

6 Protection of Human Subjects

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

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

11 1000 Introduction.

12 1100 California State University, Long Beach has a moral and legal responsibility to safeguard
13 the rights, welfare, and dignity of human subjects involved in research. The University is
14 committed to the ethical principles for the protection of human subjects in research set forth in
15 the Belmont Report of the National Commission for the Protection of Human Subjects of
16 Biomedical and Behavioral Research (1979). The basic ethical principles outlined in the Belmont
17 Report are respect for persons, beneficence, and justice.

18 1110 Respect for persons dictates that researchers must obtain informed consent from all
19 human subjects invited to participate in research. In order to respect subject autonomy, the
20 consent process includes giving subjects full and comprehensible information about the research
21 and providing a clear assurance of the subjects' voluntary participation.

22 1120 B eneficence is the essence of concern for the well-being of subjects, and requires that
23 the risk of harm to subjects is the least possible, and that the sum of benefits to the subject and
24 the importance of the knowledge to be gained so outweigh any remaining harm as to justify a
25 decision to allow this risk.

26 1130 Justice requires that the selection of human subjects should be fair and equitable and
27 that the risks and benefits of research should be distributed among subjects in a fair and
28 equitable manner, with particular concern for subjects whose personal status or condition as
29 children, prisoners, patients, or impoverished persons places them in a vulnerable or dependent
30 position. [Language on principles adopted directly from UCLA policy]

31 1200 The University affirms its commitment to the importance of research involving human
32 subjects and strives to ensure the widest opportunity for its faculty and students to engage in
33 this essential activity. A vital safeguard of the privilege of conducting such research, however, is
34 the institutional review of all research projects to minimize the possibility of unacceptable or
35 unnecessary levels of risk to the rights, welfare, and dignity of human subjects. Careful review of
36 this type also enhances the likelihood that any given research project will yield results that are
37 accepted as valid by the scholarly community.

38 1300 Toward this end, and to comply with the requirements of federal law, the University has
39 created an Institutional Review Board for the Protection of Human Subjects (IRB). To assist the
40 individual researcher in protecting the rights of human subjects and to minimize the potential
41 legal liability of the investigator and the University should a human being be placed at risk, the
42 IRB is instructed to review all research projects involving human subjects where there may be an
43 element of risk but to do so in the spirit of an advisor and consultant, rather than as an

44 adversary of the researcher. Thus, if an ethical problem exists, the IRB will make every
45 reasonable effort to work with the researcher in revising the protocol. In this light the IRB will
46 seek to judge not the merit or social sensitivity of the research but only the risks and benefits of
47 the research in relationship to the protection of human subjects.

48 2000 Background

49 2100 The Public Health Service has had a rule since 1966 that "support of clinical research and
50 investigation involving human beings should be provided only if the judgment of the investigator
51 is subject to prior review by his institutional associates to assure an independent determination
52 of the protection of the rights and welfare of the individual or individuals involved, to the
53 appropriateness of the methods used to secure informed consent, and of the risks and potential
54 medical benefits of the investigation."

55 2200 Congress provided a statutory basis for this rule in Title II of the National Research Act of
56 1974 (Public Law 93-348), which also established a National Commission for the Protection of
57 Human Subjects in Biomedical and Behavioral Research, charged with the responsibility of
58 identifying "the basic ethical principles which should underlie the conduct" of such research and
59 developing guidelines that researchers must follow. Today the Office for Protection from
60 Research Risks, an agency of the U.S. Department of Health and Human Services, is charged
61 with the enforcement of these principles. The regulations issued by the Department of Health
62 and Human Services are codified in the Code of Federal Regulations at Title 45, Part 46
63 (commonly cited as 45 CFR 46).

64 2300 Researchers working with human subjects at CSULB are not eligible to apply for support
65 from any federal agency unless the University provides a written assurance that must include,
66 among other things, "a statement of principles governing the institution in the discharge of its
67 responsibilities for protecting the rights and welfare of human subjects of research conducted at
68 or sponsored by the institution, regardless of whether the research is subject to federal
69 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 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(

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

133 c. The proposed safeguards against the risk are adequate;

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

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

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

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

141 3320 The IRB shall have the authority to require modifications of a research protocol and of
142 the project itself and to give ultimate approval or denial to the project. When the IRB approves
143 or disapproves a protocol, it shall furnish a written statement to the investigator. The decision to
144 approve a protocol requires a majority of the quorum at the time of the vote (see Section III.E
145 on Membership). The IRB may take any of the following actions:

146 a. Classify the protocol as exempt;

147 b. Approve the protocol as submitted;

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

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

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

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

153 g. Reject the protocol. [45 CFR 46.109]

154 3330 The IRB shall consider only the risks and benefits of the research being reviewed
155 relative to the possible harm of the human subjects involved. Research merit and social
156 sensitivity or other socio-political considerations shall not enter into judgments concerning a
157 protocol. Issues and concerns about research which arise during the IRB's deliberations, but
158 which go beyond or are unrelated to the protection of human subjects, may be referred to the
159 Scholarly and Creative Activity Committee for its consideration, or to the Provost and Senior Vice
160 President for Academic Affairs and Executive Committee of the Academic Senate.

