## SOP 1.2.3 Research with Existing Data

**General Description:**

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.. 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.

*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.

*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 it is publicly available and de-identified.

*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 subjects 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 46.104(d)4. Researchers must submit the necessary protocol application to the IRB for the formal determination of exemption.

*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 IRB office and/or IRB.

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

*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 non-exempt 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(f)(3).

**Procedures:**

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

1. If yes, investigators must submit an Existing Data application for IRB review and approval through IRBNet.
2. If no, investigators are encouraged to submit the Human Subjects Determination form. If funders, publications or other entities require formal documentation, the PI must submit either the Human Subjects Research Determination Form or the Existing Data application to the IRB through IRBNet and the IRB office/IRB will issue formal documentation.

**Related Forms, Guidance, and SOPs:**

- 45 CFR 46.101
- 21 CFR 56.104
- Based on Guidance from University of Missouri, "Secondary Data Projects"

**Responsibility:**

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff

**Approval and Version History:**

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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| **Date First Effective:** | November 19, 2014 |
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| **Current Version #:** | 3 |

| Approved By | Title and Division | Date Approved |
|---|---|---|
| Aurali Dade | Associate Vice President, Research Development, Integrity and Assurance | January 21, 2019 |
| Laurie Meamber | IRB Chairperson | January 21, 2019 |