UNIVERSITY OF CALIFORNIA
SANTA CRUZ
Institutional Review Board

Policy on Initial IRB Review

Effective date: 08-23-2018

I. Background

As an institution that receives federal funding, UCSC personnel engaged in human subjects research must submit their activities for review and receive IRB approval or exempt determination before conducting human research activities. This policy outlines criteria for expedited and full committee initial review of human subjects research. Please see Policy on Exempt Review for studies that meet exempt criteria.

II. Definitions

a. *Clinical investigation (FDA): Any experiment that involves a test article (drug, device, or biologic) and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.*
b. *Engagement: Personnel interact or intervene with human subjects or analyze identifiable private data for research purposes, including but not limited to recruiting, consenting, conducting study procedures, and analyzing data with access to identifiers.*
c. *Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.*
d. *Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.*
e. *Research (DHHS): A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*
f. *Test Article (FDA): Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.*

III. Initial Review Submission Requirements and Procedures

a. *Researchers:* The Principal Investigator/Faculty Sponsor is required to submit a Full Protocol Form for IRB review, along with any applicable supplemental materials (e.g., recruitment materials, consent documents unless requesting waivers, study instruments, data collection forms, Requests to Review Research for Another IRB, etc.). Approval is needed before any human research activities begin. The researcher must respond to any comments sent from either the administrative review or IRB review before the application can move forward.

b. *ORCA:* ORCA does an administrative review of protocols in the order of receipt, sends comments to researchers as appropriate, and once response to comments are received, ORCA sends expedited reviews to the Chair or their designee, and schedules a full committee meeting for studies that are potentially greater than minimal risk or do not meet expedited criteria.

IV. IRB Review and Actions

The IRB will review the application based on the criteria for IRB review in DHHS or FDA regulations, or equivalent when applicable.

a. Expedited review: The IRB Chair or their designee conducts the review. The expedited reviewer can approve it, require modifications, or refer it to the full board.

b. Full committee review: A quorum of the IRB meets to discuss the protocol and reviews it based on the criteria for IRB review. The Board can approve it, require modifications if the comments are specific and direct, defer it if they cannot determine criteria for approval, or disapprove the research if risks outweigh benefits.

V. Criteria for IRB Approval (DHHS) and Ethical Principles (Belmont Report)

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

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should 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.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116 (unless criteria for a waiver or alteration of consent are met).

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 (unless criteria for waiver of documentation of consent are met).

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

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

When some or all of the subjects are likely to be vulnerable to coercion or 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.

If the research subjects include pregnant women, fetuses, and/or neonates, children, or prisoners, the IRB must assure criteria for

additional protection of these vulnerable populations as met as outlined in 45 CFR 46 subparts B, C, D.

b. The IRB is also guided by the three ethical principles described in the Belmont Report of the National Commission for the Protection of Human Subjects:

> Respect for persons-researchers should obtain the informed consent of all human subjects invited to participate in research. In order to respect subject autonomy, the consent process should include giving subjects full and comprehensible information about the research and provide clear assurances of the subjects' voluntary participation.
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> Beneficence-the risk of harm to subjects should be the least possible, and the sum of benefits to the subjects and the importance of the knowledge to be gained should so outweigh the remaining risk of harm to the subject as to warrant a decision to allow this risk.
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> Justice-the selection of human subjects should be fair and equitable and 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, impoverished persons places them in a vulnerable or dependent status.

VI. Documentation

The IRB will document and notify the researcher of the approval date, the approval period (1 year for studies following PHS requirements such as NIH funded studies or greater than minimal risk research, 3 years for other minimal risk research, unless the IRB determines more frequent review is needed due to unknown risks or noncompliance), any waivers of consent, and any approval for inclusion of special populations. Full committee meetings will record controverted issues and their resolution in the minutes. Once approval is received research may begin as written. If changes are needed, they first must be submitted and approved before enacting them unless to prevent immediate hazard to subjects.

VII. References

a. 45 CFR 46.102, 45 CFR 46.109, 45 CFR 46.111, OHRP Engagement Guidance 2008
b. 21 CFR 50, 21 CFR 56.109, CFR 56.111, 21 CFR 312, 21 CFR 812