

## Guidelines for Writing a Banking/Repository Protocol

A complete description of the proposed banking activity (i.e., protocol) must be submitted with the "Initial Review of Human Subjects Research" application for IRB review. The research protocol should provide IRB members with the information needed to determine that regulatory and Human Research Protection Program (HRPP) policy requirements have been met. There is no required format or template; different sections and formatting may be used, provided the necessary information is included.

For additional information (including information on informed consent for banking, storage, and security), please see HRPP policy, [Research Involving Data and/or Biological Specimens](#).

### I. Objectives

Clearly state the purpose and/or reasons for creating the bank/repository.

### II. Background and Rationale

As applicable, summarize the available research/resources (including published data) to provide justification for creating the bank. Describe the significance of the banking project, including potential benefit for individual participants, the field of study, and/or society.

### III. Type(s) of Data/Specimens to be Collected and Stored

Provide a detailed description of the information/materials to be collected and stored. Include whether personal identifiers will be retained and/or linked to the data and/or specimens.

### IV. Procedures

Include/consider the following:

#### A. Sample (Population)

- Explain the circumstances and source(s) of data/specimen collection (e.g., obtained directly from participants, from a secondary source, etc.). For banking of previously collected materials, include as much information as possible regarding the original collection/source.
- Describe the characteristics of the participants whose materials will be included in (and, as applicable, excluded from) the bank, and include the total number of participants from whom data/specimens will be obtained.

#### B. Recruitment Process

- Describe the procedures that will be used to identify, recruit, and/or screen participants, as applicable.
- Note: All recruitment materials to be used (ads, postings, scripts, letters, websites, etc.) must also be submitted for IRB review.

#### C. Consent Process

- Explain the process for obtaining informed consent (or, for children, parental permission) for collection of data and/or biological specimens that will be stored for future research. Note: Assent (from those who cannot provide informed consent themselves) may also be required.
- Include plans to obtain HIPAA research authorization when the data collected include protected health information.

- If children will be enrolled, include plans to obtain their informed consent once these participants become adults if data/specimens will continue to be used.
- Note: All materials to be used (consent forms, assent forms, permission forms, consent scripts, etc.) must also be submitted for IRB review.

#### **D. Collection Procedures**

- Provide a detailed description of all processes/interventions involved in the data/specimen collection.
- Note: All materials to be used (instruments, questionnaires, interview guides, data collection forms, etc.) must also be submitted for IRB review.

#### **E. Storage Procedures**

- Describe the governance and/or oversight structure of the bank. Discuss the roles and responsibilities of individuals involved in the bank's management and operations.
- Describe how the data/specimens will be stored, i.e., if they will be identifiable, coded, or de-identified. For definitions of these terms, see [Research Involving Data and/or Biological Specimens](#).
- Include the physical location/equipment and security provisions for data/specimen storage. For more information regarding requirements for handling data, see university policies, [Policy on Institutional Data](#) and [Research Data Policy](#).
- Provide the length of time data/specimens will be stored.
- Describe the procedures to withdraw participants' data/specimens from future research. Include methods for tracking participants' decisions regarding data/specimen use.
- Include a plan for continuing repository operations in the absence (or departure) of the principal investigator (as applicable).
- Include the process for destruction or de-identification of identifiable or coded data/specimens at the end of the retention period (as applicable).

#### **F. Procedures for Releasing Data/Specimens**

- Discuss any limits on data/specimens' intended future use (e.g., for cancer research only).
- Include with whom data/specimens may be shared (including non-Ohio State researchers, commercial entities, etc.).
- Describe the process for requesting and releasing data/specimens. Note: All materials to be used (e.g., applications to access materials, data use agreements, etc.) must also be submitted for IRB review.
- Explain how data/specimens will be released (i.e., identifiable, coded, or de-identified). Outline the safeguards to ensure that materials are properly released and that confidentiality is not compromised.
- Include the process for verifying a requesting investigator's approval (and consent/HIPAA authorization, as applicable) to access the materials.
- Address the process for handling incidental findings.

#### **V. Bibliography**

Include a reference list of literature cited.