved or a waiver of informed consent has been granted. [45 CFR 46.116]

3230 Cooperative research: research activities may involve investigators from other institutions. If the subjects, in whole or in part, are drawn from the University, the CSULB investigator is responsible for submitting the proposal to the University's IRB for review and approval. If the subjects are not drawn from the University, then the principal investigator shall submit the proposal to the principal investigator's IRB, except that if there is no identified principal investigator, or if the principal investigator's institution does not have an IRB approved by the U.S. Department of Health and Human Services, then the CSULB investigator shall be responsible for submitting the proposal to the University's IRB for review and approval. In the case of cooperative research by CSULB faculty and/or students with researchers at other institutions, a process of joint review, reliance upon another qualified IRB, or a similar arrangement that meets the spirit of this policy, complies with federal regulations, and is approved by the Provost and Senior Vice President for Academic Affairs or designee may also be used. [45 CFR 46.114]

3240 Final responsibility for the protection of human subjects and adherence to ethical standards rests with the University in the case of all research projects conducted under University aspices; however, the faculty, staff, and students conducting such research share the primary responsibility for assuring that their research is properly conducted. Consequently, the University requires that all persons at CSULB involved in activities involving human subjects be familiar with, and at all times comply with, the provisions of this document. Deans, department chairs, and program directors are required to bring the provisions of this policy to the attention of their faculty, staff, and students. Principal investigators are required to submit in a timely manner a protocol and informed-consent form for review by the IRB.

3300 Responsibilities of the IRB

3310 The IRB shall evaluate all research activities involving human subjects. The IRB shall evaluate both the written protocol and the informed-consent form to determine that they are in compliance with the provisions of this policy. Toward this end, the IRB shall evaluate each protocol to determine whether:

a. The protocol is complete;

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

c. The proposed safeguards against the risk are adequate;

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

e. The selection of subjects is equitable, taking into account the purposes of the research and the setting in which the research will be conducted;

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

g. For research which involves more than minimal risks, the benefits to the subjects outweighs those risks. [45 CFR 46.111]

3320 The IRB shall have the authority to require modifications of a research protocol and of the project itself and to give ultimate approval or denial to the project. When the IRB approves or disapproves a protocol, it shall 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 (see Section III.E on Membership). The IRB may take any of the following actions:

a. Classify the protocol as exempt;

b. Approve the protocol as submitted;

c. Approve the protocol contingent upon the incorporation by the research of specified minor revisions;

d. Request outside review of the protocol prior to reconsideration;

e. Require significant modification of the protocol prior to resubmission;

f. Request the investigator to discuss identified problems with the IRB;

g. Reject the protocol. [45 CFR 46.109]

3330 The IRB shall consider only the risks and benefits of the research being reviewed relative to the 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 during the IRB's deliberations, but which go beyond or are unrelated to the protection of human subjects, may be referred to the Scholarly and Creative Activity Committee for its consideration, or to the Provost and Senior Vice President for Academic Affairs and Executive Committee of the Academic Senate.

3340 The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. It shall have the authority to observe, or have a third party observe, both the consent process and the research itself. [45 CFR 46.103 (b) (4) (ii)]

3350 The IRB shall develop a set of written procedures which it will follow:

a. For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator;

b. For determining which projects, if any, require review more often than annually and/or verification from sources other that the investigator that no material changes have occurred since the previous review;

c. For ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and

d. For ensuring prompt reporting to the IRB, the Provost and Senior Vice President for Academic Affairs, and the head of any external funding agency of any unanticipated problems involving risks to subjects or others or any suspension or termination of IRB approval. [45 CFR 46.103 (b) (4) and (5)]

3360 The IRB shall develop and keep current a manual on the protection of human subjects, copies of which shall be made available to all members of the IRB and to all faculty and staff engaged in research involving human subjects. Copies of this manual and all supporting documents shall be made available on appropriate University Web sites. Additional copies may be made available for purchase by students through the 49er Shops, Inc. The manual shall include, at a minimum, the following materials: (a) the Code of Federal Regulations, Title 45, Department of Health and Human Services, Part 46, Protection of Human Subjects; (b) National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (1979); (c) American Psychological Association, "Ethical Principles in the Conduct of Research with Human Participants (1982); (d) this policy statement; (e) the written procedures developed by the IRB; (f) copies of all forms developed by the IRB; and (g) guidelines on how to fill in each of these forms correctly and completely.

3370 The IRB shall meet at least once a month throughout the academic year. Meeting times and dates shall be established and published for the entire academic year at the beginning of each fall semester.

