UNIVERSITY OF CALIFORNIA
SANTA CRUZ
Institutional Review Board

Policy on IRB Regulatory Flexibility

Effective date: 9/20/2019

I. Background

UC Santa Cruz has a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) within the Department of Health and Human Services to comply with and enforce human research regulations and policies. This FWA allows some flexibility in applying human subjects federal regulations to non-federally supported research while providing equivalent protections. To be eligible for this flexibility, studies must meet the following criteria:

- Minimal risk
- 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)
- NOT be defined as a "clinical trial" by the NIH
- NOT FDA-regulated

This policy outlines how UCSC applies regulatory flexibility.

II. Definitions

Some HHS Common Rule definitions have been paraphrased below. Wherever the following definitions differ from the HHS definition, the HHS definition shall prevail.

a. *Clinical Trial (NIH):* A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes
b. *Minimal Risk:* 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. *Single IRB Policy for Multi-site Research (sIRB):* The NIH requires a single IRB to serve as the IRB of record for domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research.

III. Administrative Flexibility

1. Exempt Category 3x: For qualifying studies involving benign behavioral interventions, researchers may qualify for exemption using this category.
2. sIRB; For qualifying multi-site studies, single IRB review is not mandatory.

IV. Exemption Category 3X (UC Only)

When eligibility criteria are met, UCSC uses an additional exemption category not recognized in the Common Rule. Category 3X applies to minimal risk research activities that will not induce distress beyond that of daily life 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:

a. 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.
b. Children/minors as subjects.
c. Federal personnel or the Department of Veterans Affairs.
d. Procedures, devices, or drugs subject to FDA oversight.
e. Biomedical procedures.
f. Clinical interventions.
g. Sponsor or other contractual restrictions.
h. An NIH-issued Certificate of Confidentiality to protect identifiable research data.
i. Deception or incomplete disclosure to subjects.
j. Identifiable, private existing data.
k. 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. Investigator Responsibilities

Regulatory flexibility notwithstanding, the Principal Investigator must follow their protocol as approved and report all changes to the research according to the UCSC Policy on Amendments. If any change causes the research to no longer qualify for regulatory flexibility, the federal regulations shall apply.

VI. References

45 CFR 46.102, https://grants.nih.gov/policy/clinical-trials/definition.htm