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

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

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

175 d. For ensuring prompt reporting to the IRB, the Provost and Senior Vice President for

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

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

296 c. Records of continuing review activities.

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

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

300 ~~3390~~ The Director of Research shall insure that the IRB is provided full and accurate
information on the available at all meetings of the IRB

331 3900 Research Exempt from IRB Review

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

334 3910 Research conducted in established or commonly accepted educational settings, involving
335 normal educational practices, such as (a) research on regular and special education instructional
336 strategies, or (b) research on the effectiveness of or the comparison among instructional
337 techniques, curricula, or classroom management methods.

338 3920 Research involving the use of educational tests (cognitive, diagnostic, aptitude,
339 achievement), survey procedures, interview procedures or observation of public behavior, unless
340 (a) the information obtained is recorded in such a manner that human subjects can be identified,
341 directly or through identifiers linked to the subjects; and (b) any disclosure of the human
342 subjects' responses outside the research could reasonably place the subjects at risk of criminal
343 or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

344 3930 Research involving the use of educational tests (cognitive, diagnostic, aptitude,
345 achievement), survey procedures, interview procedures, or observation of public behavior that is
346 not exempt under paragraph 2 of this section, if (a) the human subjects are elected or appointed
347 public officials or candidates for public office; or (b) federal statute(s) require(s) without
348 exception that the confidentiality of the personally identifiable information will be maintained
349 throughout the research and thereafter.

350 3940 Research, involving the collection or study of existing data, documents, records,
351 pathological specimens, or diagnostic specimens, if these sources are publicly available or if the
352 information is recorded by the investigator in such a manner that subjects cannot be identified,
353 directly or through identifiers linked to the subjects.

354 3950 Research and demonstration projects which are conducted by or subject to the approval
355 of government agencies, and which are designed to study, evaluate, or otherwise examine (a)
356 public benefit or service programs; (b) procedures for obtaining benefits or services under those
357 programs; (c) possible changes in or alternatives to those programs or procedures; or (d)
358 possible changes in methods or levels of payment for benefits or services under those programs.

359 3960 Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome
360 foods without additives are consumed or (b) if a food is consumed that contains a food
361 ingredient at or below the level and for a use found to be safe, or agricultural chemical or
362 environmental contaminant at or below the level found to be safe, by the Food and Drug
363 Administration or approved by the Environmental Protection Agency or the Food Safety and

373 4010 Faculty members often give instructional demonstrations or conduct other activities in a
374 classroom setting that involve the use of human subjects, typically students in the class. The
375 responsibility for proper conduct of such instructional demonstrations or activities is borne by the
376 individual faculty member and is not subject to review by the IRB. The instructor shall be aware
377 of any potential risks to the dignity, rights, or welfare of the subjects, make those risks known to
378 the potential subjects, and (if more than minimal risk is involved) inform the subjects of their
379 rights as embodied in this document.

380 4020 The responsibility for informing students of the potential risks in such participatory
381 instructional activities lies with the instructor. Each student shall be informed in writing during
382 the first week of class of any potential risks involved in such activities and should be allowed to
383 pursue possible alternatives with the instructor if, in the opinion of the student, the risks appear
384 excessive.

385 4030 The responsibility for providing properly maintained and supervised equipment rests
386 with the department or program offering the courses. This responsibility extends to the
387 availability of personnel properly trained to operate the equipment as well as any emergency
388 equipment necessary in case of an accident.

389 4100 Appeal of an IRB Decision

390 If a protocol is disapproved by the IRB, the reason(s) for disapproval shall be provided in
391 writing to the investigator. The investigator may appeal a decision on procedural grounds only to
392 the Provost and Senior Vice President for Academic Affairs within twenty (20) instructional days
393 following written notification of the IRB decision. The Provost will review the appeal and may
394 elect to confer with the IRB. Federal regulations, however, provide that a negative decision of
395 the IRB may not be overturned by any other University official or body. [45 CFR 46.109 (d) and
396 46.112]

397 5000 Legal Assurances

398 5100 Legal Liability of the University for Acts of Committee Members

399 Duly appointed committee members who, while acting in the course and scope of their
400 committee assignments, carry out their obligations in good faith and exercise good judgement
401 will be provided defense by the University in the event of legal action and full coverage from its
402 liability pool in the event of an adverse decision.

403 5200 Legal Liability of the University for Acts of Researchers

404 Employees or former employees may request that the University defend them against any
405 claim or action alleging injury due to negligence within the scope of their employment.
406 Employees who, while acting in the course and scope of their employment, carry out their
407 obligations in good faith and exercise good judgment, will be provided defense by the University
408 in the event of legal action and full coverage from its liability pool in the event of an adverse
409 decision. The University will not defend an employee, however, if it is determined that the action
410 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

416 If any reviewing body believes that the proposed activity violates any law, may possibly
417 violate any law, or may otherwise contain some significant legal issue, the protocol shall be