3400 Criteria for Approval of Research

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

3410 Risks to subjects are minimized, either by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, or by using procedures which are already being performed on the subjects for diagnostic or treatment purposes.

3420 Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and in relation to the importance of the knowledge that may reasonably be expected to result.

3430 The selection of subjects is equitable. The IRB must be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

3440 Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be appropriately documented.

3450 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

3460 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

3470 When some or all of the subjects are likely to be vulnerable to coercion or other undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. [45 CFR 46.111]

3500 Membership of the IRB

3510 Federal regulations require that the members of the IRB collectively have sufficiently varying backgrounds to assure that they can promote the complete and adequate review of those types of research activities commonly conducted by the University. The membership of the IRB must be highly qualified by experience and expertise, and must be sufficiently diverse in terms of race, gender, cultural background, and sensitivity to community attitudes as 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.

3520 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, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

3530 Accordingly, the membership of the CSULB Institutional Review Board for the Protection of Human Subjects shall be constituted as follows:

3531 Eleven tenured members of the faculty, appointed by the President. Of these members, at least six must hold the rank of professor, three must represent scientific disciplines, and three must represent nonscientific disciplines. Of the minimum of three members from scientific disciplines, one must have expertise in such medically relevant issues as physically invasive procedures, physical therapy, and pharmacology. Of the minimum of three members from nonscientific disciplines, one must have expertise in survey research and assessment.

a. Faculty members may nominate themselves or may be nominated by department chairs.

b. The Provost and Senior Vice President for Academic Affairs shall receive the nominations and develop a slate of recommendations for presentation to the Academic Senate.

c. The Senate may concur or decline to concur with the slate of recommendations.

d. If the Senate concurs, the slate of recommendations shall be forwarded to the President for consideration of appointment to the IRB.

e. If the Senate declines to concur, the Provost and Senior Vice President shall develop a revised slate of nominations for presentation to the Senate.

3532 Two members shall be individuals not otherwise affiliated with the University and who are not part of the immediate family of any person affiliated with the University. These members shall be appointed by the President. [45 CFR 46.107]

3533 The Director of Research (ex officio, with full voting rights).

3534 The Dean of Graduate Studies (ex officio, with full voting rights).

3535 Terms of appointment (except for ex officio members) are for three years. Faculty members and community members alike will experience an exceptionally heavy workload associated with service on the IRB. Accordingly, the Academic Senate recommends that the Provost and Senior Vice President for Academic Affairs develop a plan to provide an appropriate level of assigned time for faculty members and equivalent compensation for community members, with additional assigned time or compensation for the chair of the IRB.

3600 Operation of the IRB

3610 The IRB shall, at the first meeting of each academic year, select two of its members to be chair and vice chair, respectively. These officers shall each have had at least one prior year of service on the IRB.

3620 Except when an expedited review procedure is used (see Section III.H, below), the IRB shall review proposed research at a convened meeting at which a majority of the membership is present, including at least one member representing a nonscientific discipline. In order for a proposed research project to be approved, it shall receive an affirmative vote from a majority of those members present at the meeting. [45 CFR 46.108]

3630 The IRB shall develop a written set of procedures to govern its review of research protocols and documentation of informed consent and to guide researchers in their preparation of materials for submission. [45 CFR 46.103 (b) (4)]

3640 The IRB shall develop forms for researchers to use when applying for initial approval of a protocol, for applying for annual renewal of an existing protocol, for modifying an existing protocol, and for requesting confirmation that a research project involving human subjects is exempt from IRB review.

3700 Role of the Director of Research

3710 The Director of University Research shall maintain the roster of IRB membership, ensuring that the Provost and Senior Vice President for Academic Affairs is made aware of resignations or other reasons for nonparticipation.

3720 The Director of Research shall maintain a complete and accurate record of the proceedings of all meetings of the IRB and shall annually prepare a summary of these activities for submission to the Provost and Senior Vice President for Academic Affairs and to the Executive Committee of the Academic Senate. Federal regulations require that documentation of IRB proceedings be maintained for a minimum of three years (dating from the conclusion of research in the case of completed projects) and include all of the following: [45 CFR 46.115]

a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

b. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

c. Records of continuing review activities.

d. Copies of all correspondence between the IRB and the investigators.

e. Statements of significant new findings provided to subjects. [45 CFR 46.115 (a) (1) through (4) and (7)]

3730 The Director of Research shall insure that the IRB is provided full and accurate information on the available at all meetings of the IRB; and that the assurances required by regulation are properly prepared, signed, and delivered to the responsible authorities.

