

V. MISCELLANEOUS CATEGORIES OF RESEARCH

International Research

Research in foreign countries presents special concerns regarding the rights and welfare of human participants.

- All human participants research in foreign countries must be reviewed by the full IRB, regardless of the nature of the research.
- All materials, including consent forms, must have English language translations included with the protocol.
- Documentation of permission from local authorities is generally required before approval can be granted.
- Each site must have a federal-wide assurance on file with The Office for Human Research Protections. In certain circumstances, a Memorandum of Understanding may be used instead of the federal-wide assurance.

Survey Research

A survey may cause emotional upset or worries about breach of confidentiality. Although most questionnaire studies do not require a signed consent form, researchers must still ensure that participants are given informed consent to participate in the study. All questionnaires must include a cover sheet or instructions to participants that provides them with the same information that would be included in a consent form.

Secondary Analysis of Existing Data Research

“Existing” data is defined as information already collected at the time the research is initiated. When submitting a protocol for secondary analysis of existing data, the researcher must provide the following information: Name of data set; Where the data were obtained; What information is being extracted; If the data are available publicly or if permission must be obtained; Documentation of permission to use the data (if applicable); If there are identifiers/links to identifying information and Procedures for storage and disposal of data.

Research that involves secondary analysis of **public use data sets** is exempt, if it falls under certain criteria. The IRB has final responsibility for determining whether a data set falls under this category or needs a full protocol.

The IRB recognizes that the term “**meta-analysis**” may mean different things in different fields. In the social sciences, the term is commonly used to describe an analysis and summary of a number of published studies using **ONLY** data that are reported in published form; there is no analysis of raw data. Because it involves neither contact with human participants nor secondary analysis of raw data, this type of meta-analysis does not need to be reviewed by the IRB. **HOWEVER**, if the meta-analysis involves any analysis of newly collected data, with or without identifiers, it **MUST** be reviewed by the IRB.