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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 inv ited 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 B eneficence 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 remainin g 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 Univ ersity 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 resea rch, 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 tha t 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 revi ew 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 reas onable 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 subj ects.

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 insti tutional 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 a nd 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 R isks, 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, Par t 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 regu lation," and the designation of an IRB "established in accordance with the requirements of this policy," that is, 45 CFR 46.103. This policy statement 0 s2(t)-1(s)1(a)8,07"g th hicy stat43(m)3(ea)2(r)2(e)3( )1(a)8(t)-1(

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 potentia l 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 researc h 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 u pon 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 inv estigator 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.

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 report ing 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

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 inves tigators.

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

1390 The Director of Research shall insure that the IRB is provided full and accurate information on the available at all me etings of the IRB1c4os R5(dc4)2(e)3( )1B5<</MCID 568u acc s 62 c(e)1( )1(at)-1

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

4010 Faculty members often give instructional demonstrations or conduct other activitie s 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 revie w 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 embo died 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 poten tial 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 a n 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 Acad emic 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 no t 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 decisio n.

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 ev ent 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 t

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