Databases and repositories (sometimes called registries, banks, libraries, or contact lists) are used to store data and/or biospecimens for future use. When the use is for clinical purposes or quality improvement (QI), IRB approval is not required. However, when the use is for research purposes, the databases/ repositories must be approved by the IRB.

Helpful Tools:

- Expedited Research Protocols
- Exempt Determinations
- Human Subjects Research Determinations
- Definitions of Identifiable, Limited, Coded, and De-Identified Data Sets

WHAT IS A DATABASE?

- A collection of health information/data
- Data is maintained over time
- Access to the data is controlled
- Multiple individuals may use this information for a variety of objectives
- The data may be identifiable or coded

WHAT IS A REPOSITORY?

- A collection of biospecimen
- Biospecimen are maintained over time
- Access to the biospecimen is controlled
- Multiple individuals may use this information for a variety of objectives
- The biospecimen may be identifiable or coded

**Storage of biospecimen and health information/data is considered both a database and repository.*

WHEN DOES A DATABASE OR REPOSITORY REQUIRE IRB REVIEW?

- When the principal purpose is research; and,
- The data and/or biospecimen will be used by the PI/study team, other researchers in the University, or researchers at other institutions

WHAT TYPE OF APPLICATION SHOULD I SUBMIT TO THE IRB FOR A DATABASE OR REPOSITORY?

The study team should submit a new Expedited application to the IRB for review, even if the data and/or biospecimen will be de-identified.

The IRB approval is only for the creation of the database or repository. Use of the stored data and/or biospecimen for a research project requires a separate submission to the IRB. Each project will need its own approval or determination

WHAT SHOULD I SUBMIT TO THE IRB IF I WANT TO USE DATA AND/OR BIOSPECIMEN STORED IN A DATABASE OR REPOSITORY?

The IRB wants formal documentation of all projects taking place using data and/or biospecimen from a research database or repository, even if the information is de-identified.

If the data and/or biospecimen you will receive is identifiable or coded, you should submit either an Exempt or Expedited application depending on if you will destroy the identifiers/code at the end of the study.

If the data and/or biospecimen you will receive is completely de-identified AND neither you nor anyone else on the study team will have access to identifiers, you should submit a Non-Human Subjects Research Determination.

OUTLINE FOR A TYPICAL DATABASE PROTOCOL

1. Background Information and Rationale
    a. Introduction
    b. Compliance Statement
    c. Relevant Literature and Data
2. Study Objectives
    a. Primary Aim
    b. Secondary Aim(s)
3. Investigational Plan
    a. General Schema of Registry/Repository Design
        i. Sites Involved
        ii. Total number of subjects projected
        iii. Overview of Collection
    b. Study Duration
    c. Study Population
        i. Inclusion Criteria
        ii. Exclusion Criteria
        iii. Justification for Collection of Vulnerable Population Data
4. Study Evaluations and Measurements
    a. Medical Record Review/PHI Elements Collected
    b. Questionnaires, Surveys, Interviews
5. Registry/Repository Administration
    a. Data Collection and Management
        i. Storage of Data
        ii. Confidentiality
    b. Sharing Data with Future Investigators
    c. Regulatory & Ethical Considerations

OUTLINE FOR A TYPICAL REPOSITORY PROTOCOL

1. Background Information and Rationale
    a. Introduction
    b. Compliance Statement
    c. Relevant Literature and Data
2. Study Objectives
    a. Primary Aim
    b. Secondary Aim(s)
3. Investigational Plan
    a. General Schema of Registry/Repository Design
        i. Sites Involved
        ii. Total number of subjects projected
        iii. Overview of Collection
    b. Study Duration
    c. Study Population
        i. Inclusion Criteria
        ii. Exclusion Criteria
        iii. Justification for Collection of Vulnerable Population Data
4. Study Procedures
    a. Screening
    b. Specimen Collection
    c. Subject Completion/Withdrawl
5. Study Evaluations and Measurements
    a. Medical Record Review/PHI Elements Collected
    b. Questionnaires, Surveys, Interviews
    c. Biospecimen and Collection Procedures
6. Registry/Repository Administration
    a. Data Collection and Management
        i. Storage of Data
        ii. Confidentiality
    b. Biospecimen Collection and Management
    c. Sharing Data and Specimen with Future Investigators
    d. Regulatory & Ethical Considerations