

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 Beneficence 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
70 this policy," that is, 45 CFR 46.103. This policy statement constitutes the required statement of
71 principles.

72 **3000 Institutional Review Board for the Protection of Human Subjects**

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

76 3100 Definitions

77 3110 Research means a systematic investigation, including research development, testing and
78 evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet
79 this definition constitute research for purposes of this policy, whether or not they are conducted
80 or supported under a program which is considered research for other purposes. For example,
81 some demonstration and service programs may include research activities. [45 CFR 46.102 (d)]

82 3120 Human subject means a living individual about whom an investigator (whether
83 professional or student) conducting research obtains (1) data through intervention or interaction
84 with the person, or (2) identifiable private information. [45 CFR 46.102 (f)]

85 3130 Minimal risk means that the probability and magnitude of harm or discomfort anticipated
86 in the research are not greater in and of themselves than those ordinarily encountered in daily

87 life or during the performance of routine physical or psychological examinations or tests. [45 CFR
88 46.102 (i)]

89 3200 Application of Policy

90 3210 This policy applies to all faculty, staff, and students whenever they are supervising or
91 conducting research activity involving human subjects, regardless of whether the subjects are
92 members of the University community. Non-University personnel may also come under the
93 purview of this policy when their research or related activities utilize members of the University
94 community. Both funded and non-funded research activities are covered by this policy. [45 CFR
95 46.103 (b)(1)]

96 3220 No research involving human subjects may be conducted by University faculty, staff, or
97 students, or by non-University personnel in instances where members of the University
98 community are serving as the subjects, prior to approval being granted under the appropriate
99 provisions of this policy. This restriction applies equally to all three categories of review:
100 standard, expedited, and exempt. No contact of any kind may be made for purposes of research
101 with actual or prospective subjects until after the appropriate informed-consent form has been
102 reviewed and approved or a waiver of informed consent has been granted. [45 CFR 46.116]

103 3230 Cooperative research: research activities may involve investigators from other
104 institutions. If the subjects, in whole or in part, are drawn from the University, the CSULB
105 investigator is responsible for submitting the proposal to the University's IRB for review and
106 approval. If the subjects are not drawn from the University, then the principal investigator shall
107 submit the proposal to the principal investigator's IRB, except that if there is no identified
108 principal investigator, or if the principal investigator's institution does not have an IRB approved
109 by the U.S. Department of Health and Human Services, then the CSULB investigator shall be
110 responsible for submitting the proposal to the University's IRB for review and approval. In the
111 case of cooperative research by CSULB faculty and/or students with researchers at other
112 institutions, a process of joint review, reliance upon another qualified IRB, or a similar
113 arrangement that meets the spirit of this policy, complies with federal regulations, and is
114 approved by the Provost and Senior Vice President for Academic Affairs or designee may also be
115 used. [45 CFR 46.114]

116 3240 Final responsibility for the protection of human subjects and adherence to ethical
117 standards rests with the University in the case of all research projects conducted under
118 University auspices; however, the faculty, staff, and students conducting such research share the
119 primary responsibility for assuring that their research is properly conducted. Consequently, the
120 University requires that all persons at CSULB involved in activities involving human subjects be
121 familiar with, and at all times comply with, the provisions of this document. Deans, department
122 chairs, and program directors are required to bring the provisions of this policy to the attention
123 of their faculty, staff, and students. Principal investigators are required to submit in a timely
124 manner a protocol and informed-consent form for review by the IRB.

125 3300 Responsibilities of the IRB

126 3310 The IRB shall evaluate all research activities involving human subjects. The IRB shall
127 evaluate both the written protocol and the informed-consent form to determine that they are in
128 compliance with the provisions of this policy. Toward this end, the IRB shall evaluate each
129 protocol to determine whether:

130 a. The protocol is complete;

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.

161 3340 The IRB shall conduct continuing review of research covered by this policy at intervals
162 appropriate to the degree of risk, but not less than once per year. It shall have the authority to
163 observe, or have a third party observe, both the consent process and the research itself. [45 CFR
164 46.103 (b) (4) (ii)]

165 3350 The IRB shall develop a set of written procedures which it will follow:

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
176 Academic Affairs, and the head of any external funding agency of any unanticipated problems
177 involving risks to subjects or others or any suspension or termination of IRB approval. [45 CFR
178 46.103 (b) (4) and (5)]

179 3360 The IRB shall develop and keep current a manual on the protection of human subjects,
180 copies of which shall be made available to all members of the IRB and to all faculty and staff
181 engaged in research involving human subjects. Copies of this manual and all supporting
182 documents shall be made available on appropriate University Web sites. Additional copies may
183 be made available for purchase by students through the 49er Shops, Inc. The manual shall
184 include, at a minimum, the following materials: (a) the Code of Federal Regulations, Title 45,
185 Department of Health and Human Services, Part 46, Protection of Human Subjects; (b) National
186 Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The
187 Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of
188 Research" (1979); (c) American Psychological Association, "Ethical Principles in the Conduct of
189 Research with Human Participants (1982); (d) this policy statement; (e) the written procedures
190 developed by the IRB; (f) copies of all forms developed by the IRB; and (g) guidelines on how to
191 fill in each of these forms correctly and completely.