3740 The Director of Research shall call extra meetings of the IRB as required to conduct normal business or at the special request of the Provost and Senior Vice President for Academic Affairs or the Dean of Graduate Studies.

3750 The Director of Research shall assist the Provost and Senior Vice President for Academic Affairs in developing and conducting a workshop or series of workshops for members of the IRB and interested researchers so that they may become more familiar with, and comfortable in applying, both federal regulations and campus policies governing the conduct of research using human subjects. The workshops shall be offered at appropriate intervals, without cost to participants, and should be conducted by external consultants hired by the University for that purpose.

3800 Expedited Review

3810 The IRB may use an expedited procedure to review either minor changes in previously approved research protocols during the period of less than one year for which those protocols have already been approved, or to provide initial approval for new protocols involving specific categories of research designated by the Secretary of Health and Human Services as involving no more than minimal risk. Examples of categories so designated include collection of biological specimens by noninvasive means, collection of data from voice, video, digital, or image recordings, and research on individual or group characteristics or behavior or research employing survey, interview, or oral history techniques. The full current list may be found in the Federal Register and will be distributed to IRB members by the Director of Research.

3820 An expedited review may be carried out by the chair of the IRB or by one or more members of the IRB designated by the chair. In reviewing the research, the reviewer(s) may exercise all of the authority of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only following standard review at an IRB meeting.

3830 The procedures developed by the IRB shall include provision for a method by which all members will be informed of approvals of research proposals under the provision for expedited review. [45 CFR 46.110]

3900 Research Exempt from IRB Review

Certain types of research activity in which the only involvement of human subjects is in one or more of the following categories are exempt from review by the IRB:

3910 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

3920 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (a) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure 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, employability, or reputation.

3930 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

3940 Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3950 Research and demonstration projects which are conducted by or subject to the approval of government agencies, and which are designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

3960 Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [45 CFR 46.101 (b) (1) through (6)]

3970 Researchers who believe that their projects involving human subjects are exempt from IRB review because they are included in one or more of the categories enumerated above shall submit to the Director of Research a completed copy of the form developed by the IRB to document such exemption. The Director of Research shall review all such claims of exemption and either approve them or refer them to the chair of the IRB. If the chair of the IRB does not believe that the proposed research is exempt, the researcher shall submit a complete protocol for regular or expedited IRB review, as appropriate.

4000 Instructional Demonstrations and Activities

4010 Faculty members often give instructional demonstrations or conduct other activities in a classroom setting that involve the use of human subjects, typically students in the class. The responsibility for proper conduct of such instructional demonstrations or activities is borne by the individual faculty member and is not subject to review by the IRB. The instructor shall be aware

of any potential risks to the dignity, rights, or welfare of the subjects, make those risks known to the potential subjects, and (if more than minimal risk is involved) inform the subjects of their rights as embodied in this document.

4020 The responsibility for informing students of the potential risks in such participatory instructional activities lies with the instructor. Each student shall be informed in writing during the first week of class of any potential risks involved in such activities and should be allowed to pursue possible alternatives with the instructor if, in the opinion of the student, the risks appear excessive.

4030 The responsibility for providing properly maintained and supervised equipment rests with the department or program offering the courses. This responsibility extends to the availability of personnel properly trained to operate the equipment as well as any emergency equipment necessary in case of an accident.

4100 Appeal of an IRB Decision

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 a decision on procedural grounds only to the Provost and Senior Vice President for Academic Affairs within twenty (20) instructional days following written notification of the IRB decision. The Provost will review the appeal and may elect to confer with the IRB. Federal regulations, however, provide that a negative decision of the IRB may not be overturned by any other University official or body. [45 CFR 46.109 (d) and 46.112]

5000 Legal Assurances

5100 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 judgement will be provided defense by the University in the event of legal action and full coverage from its liability pool in the event of an adverse decision.

5200 Legal Liability of the University for Acts of Researchers

Employees or former employees may request that the University defend them against any claim or action alleging 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 full coverage from its liability pool in the event of an adverse decision. The University will not defend an employee, however, if it is determined that the action or omission involved was not within the employee's scope of employment, or that it was based upon actual fraud, corruption, or 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, 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.

5300 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 Provost and Senior 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:

a. The involvement of minors;

b. The involvement of adults whose competence to give consent may be subject to question; and

c. The necessity for the investigator to perform acts requiring license under provisions of the law.

EFFECTIVE: Fall 2000