

Public Data Sets

Projects that only involve secondary data analysis of data sets with identifiable information but do not involve interactions or interventions with humans, **still require IRB review**, because the definition of “human subjects” at 45 CFR 46.102(f) includes living individuals *about whom an investigator obtains identifiable private information for research purposes*.

Projects that use de-identified data sets only, and do not involve interactions or interventions with humans, would not require IRB review; however, only the IRB may make that determination.

Secondary analysis of restricted data (e.g. data that require a data use agreement, obtain permission to access, etc.) requires IRB review.

If a research study involves secondary analysis of publicly available data (de-identified) and utilizes additional procedures/methods that do meet the criteria of human research, the entire project must be submitted for IRB review.

The use of public use data (de-identified) will require IRB review if:

- Research involves merging of any of the data sets in such a way that individuals might be identified, or
- The researcher will expand the public data sets with identifiable, or potentially identifiable data.