

Determining Whether Human Subjects Are Involved in Research When Obtaining Existing Data/Biological Specimens

This worksheet is being provided to investigators as a supplement to CPHS' Guidelines on [Research Involving the Secondary Use of Existing Data](#). It is intended to be used as a self-screening form and the questions below are important to consider when deciding if a research project requires IRB review. For further guidance, a formal determination, or if you have questions, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

1. **Is the study regulated by the Food and Drug Administration (FDA)?**

For example: A study testing the safety or efficacy of an in vitro diagnostic device using human specimens.

For more information about when a study is considered FDA-regulated, see: [What research falls under FDA regulations](#).

- If YES, this study will likely require IRB review.

2. **Are the data/specimens on the “shelf” (i.e., all data/specimens are currently existing)?**

- If NO, this study does not qualify as a secondary analysis of existing data/specimens study.

3. **Publicly-Available Data:**

Are the data truly publicly available?

Public data can be accessed freely without special permission or application (e.g., accessible by anyone on the Internet), and is not considered “private.” Private information is defined as information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical or school record).

Note: This excludes data accessed through the ‘Dark Internet.’ If data will be accessed through the ‘Dark Internet’, then this study will likely need IRB review.

- If YES, the data is truly publicly available, this study does not constitute research with human subjects and IRB review is not required.

4. **Restricted-Use Data:**

Certain agencies and research organizations release files to researchers with specific restrictions regarding their use and storage. This constitutes research with human subjects and typically requires non-exempt level IRB review.

For more information, see: the “Restricted Use Data” section beginning on page 3 of the CPHS' Guidelines on [Research Involving the Secondary Use of Existing Data](#).

5. Other Existing Data/Specimens:

I. De-identified Data

Will the data/specimens be completely de-identified?

For information about what constitutes identifiable information, see: [What constitutes “identifiable information”?](#)

➤ If YES, go to Part III (“Coded Data”) below.

II. Protected Health Information

Are the data considered protected health information (PHI) under HIPAA?

For information about what constitutes PHI, see: [What constitutes “identifiable information”?](#)

➤ If YES, the data set is considered PHI and any of the 18 identifiers are included, this research will require IRB review.

III. Coded Data

Will the data/specimens be coded?

Coded means that:

a. identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and

b. a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

➤ If YES, answer the following questions:

- i. *Will the key to decipher the code be destroyed before the data is received by the investigator?*
 - If YES, this study does not constitute research with human subjects and IRB review is not required.
- ii. *Is the key to decipher the code held by the investigator’s faculty advisor?*
 - If YES, the use of the data does constitute research with human subjects and typically requires non-exempt level IRB review.
- iii. *Will the investigator and the holder of the key enter into an agreement prohibiting the release of the key under any circumstances?*
 - If YES, then this study does not constitute research with human subjects and IRB review is not required.