**STANDARD OPERATING PROCEDURES**

**FOR A RESEARCH [TISSUE OR DATA] BANK**

**TEMPLATE**

**PURPOSE**

This guidance document may be used as a resource for investigators who wish to develop standard operating procedures in order to establish a research [tissue or data] bank, otherwise known as a repository.

This guidance applies to activities that include the collection and storage of blood, tissue, or other biological materials (excluding embryos\* or embryonic stem cells\*) and/or health data that will be used by a single investigator or shared with multiple investigators for future research not yet defined, including genetic (but not stem cell\*) research.

This guidance does not apply to the collection and storage of specimens or data as part of a single IRB-approved protocol for defined research purposes.

\*Contact your local IRB office if you need guidance on IRB review of research with or ‘banking’ of embryos, embryonic stem cells or stem cells.

##### STUDY INFORMATION

Principle Investigator Name:

Study Title:

Date Created:

##### HELP

<https://orra.rutgers.edu/contactus>

# Administrative

Provide business information about the research [tissue OR data] bank as outlined below, including funding source(s). Clarify if it is a freestanding entity, virtual, or part of an institution. If ownership is an incorporated entity, please also identify all persons who hold ownership interest in it.

Identify and provide contact information for the person serving as Director. The Director is responsible for all aspects of the operation of the repository, to the IRB and, ultimately, to subjects. The Director is otherwise known as the “Principal Investigator”.

* Repository Name, Location, Address, Telephone
* Ownership
* Funding source(s)
* Director Name, Contact Information

# Research [Tissue OR Data] Bank Purpose of Operation

A research [tissue OR data] bank is defined as an entity that receives, stores, processes and/or disseminates [specimens and/or health information], as needed, for future research. It includes the physical location as well as the full range of activities associated with its operation. In this section, outline the mission or purpose of your proposed [tissue OR data] bank, the types of [specimens and/or data] to be collected, scope of research foci (i.e., diseases, conditions or processes), anticipated volume of its holdings, the scientific value of its collection and known or potential risks of harm or benefit to the subjects providing specimens and/or information. If this is a Research Tissue Bank, identify which, if any, samples are pre-existing—tissue collected solely for clinical purposes that are no longer needed for patient care, and any tissue in a pre- existing research tissue bank—and whether any samples are from deceased persons. If the specimens to be collected include known pathogens, please note that here and be sure to outline precautions to be taken to prevent contagion in the sub-section labeled “Biosafety”.

# Statement of Purpose

* Biological Materials (Specimens) and/or Data to be Collected
* Capacity (Size/Volume of Holdings)
* Scientific Value of Proposed Collection
* Known and/or Potential Risks of Harm and Benefit

## Research [Tissue or Data] Bank Plan of Operations

Outline the operations of the research [tissue or data] bank as highlighted below.

### Table of Organization/Operation

Provide a table of organization/operation that delineates all key personnel positions necessary to ensure proper oversight and functioning of the activities necessary to create and maintain the research [tissue or data] bank. Include job descriptions for each key position. Identify the names of individuals who serve in key personnel position. Please indicate the position/person serving as the honest broker (see data management section below).

**[Specimen and/or Health Information] Collection**

In this section specify how [specimen or health information] collection will be accomplished. (If this is a Research Tissue Bank, be sure to outline collection procedures for each type of specimen collected.

**[Specimen and/or Health Information] Sources**

Research Tissue Bank: i.e., patients, deceased persons, preexisting samples, etc. Research Data Bank: i.e., lab reports, counseling records, intake forms, etc.

### Collection & Collection Locations

Outline collection procedures and identify collection locations. Also, indicate the personnel responsible for collection tasks identified in this section.

### Eligibility Criteria

List the inclusion and exclusion criteria for subject participation in the research [tissue OR data] bank and provide a justification for same. [Specimens and/or health information] collected should reflect the demographic characteristics and diversity of the population appropriate to the scientific goals of the research [tissue OR data] bank outlined in the Purpose of Operation.

### Minority and Vulnerable Populations

The burdens and benefits of research must be fairly distributed among the populations that stand to benefit from it. No group of persons—women, pregnant women, children, minorities—should be categorically excluded from the research without a good scientific or ethical reason to do so. Note any additional efforts you will take to overcome any anticipated barriers to participation (i.e., language, access, etc.).

### Recruitment Plan

Explain the activities used to generally recruit subjects to participate in the research [tissue OR data] bank. Itemize specific consent procedures in the Consent section.

### Non U.S. Specimen and/or Health Information Sources

If [specimens and/or health information] will be included that derives from persons living outside the United States, provide a justification for their inclusion and outline the international laws that permit such a transfer of [specimens and/or health information].

## Specimen Processing and Annotation

Specify how specimen processing and annotation will be accomplished. Also, indicate the personnel responsible for processing and annotation tasks identified in this section. (Skip this section if you are developing a Research Data Bank.)

