Policy on IRB Regulatory Flexibility

Effective date: 04-26-2018

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. In addition to not being federally funded, studies must not be defined as a “clinical trial” by the NIH, and studies also must be minimal risk and not FDA-regulated. This policy outlines where UCSC applies flexibility within the regulations.

II. Definitions
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. Exempt Category 3x: UC Category 3x: Minimal risk exempt 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. See https://officeofresearch.ucsc.edu/compliance/services/irb13_exempt_categories.html for all exclusions.
c. 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.

III. Administrative Flexibility
1. Continuing Review Period
   a. For qualifying studies, the IRB can determine non-exempt studies to have a 3-year expiration period versus a 1-year period.
2. Exempt Category 3x
a. For qualifying studies, researchers may qualify for exemption using this category that includes benign interventions.

IV. Exclusion Criteria
a. Federally funded research
b. Research that meets NIH definition of a clinical trial
c. FDA regulated research
d. Category 3x exclusions:
   i. Federally funded research, or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts;
   ii. Prisoners as subjects.
   iii. Children/minors as subjects.
   iv. Federal personnel or the Department of Veterans Affairs.
   v. Procedures, devices, or drugs subject to FDA oversight.
   vi. Biomedical procedures.
   viii. Sponsor or other contractual restrictions.
   ix. An NIH-issued Certificate of Confidentiality to protect identifiable research data.
   x. Deception or incomplete disclosure to subjects.
   xi. Identifiable, private existing data.
   xii. 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
The Principal Investigator receiving the benefit of one of these flexibility measures must still follow their protocol as approved and must report all changes to research.

Note if the change causes the research to no longer qualify for the flexibility measure it will be lifted.

VI. References