

GUIDANCE ON PUBLIC USE DATA FILES

It is IRB policy that research that only involves secondary analysis of pre-approved public data files does not require IRB approval, as it does not constitute human subject research as defined in 45 CFR 46.102.

Such public use data files must adhere to the following rules:

- a. the data file must be publicly available to any researcher through unlimited access or via a member institution or for a fee;
- b. the original data collection was gathered in anonymous form or on unknown persons, or the original data collection was gathered on identified subjects but the data file has been stripped of direct identifiers and indirect identifiers that may risk disclosure of subjects' identity; and
- c. a formal disclosure analysis was performed to reasonably prevent the identification of individual subjects using variables within the database.

The following databases are recognized as public use databases:

- Inter-University Consortium for Political and Social Research (ICPSR)
- U.S. Bureau of the Census
- National Center for Health Statistics
- National Center for Educational Statistics
- Centers for Disease Control and Prevention
- National Election Studies
- Roper Center for Public Opinion Research

The IRB staff should be consulted if there are any doubts about the applicability of this policy to other databases.