* Processing
* Specimen Characterization and Quality Control Testing Data Collection and Specimen Annotation

#### Specimen Storage

Specify how specimen storage will be accomplished. Be sure to construct SOPs specific to each type of specimen to be collected. Also, indicate the personnel responsible for storage tasks identified in this section. (Skip this section if you are developing a Research Data Bank.)

##### Number and Types of Specimens in Storage

##### Storage Techniques

* Freezer Maintenance and Backup
* Quality Control, Auditing and Standardization for Specimen Storage

**[Specimen and/or Health Information] Distribution**

In this section specify how [specimen and/or health information] distribution will be accomplished. Outline the role of the Honest Broker in this process (see Data Collection & Records Management Section for the role of the Honest Broker). Also, indicate the personnel responsible for distribution tasks identified in this section.

**Researcher Access Qualifications and IRB Requirements**

Describe who may have access to specimens and/or health information. Outline what procedures are in place to assure individual research projects will only be conducted with prior IRB review and approval.

### Shipment & Tracking of [Specimens and/or Health Information] to Researchers

### Fees

## Biosafety

Specimen handling—collection, storage and distribution—expose personnel to risks involving infectious agents and chemicals. Outline your standard operating procedures to assure employee safety to prevent exposure and policies and procedures should an exposure incident occur.

PLEASE NOTE: Institutional Biosafety Committee review and registration is required for all research and/or clinical laboratories whose personnel work with pathogens, potentially infectious materials, human and non-human primate blood, fluids, and tissues, human cell lines, select agents and toxins, and rDNA.

For All Campuses: <http://rehs.rutgers.edu/biosafety.php>

(Skip this section if you are constructing a Research Data Bank.)

# Data Collection and Records Management

In order to assure usefulness for scientific research, a robust records management system and responsible custodianship are necessary—careful planning, adequate and accurate information about [specimens and/or health information], procedures to assure the privacy of research subjects and confidentiality of their personal and protected health information. Describe your data collection and records management system here.

### Types Of Data To Be Collected

Identify the types of private and protected health information and clinical data to be collected and demonstrate how their collection is relevant and necessary to the research goals of the research [tissue OR data] bank outlined in the Purpose of Operation Section.

### Data Collection Techniques

Highlight procedures for the performance of each step in the collection, processing, storage and security of data collected. Records must be created and maintained in a manner that allows all steps to be clearly traced and ensure [specimen and/or health information] chain of custody. Append examples of log forms to be used, as applicable.

### Data Storage Techniques

Provide a description of where and how [specimens and/or health information] will be coded and linked to subjects’ personal identifying information, and how such information will be protected. Define when identifiers (such as HIPAA identifiers or the code(s) linking the [specimens or information] to identifiers will be destroyed.

Identify the software platform(s) that will be used to track all phases of [specimen and/or health information] acquisition, processing, storage, handling, QA/QC, and distribution. If the system is non-standard/custom, please describe its capabilities. An informatics system should be robust and reliable to sustain, not only day-to-day operations, but be able to meet changing technologies and scientific needs. Interoperability of systems is critical to data and specimen exchange.

### Data Destruction Requests

Include procedures that respect subjects’ wishes to have their [samples and/or health information] removed or destroyed and document such removal/destruction.

**Record Retention**

Unless otherwise specified by contract, policy or regulation, establish a period of time during which all records are retained. A policy should also be in place for the destruction or return of records that no longer need to be retained.

### Data Encryption and Security

Security systems should be adequate to ensure the confidentiality and security of all stored records and demonstrate HIPAA compliance http://privacyruleandreseach.nih.gov/reearch\_repositories.asp. Paper files containing confidential or otherwise protected health information about subjects should be stored in locked, fire and water proof enclosures with controlled access.

### Honest Broker

An honest broker is the individual in the organization with the authority to act on behalf of an organization to link research identifiers and clinical identifiers in order to provide data, specimens or images to researchers without revealing the identity of subjects. The honest broker cannot be a member of the clinical or research team. Identify the position/person assigned as the honest broker and outline the policies and procedures that enable the honest broker to perform his/her function.

### Data Use Agreements

Data Use Agreements outline the terms and conditions under which the research [tissue or data] bank will disclose subjects’ protected health information in the form of a limited data set to the data recipient(s), such as sponsors, co-operating institutions and/or researchers. The terms “protected health information” and “limited data set” shall have the same definitions as found in the HIPAA Privacy Rule 45 CFR 164.501 and 45 CFR 164.514(e)2. <http://privacyruleandresearch.nih.gov/>

### Material Transfer Agreements

Material Transfer Agreements specify the rights, obligations, and restrictions of both the providing and receiving institutions with respect to issues such as ownership, publication, intellectual property and permitted use liability.

Contact the *Rutgers Export Control Unit* for instruction on how to develop Rutgers-approved Material Transfer Agreements. <https://orra.rutgers.edu/exportcontrol>

**Certificate of Confidentiality (if applicable)**

Certificates of Confidentiality, issued by the National Institutes of Health to protect identifiable research information from forced disclosure, may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. Certificates of Confidentiality allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level.

They help protect researchers and institutions from being compelled to disclose information that would identify research subjects, and assure confidentiality and privacy to subjects. Indicate whether you plan to secure a Certificate of Confidentiality from the National Institutes of Health.