192 3370 The IRB shall meet at least once a month throughout the academic year. Meeting times
193 and dates shall be established and published for the entire academic year at the beginning of
194 each fall semester.

195 3400 Criteria for Approval of Research

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

198 3410 Risks to subjects are minimized, either by using procedures which are consistent with
199 sound research design and which do not unnecessarily expose subjects to risk, or by using
200 procedures which are already being performed on the subjects for diagnostic or treatment
201 purposes.

202 3420 Risks to subjects are reasonable in relation to anticipated benefits, if any, to the
203 subjects, and in relation to the importance of the knowledge that may reasonably be expected to
204 result.

205 3430 The selection of subjects is equitable. The IRB must be particularly cognizant of the
206 special problems of research involving vulnerable populations, such as children, prisoners,
207 pregnant women, mentally disabled persons, or economically or educationally disadvantaged
208 persons.

209 3440 Informed consent will be sought from each prospective subject or the subject's legally
210 authorized representative and will be appropriately documented.

211 3450 When appropriate, the research plan makes adequate provision for monitoring the data
212 collected to ensure the safety of subjects.

213 3460 When appropriate, there are adequate provisions to protect the privacy of subjects and
214 to maintain the confidentiality of data.

215 3470 When some or all of the subjects are likely to be vulnerable to coercion or other undue
216 influence, such as children, prisoners, pregnant women, mentally disabled persons, or
217 economically or educationally disadvantaged persons, additional safeguards have been included
218 in the study to protect the rights and welfare of these subjects. [45 CFR 46.111]

219 3500 Membership of the IRB

220 3510 Federal regulations require that the members of the IRB collectively have sufficiently
221 varying backgrounds to assure that they can promote the complete and adequate review of
222 those types of research activities commonly conducted by the University. The membership of the
223 IRB must be highly qualified by experience and expertise, and must be sufficiently diverse in
224 terms of race, gender, cultural background, and sensitivity to community attitudes as to promote
225 respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The
226 IRB may not consist entirely of men or entirely of women, or primarily of members of one
227 discipline.

228 3520 In addition to possessing the professional competence necessary to review specific
229 research activities, the IRB shall be able to ascertain the acceptability of proposed research in
230 terms of institutional commitments and regulations, applicable law, and standards of professional
231 conduct and practice. The IRB shall, therefore, include persons knowledgeable in these areas. If
232 the IRB regularly reviews research that involves a vulnerable category of subjects, such as
233 children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB shall
234 include one or more individuals who are primarily concerned with the welfare of these subjects.

235 3530 Accordingly, the membership of the CSULB Institutional Review Board for the Protection
236 of Human Subjects shall be constituted as follows:

237 3531 Eleven tenured members of the faculty, appointed by the President. Of these
238 members, at least six must hold the rank of professor, three must represent scientific disciplines,
239 and three must represent nonscientific disciplines. Of the minimum of three members from
240 scientific disciplines, one must have expertise in such medically relevant issues as physically
241 invasive procedures, physical therapy, and pharmacology. Of the minimum of three members
242 from nonscientific disciplines, one must have expertise in survey research and assessment.

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

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

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

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

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

252 3532 Two members shall be individuals not otherwise affiliated with the University and who
253 are not part of the immediate family of any person affiliated with the University. These members
254 shall be appointed by the President. [45 CFR 46.107]

255 3533 The Director of Research (ex officio, with full voting rights).

256 3534 The Dean of Graduate Studies (ex officio, with full voting rights).

257 3535 Terms of appointment (except for ex officio members) are for three years. Faculty
258 members and community members alike will experience an exceptionally heavy workload
259 associated with service on the IRB. Accordingly, the Academic Senate recommends that the
260 Provost and Senior Vice President for Academic Affairs develop a plan to provide an appropriate
261 level of assigned time for faculty members and equivalent compensation for community
262 members, with additional assigned time or compensation for the chair of the IRB.

263 3600 Operation of the IRB

264 3610 The IRB shall, at the first meeting of each academic year, select two of its members to
265 be chair and vice chair, respectively. These officers shall each have had at least one prior year of
266 service on the IRB.

