



Institutional Review Board

Datasets Not Requiring SEU IRB Review¹

Policy:

The SEU Institutional Review Board recognizes that certain datasets are considered to not involve “human subjects” as defined by federal regulations and guidelines. The use of such datasets for research does not require IRB review or a determination of exempt status. As a service to researchers, the SEU IRB maintains a list of datasets it has evaluated as not involving human subjects.

Definitions:

- ***Publicly available:*** The general public can obtain the information. Datasets are not generally considered publicly available if access to the data is limited to researchers.
- ***De-identified:*** The data do not contain information that can be used to readily ascertain the identity of the individuals, nor to associate an individual with the information. This includes data that are anonymous or coded (when the user has no access to the link between the code and the identifiers, and when the code is not derived from or related to information about the individuals).

Purpose:

This document provides (1) a list of the datasets that the IRB has determined do not require IRB review or an exempt determination, and (2) guidance about the nature and use of these datasets.

Relevance:

Datasets on the list at the end of this document do not involve “human subjects” (as defined by federal regulations and guidance). Therefore, their use requires neither IRB review, an exempt determination, nor are users required to complete the NIH human subjects training.

Considerations:

Incomplete list: The list is provided as a service to researchers, by identifying datasets that have

¹ Much of the language and organization for this SOP was derived from the National Bureau of Economic Research (NBER).

already been vetted by the IRB. It is not intended to be a complete list of all datasets that do not involve human subjects. Researchers are welcome to consult with the IRB Chair about other datasets.

Exceptions: The following uses of the datasets listed below require prior IRB review or a determination of exempt/expedited status:

- Merging datasets in such a way that individuals may be identified.
- Enhancing a dataset with identifiable or potentially identifiable data.
- Research that consists of using one or more datasets on this list and also (1) the collection or use of private, identifiable data and/or (2) interactions or interventions with humans.

Data Use Agreements: The dataset holder may require the researcher or the researcher's institution to sign a Data Use Agreement (DUA) that explicitly requires IRB approval or an exempt/expedited determination. This condition of use must be honored, even for datasets on this list.

- NIH dbGaP Controlled Access datasets are a common example. Federal regulators have advised NIH that the use of either public access or controlled access dbGaP datasets is not human subjects research because the data are coded and the identity of individuals from whom the data were obtained are not be readily ascertainable. However, in IRB's experience, NIH frequently requires IRB approval as part of the use agreement.
- The IRB will provide the documentation of IRB approval or exempt status. However, the IRB is not authorized to sign DUAs. DUAs that require an institutional signature should be signed by Danny Lorenty, Vice President for Institutional Effectiveness and Technology.

DATASETS whose research use does not require IRB review or an exempt determination:

- Afrobarometer
- Asian Barometer Survey
- Eurobarometer
- European Social Survey (ESS)
- Healthcare Cost and Utilization Project (H-CUP) healthcare databases
 - The Nationwide Inpatient Sample (NIS)
 - The Kids' Inpatient Database (KID)
 - The State Inpatient Databases (SID)
 - The State Ambulatory Surgery Databases (SASD)
 - The State Emergency Department Databases (SEDD)
- Inter-University Consortium for Political and Social Research (ICPSR)

- Latin American Public Opinion Project (LAPOP) Lab
 - AmericasBarometer
- Latinobarómetro
- National Cancer Institute Surveillance Epidemiology and End Results Program(SEERS)
- National Center for Health Statistics
 - NHANES: National Health and Nutrition Examination Survey
 - NHCS: National Health Care Survey
 - NHIS: National Health Interview Survey
 - NIS: National Immunization Survey
 - LSOAs: Longitudinal Studies of Aging
 - NSFG: National Survey of Family Growth
 - SLAITS: State & Local Area Integrated Telephone Survey
 - Vital Statistics: National Vital Statistics System
- National Center for Education Statistics
- National Hospital Ambulatory Medical Care Survey (NHAMCS)
- National Longitudinal Survey (NLSY)
 - National Longitudinal Survey of Youth 1997 (NLSY97)
 - National Longitudinal Survey of Youth 1979 (NLSY79)
 - NLSY79 Children and Young Adults
 - National Longitudinal Survey of Young Women and Mature Women
 - National Longitudinal Survey of Young Men and Mature Men
- Survey of Consumer Finances (SCF)
- U.S. Bureau of the Census
 - Census
 - American Community Survey (ACS)
- U.S. Bureau of Labor Statistics
- World Values Survey (WVS)