Learn more at <http://grants.nih.gov/grants/coc/contacts.htm>.

## Consent Process

Informed consent, required by federal law (45 CFR 46 Subpart A), aims to respect persons’ rights to autonomy by presenting potential subjects with sufficient information to make an informed decision to participate in research studies and research tissue or data banks that lead to research studies. Consent information should describe the nature, purpose and activities of the research [tissue or data] bank and should be as specific as possible. You may find a template to guide your efforts at <https://orra.rutgers.edu/formsandtemplatesirb>.

If consent will be obtained, not by agents/employees of your research [tissue OR data] bank, but by other researchers, organizations or collections locations, outline your procedures for obtaining evidence of subject consent, use preferences and permissions, and requests for discontinuation of participation. Regardless of the level of involvement of your bank in the informed consent process, you must ensure that the research uses of [specimens and health information] are consistent with the documented wishes of the subjects.

Disregard the sections on consent, assent and surrogate consent if [specimens and/ health information] will be de-identified by the sending entity/organization/collection location prior to receipt by the research [tissue OR data] bank.

### Consent

Outline how, where and by who informed consent will be obtained from subjects providing [specimens and/or health information]. Describe the timing and context of consent (e.g., a week before surgery) and how long subjects will be given to consider participation (e.g., day of surgery). Describe the qualifications and experience of the individuals who will obtain consent (e.g., genetic counselor, physician, clinical coordinator, etc.) and the availability of the principal investigator(s) to answer additional questions/concerns if necessary. Identify how and where your consent procedures will be documented.

### Assent & Re-Consent

If minors will be invited to participate in the bank, provide the same information outlined at the Consent section found above and your procedures for re-consent at the age of majority (age 18 in New Jersey), as applicable.

### Surrogate Consent

Inviting participation by persons unable to consent on their own behalf is usually not appropriate since there are no direct benefits to the individual. However, if you propose to obtain [tissue and/or health information] from persons who have surrogate representation, please see <https://orra.rutgers.edu/hspp-guidance-toolkit> for further information about protections and consent procedures for persons unable to consent on their own behalf.

### Waiver of Consent

If consent will not be obtained for the collection, storage and distribution of [specimens and/or health information], explain:

* Why the research involves no more than minimal risks to the subjects;
* Why the waiver of consent/authorization will not adversely affect the rights and welfare of subjects;
* Why banking activities cannot practicably be carried out without the wavier; and
* Outline community education efforts planned to otherwise inform the targeted community about bank collection and use activities as well as the scientific value of its use.

##### Re-Contact

If you anticipate the need to re-contact subjects to obtain consent for new types of research or collect additional [specimens and/or health information], outline permissible reasons for re-contact and how and when re-contact would or might occur.

If you anticipate the possibility of re-contact to provide clinically useful and validated information, please provide evidence or procedures which you will follow to (Skip this and go on to Community Education if you are creating a Research Data Bank):

* Obtain CLIA-Certification Or Other Appropriate Qualifications Of The Laboratory Providing Results;
* Re-Contact Subjects;
* The Kinds Of Information You May Return; And
* Identify And Provide The Qualification Of The Medical Professional(S) Authorized To Return Research Results, As Well As, The Availability Of Clinical Staff To Provide Additional Support To The Subject.

##### Community Education

Outline any community education efforts planned to inform and educate the general community about [tissue and/or health information] bank collection and use activities as well as the scientific value of its use, especially if [specimen and/or health information] collection will occur without subjects’ knowledge or consent (such as, thru collection of de-identified tissue from hospital pathology). If specific populations will be targeted for specific types of research, outline those education outreach efforts as well. Advance planning for community education and outreach will help minimize bias in collection, as well as, address possible future concerns about respect for persons’ autonomy and distributive justice.

## Quality Control/Assurance & Data Safety Monitoring

The primary goals of quality control/assurance efforts are to prevent problems before they occur, identify problems by implementing routine and continuous monitoring procedures, and respond to problems in a timely and effective manner. Outline your training program for personnel and support staff, plans for peer review to assure both quality of science and patient care, auditing systems and procedures and to whom results will be submitted for appropriate and timely response.

Outline your data safety monitoring process. Describe who reviews and analyzes reports of any unanticipated problems, breaches of confidentiality or subjects’ complaints and forwards them to the IRB, and how and when such events are reported to the IRB. Note whether any other regulatory bodies (e.g., Rutgers HIPAA Privacy Officer, FDA, NIH, or other IRBs) require notification of such events, as applicable.

**Other Considerations**

* Other Liability Issues
* Applicable Federal, State, Local Regulations and Statutes Applicable International Regulations
* Applicable License and Certifications
* Contingency Plan(s) for the Transfer and/or Destruction of Samples and Data in the Event of the Dissolution of the Research [Tissue OR Data] Bank and Notification to Subjects (as applicable)
* IRB Review Contact your IRB Office for an Application for IRB Review of your proposed Research [Tissue or Data] Bank.