Policy on Exempt Review

Effective date: 08-23-2018

I. Background
All research at UCSC involving human subjects must receive IRB approval or exempt determination before starting. At UCSC, the Office of Research Compliance Administration (ORCA) makes exempt determinations. This policy outlines criteria for exempt review of human subjects research.

II. Exempt Review
Studies where all activities fit into one or more exempt categories are determined to be exempt from needing to meet the Criteria for IRB approval as outlined in 45 CFR 46 of the DHHS Common Rule. The categories for exemption are outlined below.

III. DHHS Common Rule Exempt Categories that UCSC employs:

a. Exemption Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. Exemption Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

c. Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
d. Exemption Category 4: Research involving the collection or study of existing* data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

e. Exemption 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. Exemption 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.

IV. UC Category 3x for studies who do not meet other categories above and are not funded by an agency that follows 45 CFR 46
Exemption Category 3x is a category only to be used if #3 is not met and the research is not funded by [https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html):

Minimal risk exempt 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. Federally funded research, or funding from non-Public Health Service (PHS) or agencies that adhere to federal regulations in their award contracts.
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. **Exempt Review Requirements and Procedures**

a. *Researchers:* The Principal Investigator/Faculty Sponsor submits an Exemption Request Form. Note that exemption determination is needed before any human research activities begin. Researchers working on exempt projects are still required to comply with IRB training requirements. See [When is IRB Training Required?](#)
b. **ORCA:** ORCA reviews exempt protocols to determine whether all activities fall under one or more exempt categories. If there is not enough information to determine this, ORCA may ask the PI and the student investigator for more information. ORCA staff may consult with the ORCA Director and/or the Chair for determinations. If the study qualifies as exempt, the PI and Student Investigator will receive an exempt determination and can begin; if not, ORCA will inform them that a non-exempt application will need to be submitted. Exempt determinations do not expire but must be carried out as written in the application.

**VI. 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 received. A new exempt determination will replace an old exempt application.

**VII. References**
45 CFR 46.101
21 CFR 56.104
21 CFR 56.105