UNIVERSITY OF CALIFORNIA
SANTA CRUZ
Institutional Review Board

Policy on Exempt 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. At UCSC, the Office of Research Compliance Administration (ORCA) makes exempt determinations. This policy outlines criteria for determining that a given human subjects research protocol is exempt.

II. Exempt Review

Studies where all activities fit into one or more federal exempt categories or UCSC-specific Category 3x are not required to meet the criteria for IRB approval as outlined in 45 CFR 46 of the DHHS Common Rule. These categories for exemption are outlined below.

III. DHHS Common Rule Exempt Categories:

a. Category 1: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. (includes most research on regular and special education instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods)
b. Category 2: Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of 3 criteria are met:
    i. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    ii. any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR
    iii. the information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination required by 45 CFR 46.111(a)(7) (which relate to there being adequate provisions for

protecting privacy and maintaining confidentiality) AND the research is not subject to subpart D.

c. Category 3:
    i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
        A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;
        B) Any disclosure of the subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR
        C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)
    ii. For the purpose of this provision, benign behavioral interventions are brief induration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
    iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
d. Category 4: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
    i. The identifiable private information or identifiable biospecimens are publicly available; OR
    ii. The information is recorded by the investigator in such a way that the identity of the subjects cannot readily be ascertained directly or

through identifiers linked to the subjects, and the investigator does not contact subjects, and the investigator will not re-identify subjects; OR

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (i.e., the use is regulated for purposes of "health care operations" or "research" or for "public health activities and purposes" as those terms are defined at 45 CFR part 164); OR

iv. The research is conducted by or on behalf of a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with certain federal statutes

e. Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

f. Category 6: Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level, and for the use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

g. Category 7: Not used at UCSC.

h. Category 8: Not used at UCSC.

IV. UCSC Exempt Category 3x

Research may only be determined exempt under Category 3x if it is not exempt under any HHS Common Rule exemption category, is not funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), AND does not meet the exclusion criteria below.

Minimal risk research activities that will not induce distress beyond that of daily life. These may include (but are not limited to) non-physically invasive interventions or performance of tasks such as: Reading/writing/drawing tasks; Physical activities such as walking, sitting, or manipulating an object; Computer tasks and/or Internet searches; Talking and/or listening to words, then making selections, or "think-aloud" exercises; Viewing media; Role-playing; Completing a specific physical or mental action ("imagining"); Passive monitoring of space (environment) with sensors; Playing a game; Height/weight measurements.

Exclusions:
1. Research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) or some non-federal agencies. Check with your sponsor to see if they follow the Common Rule.
2. Prisoners as subjects.
3. Children/minors as subjects.
4. Federal personnel or the Department of Veterans Affairs.
5. Procedures, devices, or drugs subject to FDA oversight.
6. Biomedical procedures.
7. Clinical interventions.
8. Sponsor or other contractual restrictions.
9. An NIH-issued Certificate of Confidentiality to protect identifiable research data.
10. Deception or incomplete disclosure to subjects.
11. Identifiable, private existing data.
12. The information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, and any disclosure of the subject's responses outside of the research could reasonably place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing in any other way.

V. Exemption Request Requirements and Procedures

a. Researchers*:*
   i. The Principal Investigator (PI) submits an Exemption Request Form. If applying under categories 2iii or 3iC, a Limited IRB Review Addendum must also be submitted. Researchers conducting exempt research must comply with IRB training requirements. See When is IRB Training Required?
   ii. Consent Expectations for Exempt Research: For exempt research that involves interaction with subjects (e.g., surveys, interviews, education research, computer games, etc.), researchers are expected, at minimum, to identify themselves and UCSC to subjects, state the purpose of the research, state what is expected of subjects who participate in the research, and describe the voluntary nature of the study. Researchers affirm that they will obtain subject agreement to participate in the exempt application, but consent documents/materials are not reviewed at exempt level.
   iii. Consent Expectations for Exempt Research with Limited IRB Review: When Limited IRB Review is required, researchers are expected to inform subjects that researchers are collecting identifiable information about them; what risks are reasonably anticipated if this information were inadvertently disclosed; when identifiable information will be destroyed or that it will be retained indefinitely; and how identifiable information will be protected by researchers (e.g. encryption). Researchers affirm that subjects are told the above information in the Limited IRB Review Addendum but consent documents/materials are not reviewed at exempt level with limited review.
   iv. The researcher must respond to any comments/questions from ORCA before the application can move forward.

b. ORCA*:* ORCA reviews exempt protocols in the order of receipt to determine whether all activities fall under one or more exempt categories. If there is not enough information to determine this, ORCA asks the PI and Co-PI/Student Investigator for more information. ORCA staff may consult with the ORCA Director and/or the Chair on questions. If the study qualifies as exempt, the PI and Co-PI/Student Investigator will receive an exempt determination and may begin; if not, ORCA will inform them that a non-exempt application will need to be submitted.

VI. Approval Period

Exempt determinations are valid for a period of 10 years (see UCSC Policy on Continuing Review) so long as the research is carried out as written in the application.

VII. Modifications

There is no amendment form for exempt applications. If the investigators need to make modifications to what is in the application (e.g., new procedures, new personnel, new funding, etc.), a new exempt application must be submitted and changes cannot occur until a new exempt determination is made by ORCA. Once the new exempt determination is made, the new exempt application will replace the old exempt application.

VIII. References

45 CFR 46.101
21 CFR 56. 104
21 CFR 56. 105