

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

Regulations

45 CFR 46.101(b); 21 CFR 56.104

References

HISTORY

Original: November, 2018

Revisions: