PROPOSED REGULATION TEXT
Committee for Protection of Human Subjects, Research Project Review

California Code of Regulations
Title XX.
Division XX
Chapter XX

Add Sections _____ as follows:

[NOTE: The proposed additions are shown in underline to indicate additions.]

§ XXXXX. Definitions.

The following definitions apply to sections XXXXX through XXXXX:

(a) "Adverse events" mean any of the following:

(i) Serious, unexpected adverse health effects for subjects or the general public.
(ii) Violations of ethical research behavior, including failure to provide informed consent, or protect confidentiality.
(iii) Research fraud, including misrepresentation of study findings and fabrication of data; and
(iv) Serious deviations from approved study protocols without prior Committee approval.

(b) "Committee" means the Committee for the Protection of Human Subjects within the California Center for Data Insights and Innovation.

(c) "De-identified", "de-identify" or "de-identification" means masking or statistically aggregating information in a manner that does not identify an individual, and with respect to which there is no reasonable basis to believe the information could be used to identify an individual in accordance with Title 45 of the Code of Federal Regulations section 164.514, subdivision (a).

(d) "IPA only project" means a research project that involves State data and only requires Committee review under Section 1798.24, subdivision (t) of the Civil Code.

- *NEED TO ADD MORE SPECIFICS*

(e) "Hybrid project" means a research project requiring Committee Review under Section 1798.24, subdivision (t) of the Civil Code and Title 45 of the Code of Federal Regulations Part 46.

- *NEED TO ADD MORE SPECIFICS*

(f) "Center" means the Center for Data Insights and Innovations within the California Health and Human Services Agency.

(g) "Common Rule only project" means a State funded research project requiring Committee IRB review under the Common Rule in Title 45 of the Code of Federal Regulations Part 46.

- *NEED TO ADD MORE SPECIFICS*

(h) "Expedited review" is when two Committee members carry out an expedited review of a new IPA only project and find there is a minimal risk of improper use and disclosure of individualized data after consideration of the factors set forth in Section XXXXX, herein.

(i) "Full review" means when more than fifty percent of Committee members review a new IPA only project, new hybrid project, or new Common Rule only project, for approval or disapproval.

(j) "IRB manager" means the data management system that allows researchers to make online submissions, including applications, amendments, adverse event reporting, and other workflows for Committee consideration.

(k) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge under Title 42 of the Code of Federal Regulations part 46.102.

NOTE: Authority cited: Sections…..

§ XXXXX. Purpose of the Committee for the Protection of Human Subjects.

- State of Cal Institutional review board for review of Hybrid and Common Rule only projects
    - Only for Depts who have contract with CDII.
- State of Cal IRB review board for data review

NOTE: Authority cited: Sections…..

§ XXXXX. Board Composition. [1]

§ XXXXX. Application Requirements for IPA Only Projects.

NOTE: Authority cited: Sections…..

[1] Note from Carrie Kurtural (CPHS Committee Member) for CDII - I don't see any info in law regarding board composition under H&S Code … opportunity to add it in here.

§ XXXXX. Minimal Risk Criteria for IPA Only Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Full Review for IPA Only Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Expedited Review for IPA Only Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Application Requirements for Hybrid Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Committee Review Criteria for Hybrid Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Full Review for Hybrid Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Application Requirements for Common Rule Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Committee Review Criteria for Common Rule Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Full Review for Common Rule Projects.

NOTE: Authority cited: Sections…..

§ XXXXX. Adverse Event Reporting Requirements.

NOTE: Authority cited: Sections…..