267 3620 Except when an expedited review procedure is used (see Section III.H, below), the IRB
268 shall review proposed research at a convened meeting at which a majority of the membership is
269 present, including at least one member representing a nonscientific discipline. In order for a
270 proposed research project to be approved, it shall receive an affirmative vote from a majority of
271 those members present at the meeting. [45 CFR 46.108]

272 3630 The IRB shall develop a written set of procedures to govern its review of research
273 protocols and documentation of informed consent and to guide researchers in their preparation
274 of materials for submission. [45 CFR 46.103 (b) (4)]

275 3640 The IRB shall develop forms for researchers to use when applying for initial approval of
276 a protocol, for applying for annual renewal of an existing protocol, for modifying an existing
277 protocol, and for requesting confirmation that a research project involving human subjects is
278 exempt from IRB review.

279 3700 Role of the Director of Research

280 3710 The Director of University Research shall maintain the roster of IRB membership,
281 ensuring that the Provost and Senior Vice President for Academic Affairs is made aware of
282 resignations or other reasons for nonparticipation.

283 3720 The Director of Research shall maintain a complete and accurate record of the
284 proceedings of all meetings of the IRB and shall annually prepare a summary of these activities
285 for submission to the Provost and Senior Vice President for Academic Affairs and to the Executive
286 Committee of the Academic Senate. Federal regulations require that documentation of IRB
287 proceedings be maintained for a minimum of three years (dating from the conclusion of research
288 in the case of completed projects) and include all of the following: [45 CFR 46.115]

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

303 3740 The Director of Research shall call extra meetings of the IRB as required to conduct
304 normal business or at the special request of the Provost and Senior Vice President for Academic
305 Affairs or the Dean of Graduate Studies.

306 3750 The Director of Research shall assist the Provost and Senior Vice President for Academic
307 Affairs in developing and conducting a workshop or series of workshops for members of the IRB
308 and interested researchers so that they may become more familiar with, and comfortable in
309 applying, both federal regulations and campus policies governing the conduct of research using
310 human subjects. The workshops shall be offered at appropriate intervals, without cost to
311 participants, and should be conducted by external consultants hired by the University for that
312 purpose.

313 3800 Expedited Review

314 3810 The IRB may use an expedited procedure to review either minor changes in previously
315 approved research protocols during the period of less than one year for which those protocols
316 have already been approved, or to provide initial approval for new protocols involving specific
317 categories of research designated by the Secretary of Health and Human Services as involving
318 no more than minimal risk. Examples of categories so designated include collection of biological
319 specimens by noninvasive means, collection of data from voice, video, digital, or image
320 recordings, and research on individual or group characteristics or behavior or research employing
321 survey, interview, or oral history techniques. The full current list may be found in the Federal
322 Register and will be distributed to IRB members by the Director of Research.

323 3820 An expedited review may be carried out by the chair of the IRB or by one or more
324 members of the IRB designated by the chair. In reviewing the research, the reviewer(s) may
325 exercise all of the authority of the IRB except that the reviewer(s) may not disapprove the
326 research. A research activity may be disapproved only following standard review at an IRB
327 meeting.

328 3830 The procedures developed by the IRB shall include provision for a method by which all
329 members will be informed of approvals of research proposals under the provision for expedited
330 review. [45 CFR 46.110]

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
364 Inspection Service of the U.S. Department of Agriculture. [45 CFR 46.101 (b) (1) through (6)]

365 3970 Researchers who believe that their projects involving human subjects are exempt from
366 IRB review because they are included in one or more of the categories enumerated above shall
367 submit to the Director of Research a completed copy of the form developed by the IRB to
368 document such exemption. The Director of Research shall review all such claims of exemption
369 and either approve them or refer them to the chair of the IRB. If the chair of the IRB does not
370 believe that the proposed research is exempt, the researcher shall submit a complete protocol
371 for regular or expedited IRB review, as appropriate.

372 **4000 Instructional Demonstrations and Activities**

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
411 upon actual fraud, corruption, or malice, or that the providing of such defense would involve a
412 conflict of interest. Therefore, in order to minimize the risk of incurring unnecessary liability,
413 employees are expected to adhere to all University policies and procedures. Failure to do so may
414 result in the State of California electing not to defend or indemnify.

415 5300 Submission to General Counsel

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
418 submitted to the Provost and Senior Vice President for Academic Affairs for forwarding to the
419 Office of General Counsel for evaluation. Other criteria for judging the need to submit a protocol
420 to General Counsel may include:

421 a. The involvement of minors;

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

424 c. The necessity for the investigator to perform acts requiring license under provisions of
425 the law.
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428 **EFFECTIVE: Fall 2000**