



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 802
Research Involving Secondary Data

Purpose

The purpose of this document is to describe when research involving existing data may require IRB review. Whether analysis of the secondary data requires IRB review turns in great part on whether the data is ‘identifiable’ data may contain director identifiers or indirect identifiers.

Scope

This SOP applies to all members of the University of South Alabama, the USA IRB and associated administrative staff.

Applicability

This SOP applies only to activities that involve the secondary analysis of existing data, such as public data sets, medical records, student records, data collected from previous studies including audio/video recordings, etc. that were initially collected for another purpose.

Definitions

Identifiable Information: Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Policy

Although projects that only involve secondary data analysis do not involve interactions or interventions with humans, they may still require IRB reviews, as 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*.

Existing data or specimens are those which have been collected previously for research or non-research purposes, and are in existence at the time of initial submission to the IRB. In order to be existing, the information must be “on the shelf” (i.e., it has already been collected) at the time the current research is proposed. Existing data are also called **Secondary data**. Existing data may be from another source (another investigator or institution) or have been collected by the project investigator for another purpose. Students collecting data for classroom projects should provide an application to the IRB office in advance if they intend to generalize the results instead of providing the existing data form on a post-hoc basis.

Determining whether research using existing data requires IRB review depends on the type of data, access to the information, and whether the information is individually identifiable. If data is open to the general public without restriction, or if the information is de-identified, then IRB review and approval is not necessary. If access to the data is limited, such as to persons with certain credentials, members-only, or if a data use agreement is required to access the data, the research may require IRB review and approval.

1.0 Additional Analysis by the Same Research Team

Additional analysis of data that falls within the scope of the original IRB application and consent document does not require review by the IRB. Additional analysis of data that does not fall within the scope of the original IRB application and/or consent form does require submission of an existing data application to the IRB. Researchers should contact the IRB office with any questions about whether their additional analysis is within the scope of the originally approved research.

2.0 Analysis of De-Identified, Publicly Available Data

The analysis of de-identified, publicly available data does not constitute human subjects research as defined at 45 CFR 46.102 and therefore does not require IRB review. The IRB does not require review of studies involving the analysis of existing data (if publicly available and de-identified).

3.0 Analysis of Publicly or Non-Publicly Available Data with potential access to Participant Identifiers

Some studies may involve the use of datasets that include coded private information or that are provided to researchers after the removal of all identifiers. If the information

provided to researchers is not identifiable, the study does not meet the federal definitions of human subject's research under 45 CFR 46. Research involving the analysis of private identifiable information, but where identifiable information will not be recorded by the investigator, may qualify for exempt review under 45 CFR 46.101(b)4. Researchers must submit the necessary protocol application to the IRB for the formal determination of exemption.

4.0 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 constitutes human subjects research. Studies involving analysis of this form of data require review and approval by the USA IRB office.

Situations can vary widely across data sets, holders, and access, so investigators conducting studies involving the use of existing data should consult with the USA IRB to determine whether the study constitutes human subjects research.

Procedures

1.0 Consent

Researchers using data previously collected under another study should consider whether the currently proposed research is a compatible use with what subjects agreed to in the original consent form. For nonexempt projects, a consent process description or justification for a waiver must be included in the research protocol. The IRB may require that informed consent for secondary analysis be obtained from subjects whose data will be accessed. Alternatively, the IRB can consider a request for a waiver of one or more elements of informed consent under 45 CFR 46.116(d).

When formulating the project, the Investigator should consider whether the project meets the federal definitions of research with human subjects:

- If yes, investigators must submit an IRB Exempt Application for IRB review and approval via IRBNet.
- If no, IRB review is not required. If funders, publications or other entities require formal documentation, the Investigator must submit either an IRB Exempt Application via IRBNet or request that the IRB provide a human subject's determination status via email and the IRB Office will issue a letter of determination.

Regulations

45 CFR 46.101(b); 21 CFR 56.104

References

HISTORY

Original: November, 2018

Revisions: