IRB FAQ

What is secondary research, and does it require IRB review and approval?

Secondary human subjects research makes use of existing information (data) or biospecimens collected previously for a different purpose. The existing information or biospecimens may have been collected for a non-research purpose or for a different (IRB-approved) research study. Although secondary research projects do not involve interactions or interventions with human subjects (i.e., research participants), they may still require IRB review, since the definition of "human subject" at 45 CFR 46.102(f) includes **living individuals about whom an investigator obtains *identifiable private information for research purposes***. The following guidelines should help you determine if your secondary research study requires IRB review.

Secondary research that is <u>not</u> considered human subjects research and does not need IRB review or approval

If the information or biospecimens to be used in the secondary research study are not identifiable in any way **<u>and</u>** there is no way to link the information back to the subjects from whom it was collected, the research study does <u>not</u> meet the definition of human subjects research and does <u>not</u> require IRB review and approval. Two examples of this type of research would be the following:

1. ***Public data***: Public use data sets (e.g., portions of U.S. Census data, data from the National Center for Health Statistics, etc.) are prepared with the intent of making them publicly available. The data available to the public are not individually identifiable and therefore their use and analysis would not involve human subjects.

2. ***De-identified data***: If the dataset has been **stripped of all identifying information <u>and</u> there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means)**, its subsequent use would not constitute human subjects research, since it is no longer identifiable. Identifiable means the identity of the subject is known or may be readily ascertained by the investigator or person associated with the information. In general, information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that, by their nature, a reasonably knowledgeable person could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, and ethnicity). If you are not sure if your dataset contains identifiable information, please consult with the IRB or submit a proposal for review.

Secondary research that <u>is</u> considered human subjects research and requires IRB review and approval

If the information or biospecimens to be used in the secondary research study are identifiable, the researcher must obtain IRB approval before the information can be accessed. Similarly, if the information or biospecimens have been de-identified but may be readily linked to identifiers via a code or other mechanism, the researcher must obtain IRB approval before the information can be accessed.

As an example, if a student plans to analyze coded data from a faculty advisor/sponsor who retains a key, this would be human subjects research, because the faculty sponsor is considered an investigator on the student's protocol and can readily ascertain the identity of the subjects, since he/she holds the key to the coded data. Thus, if the student's work fits within the scope of the initial protocol from which the dataset originates, the faculty sponsor (or investigator who holds the dataset) may wish to consider adding the student and his/her work to the original protocol by means of a request to change an approved study rather than having the student submit a new application for review. If the student will be conducting a different or new study using the dataset, however, an IRB application must be submitted.

Most secondary research studies that require IRB review will qualify for either an exemption (Form A) or expedited review (Form B).

Exempt Research (Form A).

1. Research involving the collection or study of existing data, documents, and records can be exempted under Category 4 on the IRB Form A if: (i) the sources of the identifiable information and data are publicly available; or (ii) the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The latter condition of this category applies in cases where the investigators initially have access to identifiable private information but abstract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include direct identifiers (names, social security numbers, addresses, phone numbers, etc.) or indirect identifiers (codes or pseudonyms that are linked to the subject's identity). Furthermore, it must not be possible to identify subjects by combining demographic characteristics (e.g., date of birth, gender, position, and place of employment). This is especially relevant in smaller datasets, where the population is confined to a limited subject pool.

2. Research involving the use of existing information and/or biospecimens collected under the provisions for broad consent can be exempted under Category 8 on the IRB Form A. Please see the FAQ on broad consent for more information.

Non-exempt Research (Form B or C).

Research that intends to use identifiable information and/or biospecimens in a secondary research study without further consent from the research participants must be approved by the IRB. In most cases, this will involve expedited review (Form B) unless the study is of a particularly sensitive nature or uses identifiable information gathered from participants of a protected population (e.g., children). For all such applications, the researcher must request a waiver of consent from the IRB and must provide a justification for why the secondary research cannot be carried out using non-identifiable information or biospecimens.

Final note: For all IRB applications approved after the implementation of the federal government's Final Rule on January 21, 2019, researchers are required to indicate on their consent form whether or not the information/biospecimens collected might be used for future (secondary) research purposes. Consequently, human subjects information or biospecimens collected under protocols approved by the IRB on or after January 21, 2019 may not be used for secondary research studies under any circumstances unless the consent form from the original study specifically states that the information may be used in future research studies. **For secondary research studies that intend to use de-identified information and/or biospecimens from research protocols approved by the IRB on or after January 21, 2019, therefore, researchers must include with their IRB application a copy of the consent form that was used to collect the data originally so that the IRB may verify that participants were informed that the collected information may be used in future studies without additional informed consent.**