

PROJECTS USING SECONDARY DATA

The IRB realizes that some research involving existing data sets and archives may not meet the definition of human subjects' research and therefore would not require IRB review; however some may meet definitions of research and may require IRB review and approval.

Analysis of De-Identified, Publicly Available Data

The IRB recognizes that the analysis of de-identified, publicly available data does not constitute human subjects research as defined at 45 CFR 46.102 and that it does not require IRB review. Many studies utilize data made available through large data consolidation bureaus and consortiums. These include:

1. [Inter-University Consortium for Political and Social Research \(ICPSR\)](#)
2. [U.S. Bureau of the Census](#)
3. [National Center for Health Statistics](#)
4. [National Center for Education Statistics](#)
5. [National Election Studies](#)

The IRB does not require review of studies involving the analysis of data held by these organizations or similar organizations, unless a project merges multiple data sets and in so doing enables the identification of individuals whose data is analyzed.

Analysis of Non-Publicly Available Data with Restricted Access to Participant Identifiers (Coded Private Information)

The IRB recognizes that increasing numbers of studies involve the analysis of non-publicly available datasets that include coded private information or that are provided to researchers after the removal of identifying information. Further, a number of data holding organizations (e.g., Bureau of Labor Statistics, Centers for Disease Control, etc.) provide statistical analysis services for investigators that generate aggregated data from data sets with private identifying information. Many of these studies do not involve human subjects. Data use permissions vary widely across data sets and holders; as such, the IRB requests that investigators conducting studies using coded private information or contracting data holders for statistical analyses of data sets involving private information seek a determination from the IRB as to whether the study constitutes human subjects research. This request is made in accordance with guidance from OHRP concerning research involving coded private information.

For studies involving the analysis of coded private information or the analysis of private information by a third party on behalf of a research team, the IRB requests that investigators submit the following information:

1. Researcher's name, title, and department
2. Title and brief description of the research study
3. Name of data set/archive that will be used

4. Description of the data access or security plan to be implemented or required by the data holder.

If the IRB determines that the project does not constitute human subjects research the PI will be informed. If the IRB determines that the project does involve human subject research the investigator will be asked to submit an application for consideration by the IRB.

Analysis of publicly available data with private identifiable information or of non-publicly available data with private identifiable information where researchers will not record individual identifiers

Research involving the analysis of publicly available data containing private identifiable information or the analysis of non-publicly available data that will not be recorded by the investigator in a manner that allows the direct or indirect identification of individuals qualifies for Exempt review (45 CFR 46.101(b)4). Research involving these analyses requires the submission of an Exempt request application.

Investigators submitting protocols involving these research procedures are asked to provide the following information in their protocol submissions to aid the IRB in making a determination of exemption.

1. Description of data set and availability
2. Description of data to be accessed for analysis
3. Copies of any data use agreements required by data holder

Analysis of Non-Publicly Available Data Containing Private Identifiable Information

Research involving the analysis of non-publicly available data that contains private identifiable information about living individuals is considered by the IRB to constitute human subjects research that is not exempt from 45 CFR 46 and IRB review requirements.

Studies involving analysis of this form of data require review by the IRB. This review is conducted under expedited or full board review procedures in accordance with the IRB's review policies. Research involving these analyses requires the submission of an Expedited request or Full Board Application.

Investigators submitting protocols involving these research procedures are asked to include the following information in their protocol submissions to aid the IRB in its review.

1. Description of data set(s) to be analyzed
2. Copies of any data use or security agreements required by data holder
3. Description of data security and access procedures