Determining the Need for IRB Review from

Definitions and Scenarios

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Definitions

Determining Whether your Research is Human Subject Research

Review the definitions of "research" and "human subject". If your work meets the definition of *research* and involves *human subjects,* it must be reviewed and approved by the IRB. If it appears that your research does not meet these definitions, speak with the IRB Chair prior to submitting an application for review. Determination that your research does not constitute research with human subjects is made by the IRB.

"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45CFR46.102(d)

"Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or

2. Identifiable private information

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes 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). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects," 45 CFR 46.102(f)

Analysis and Meta-Analysis Scenarios

Researchers interested in reviewing and consolidating the results of many studies on a given phenomenon may choose to meta-analyze these results. There are several different statistical procedures researchers can use to complete a meta-analysis. Most of these focus on measures of effect size. Often the data are drawn from study results of published and unpublished data. Some data may be analyzed from previously collected data. This data may be from a publicly available database or may be from a private data base collected by a single researcher or a group of researchers. Below are different scenarios for dealing with the IRB and human subject issues.

Scenario 1

The data to be meta-analyzed are summary data (effect sizes, sample sizes, test reliabilities, significance tests) and were previously published, presented at a conference, or provided to the researcher by the original researcher(s). This study requires certification by the IRB that no human subjects are involved. Investigators should speak with the IRB Chair.

Scenario 2

The data to be analyzed includes summary data that were previously published, presented at a conference, or provided to the researcher by the original researcher(s), as well as data analyzed from raw data sets that are publicly available (U.S. Census data, National Longitudinal Study). Publicly available raw data sets are those that are available to all researchers and the data are recorded without individual identifiers. Use of privately available new data sets requires certification of exemption or expedited review by the IRB. Speak with the IRB Chair prior to submitting an application to the IRB.

Scenario 3

The data to be analyzed includes summary data that were previously published, presented at a conference, provided to the researcher by the original researcher(s), raw data from publicly available data sets (U.S. Census data, National Longitudinal Survey), as well as raw data made available by another researcher or group of researchers. The researcher should request that the raw data be provided with no identifying information. This study requires certification by the IRB that no human subjects are involved. Investigators should speak to the IRB Chair.

Pre-Existing Data Scenarios

Federal Exemption and Expedited Categories Related to Pre-Existing Data

Exemption

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Expedited

Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis.) (NOTE: Some research in this category may be exempt from the regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

Scenarios

1. Data collection was initiated, but not completed, in a country that has no regulations concerning the protection of human subjects. Thus, the project was not reviewed by an IRB and informed consent was not obtained from subjects.

    - ❖ Researcher wants to continue with data collection in the same country.

    - Subjects are identifiable
      Procedure 1 – Submit application for review

    - Subjects are not/will not be identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
      Procedure 1 – Submit application for review

    - ❖ Researcher wants to collect additional data in another country.

    - Subjects are identifiable
      Procedure 1 – Submit application for review

    - Subjects are not/will not be identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
      Procedure 1 – Submit application for review

2. Data has been collected. Researcher wants to begin data analysis. Data was collected in a country that has no regulations concerning the protection of human subjects. Thus, the project was not reviewed by an IRB and informed consent was not obtained from subjects.

    - Subjects are identifiable.
      Procedure 1 – Submit application for review

    - Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
      Procedure 2 – Speak with IRB Chair prior to submitting application for review

3. Data has been collected and data analysis completed. Researcher wants to prepare an article for publication. Data was collected in a country that has no regulations concerning the protection of human subjects. Thus, the project was not reviewed by an IRB and informed consent was not obtained from subjects.

- Subjects are identifiable
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

- Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

4. Data was collected and analyzed several years ago. Researcher wants to prepare an article for publication. IRB approval was obtained originally, but the approval period has terminated.

- Subjects are identifiable
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

- Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

5. Data was collected and analyzed several years ago. Researcher wants to re-analyze the data. IRB approval was obtained.

- Subjects are identifiable
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

- Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

6. Data was collected and analyzed several years ago. Researcher wants to re-analyze the data. IRB approval was never obtained.

- Subjects are identifiable
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

- Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

7. Data collection, data analysis and dissertation have been completed. IRB approval was obtained originally, but the approval period has terminated. Researcher wants to re-analyze the data which are individually identifiable. Researcher will record the data in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects and destroy the original, identifiable data.
Procedure 1 - Submit application for review

8. Data has been collected. The period of IRB approval has terminated. Researcher wants to analyze the data.

- Subjects are identifiable
  Procedure 1 – Submit application for review

- Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

9. Data collection was initiated, but not completed. The project was approved by the IRB of another institution and the approval period has not terminated. It is anticipated that the data collection process must extend beyond the initial approval period.
   Procedure 1 – Submit application for review

10. Data collection, analysis and article preparation were completed. Article was not published. Researcher wants to submit the article, with revisions, for publication.

- Subjects are identifiable
  Procedure 2 – Speak with IRB Chair prior to submitting application for review

- Subjects are not identifiable through direct identifiers or indirect identifiers (codes or other identifying data contained in the survey or subjects' responses.)
  Procedure 2 – Speak with IRB Chair prior to submitting application for review