

## Suggested Framework for Additional IPA Review Criteria (Fifth Draft)

California's Information Practices Act (IPA) specifies certain minimum criteria that CPHS must consider when reviewing research applications under provisions of the IPA. In addition, CPHS may elect to consider additional factors related to data privacy and security. All research applications are currently required by the IPA to include:

- # "a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information." (Cal. Civ. Code § 1798.24(t)(1)(A).)
- # "a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information." Cal. Civ. Code § 1798.24(t)(1)(B).)
- # "sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project." Cal. Civ. Code § 1798.24(t)(1)(C).)

In reviewing the sufficiency of such plans or written assurances, a reviewer will take the following risks into consideration:

- # The requested data includes especially sensitive information about physical health, including but not limited to variables related to abortion, gender-affirming care, genetic testing, or HIV/AIDS testing
- # The requested data includes especially sensitive information about psychological health, including but not limited to variables related to clinical psychological tests, drug or alcohol abuse, sexual behavior, or suicide.
- # The requested data includes especially sensitive social, economic, or legal information, including but not limited to variables related to immigration status, law enforcement or court records, income, or credit history.
- # The requested data is for vulnerable populations described in the 2018 Common Rule (45 CFR 46), including but not limited to children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- # The researchers propose, or will later propose, to link the requested data to information from other sources, especially including those that fall within any of the previous descriptions.
- # The researchers plan to add additional years of data in the future, either to provide longitudinal information about individuals already in the data or to add information about new individuals.

- # The number or nature of variables that will be available in the data to be analyzed makes re-identification of individuals a possible risk despite researcher efforts to remove identifiers or mask the data.
- # The researchers plan to retain, for an extended time, identifiers that they propose to remove and store separately.
- # The researchers plan to disclose some or all of the data in a database that will be made available to other individuals not listed on the CPHS application.
- # The researchers plan to disclose de-identified data that may allow re-identification, even if the data conform to HIPAA safe harbor standards, taking into consideration any expert risk assessment provided by the researchers assessing the probability that individuals could be re-identified.
- # When the data were originally collected, the individuals were not told that their information would be used for research.
- # When the data were originally collected, the individuals were not told that their information would be linked to data from other sources.
- # The research and its privacy procedures would be unacceptable to the individuals whose information will be used if they were aware of it.

The approval of a research proposal shall include a review and determination that all the following additional criteria have been satisfied:

- # The researchers investigated what the individuals whose information will be used were told, when the data were originally collected, about using their information for research, and whether that was sufficient to serve as an informed consent.
- # The proposed use of data does not exceed any authorization given, at the time the data were originally collected, by the individuals whose information will be used, or would be eligible for a waiver of informed consent.
- # The research does not include obtaining especially sensitive identifiers or information which have undue risks associated with using them.
- # The research does not include obtaining especially sensitive identifiers or information unnecessary to perform the research.