Policy on Initial IRB Review

Effective date: 9/20/2019

I. Background
All research at UCSC involving human subjects must receive IRB approval or be determined exempt from IRB review before any human subjects research may begin. This policy outlines procedures for initial review of non-exempt human subjects research. Please see Policy on Exempt Review for studies that meet exempt criteria.

II. Definitions
a. Human Subject (HHS): a living individual about whom an investigator (whether professional or student) conducting research:
   (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

b. Minimal Risk: Research is considered “minimal risk” research when 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 of the general population or during the performance of routine physical or psychological examinations or tests.

c. Research (HHS): A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

III. Initial Review Submission Requirements and Procedures
a. Researchers: After the Principal Investigator (PI) has reviewed the exempt categories and concluded that the research is not eligible for exemption, they 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.). The researcher must respond to any comments/questions from ORCA or the IRB before the application can move forward.

b. ORCA: ORCA does an administrative review of protocols in the order of receipt to verify that the research is not eligible for exemption, address regulatory and technical issues, and identify studies that are potentially...
Institutional Review Board

greater than minimal risk or do not meet expedited criteria. ORCA sends comments/questions to researchers if needed. Once researchers respond, protocols that are eligible for expedited review are forwarded to the Chair or an experienced member designated by the Chair. For studies that are potentially greater than minimal risk or do not meet expedited criteria, the study must be reviewed at a convened meeting of the full board.

IV. IRB Review and Actions
The IRB will review the application to ensure that it meets the criteria for IRB approval outlined in HHS regulations, or equivalent requirements per Policy on Regulatory Flexibility.

   a. Expedited review: The IRB Chair or an experienced member designated by the Chair conducts the review. The expedited reviewer can approve the protocol, 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:

      i. Risks to subjects are minimized:

         1. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

         2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

      ii. 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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

      iii. 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. The IRB should be particularly
cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

iv. 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.

v. Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

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

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

1. The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

b. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

c. 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:

i. 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.

ii. 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.

iii. 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. Approval Period
   a. IRB approval is effective as of the date of the approval letter. Even when research is reviewed by the full board and the board votes to “Approve with modifications,” the study is not approved until ORCA verifies that the researchers have complied with required modifications and sends the approval letter.
   b. Minimal risk research may be approved for a period of no more than 10 years, after which IRB approval automatically expires unless researchers submit and obtain approval for continuing review.
   c. Greater than minimal risk research may be approved for a period of no more than 1 year, after which IRB approval automatically expires unless researchers submit and obtain approval for continuing review.
   d. IRB discretion: The IRB may require studies to receive continuing review more often at its discretion – for example, due to the nature of the study, degree of uncertainty regarding the risks involved, the vulnerability of the subject population, the inexperience of the investigator, prior noncompliance with the investigator or sponsor, or use of novel therapies.
   e. The Principal Investigator is encouraged to close a study once procedures are complete and only analysis of de-identified data remains.

VII. Documentation and Notification of Review
   a. Modifications required: If a designated reviewer or the full board requires modifications before the protocol can be approved, ORCA will notify the researcher and provide them with the issues that must be addressed. For protocols that are eligible for expedited review, the required modifications are documented in an email to the researcher. For protocols requiring full board review, the required modifications are documented in a letter from the IRB Chair and in the IRB meeting minutes. Researchers must respond in writing. Regardless of whether the protocol required full board review, the researcher’s response to required modifications may be reviewed by an experienced IRB reviewer designated by the Chair (expedited procedures). The reviewer may determine that the IRB’s issues are satisfied or else request further modifications from the researcher, in which case ORCA will notify the researcher and provide them with the remaining issues in an email. Again, the researchers must respond in writing and the review cycle continues until all IRB issues are resolved.
   b. Deferral: If the full Board votes to defer a protocol, ORCA will notify the researcher and provide them with the issues that must be addressed. The IRB’s issues are documented in a letter from the IRB Chair and in the IRB meeting minutes. Researchers must respond in writing. The researcher’s
response to a deferral must be reviewed by the full IRB at a convened meeting.

c. Approval: Once approved, ORCA will notify the researcher of the approval, including any approved consent waivers and approval for the inclusion of any special populations, the effective date, and the approval period per the above. The approval is documented in a letter from the IRB Chair and, if applicable, in the IRB meeting minutes. For protocols requiring full Board review, controverted issues and their resolution will be documented in the meeting minutes. Investigators may not initiate changes to approved research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.

d. Disapproval: If the IRB disapproves the protocol, ORCA notifies the researcher and provides them with the IRB’s reasons for the disapproval. The reasons for the disapproval are documented in a letter from the IRB Chair and in the IRB meeting minutes. The researcher may submit a different protocol based on the IRB's feedback, choose not to pursue the research, or appeal the IRB’s determination in writing. Researcher appeals must be reviewed at a convened meeting of the full IRB.

VIII. References

a. 45 CFR 46.102, 45 CFR 46.109, 45 CFR 46.111, OHRP Engagement Guidance 2008

b. Stanford University HRPP Policy Manual