RUTGERS UNIVERSITY
Office for Research

STANDARD OPERATING PROCEDURES FOR A RESEARCH REPOSITORY TEMPLATE

5.304 (HRP-503d)

DO NOT INCLUDE INSTRUCTIONS PAGE WITH YOUR SUBMISSION

This template should be used by **investigators** proposing to develop standard operating procedures in order to establish a research [biological materials (specimens) or data] bank, otherwise known as a repository.

For example, 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.

***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.**

This template should NOT be used for the collection and storage of specimens or data as part of a single IRB-approved protocol for defined research purposes.

INSTRUCTIONS:

- ✓ **[BLUE]** highlighted text guides you to construct a protocol for your research so that the IRB can better understand what you are doing.
- ✓ **[RED]** highlighted text tells you when additional supporting documents must be uploaded to eIRB+.
- ✓ If a Section of the protocol ***does not apply*** to your proposed study, keep the Section heading but replace the text that appears beneath it with "***Not Applicable***", or "***N/A***".
- ✓ **Delete** all instructional text highlighted in **[BLUE]** and **[RED]** prior to uploading the protocol to eIRB+.
- ✓ **Do not include this instruction page with your submission.**

Need Help?

Visit the Human Research Protection Program (HRPP) website https://go.rutgers.edu/HRPP-Toolkit to obtain referenced Toolkit Forms & Templates and https://go.rutgers.edu/HRPP-Guidance to obtain referenced Guidance documents. Contact your IRB Office at https://go.rutgers.edu/ContactUs if you need further assistance.

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RESEARCH REPOSITORY INFORMATION

- **Title of Research Repository:**

  [Add Protocol Title]

- **Repository Director Name (also known as Principal Investigator):**
  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".
  [Add PI Full Name and Credentials]

- **Repository Director Division & Department:**
  [Add Division & Department]

- **Repository Director Contact Info:**
  [Add PI Work Email]
  [Work Address]
  [Work Phone Number]

- **SOP Version:**
  [Update the version date that appears in the footer]

HELP
See 'Registries & Repositories' at https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/hrpp-guidance-topics

1.0 Administrative

Provide business information about the research biological materials (specimens) 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.

- **Repository Location:**
  Address
- **Repository Telephone**:
  Phone Number
- **Ownership**:
  Indicate what institution is the owner of the repository
- **Funding source(s):**
  Name the funding source (if applicable)

2.0 Repository Purpose of Operation

A research biological materials (specimens) OR data bank is defined as an entity that receives, stores, processes and/or disseminates specimens and/or data, as needed, for future research. It includes the physical location as well as the full range of activities associated with its operation.

If this is a Research biological materials (specimens) OR data Bank, 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”.

A. **Type of Repository**:
   Biological Materials (Specimens), data, or both.

B. **Statement of Purpose:**
   Outline the mission or purpose of your proposed biological materials (specimens) OR data bank

C. **Biological Materials (Specimens) and/or Data to be Collected**:
   Indicate the types of biological materials (specimens) to be collected, if applicable

   Indicate the types of data to be collected, if applicable

   Identify which, if any, samples are pre-existing—e.g. 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.

Indicate if the specimens to be collected include known pathogens. **NOTE: be sure to outline precautions to be taken to prevent contagion in the sub-section labeled "Biosafety".**

D. Capacity (Size/Volume of Holdings):
Indicate the anticipated volume of the repository's holdings

E. Scientific Value of Proposed Collection:
Indicate the scientific value of the repository's collection

F. Known and/or Potential Risks of Harm and Benefit:

i. **Risks:** Indicate the known or potential risks of harm to the subjects providing specimens and/or information.

ii. **Risk Mitigation**: Indicate the methods that will be implemented to reduce the risks of harm to the subjects providing specimens and/or information.

iii. **Direct Benefits**: Indicate the known or potential benefit to the subjects providing specimens and/or information.

3.0 Repository Plan of Operations

Outline the operations of the research biological materials (specimens) 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 biological materials (specimens) 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).

3.1 SPECIMEN Collection, Processing, and Annotation Procedures

In this section specify how specimen will be accomplished.
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 data, procedures to assure the privacy of research subjects and confidentiality of their personal and protected health information. Describe your specimen collection and records management system here.
(Be sure to outline collection procedures for each type of specimen collected.)

A. Specimens
Research Biological Materials (specimens) Bank: i.e., patients, deceased persons, preexisting samples, etc.

B. Collection & Collection Locations
Outline collection procedures and identify collection locations.

C. Repository Staff Responsible for Specimen Collection:
Indicate the personnel responsible for collection tasks identified in this section.

D. Eligibility Criteria
List the inclusion and exclusion criteria for subject participation in the research biological materials (specimens) bank and provide a justification for same. Specimens collected should reflect the demographic characteristics and diversity of the population appropriate to the scientific goals of the research biological materials (specimens) outlined in the Purpose of Operation.

E. 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.).

F. Recruitment Plan
Explain the activities used to generally recruit subjects to participate in the research biological materials (specimens) bank. Itemize specific consent procedures in the Consent section.

G. Non U.S. Specimen Sources
If specimens and/or data 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 data.

H. Specimen Processing:
Specify how specimen processing will be accomplished.

I. Specimen Characterization and Quality Control Testing Data Collection and Specimen Annotation:
Specify how specimen annotation will be accomplished (if applicable).

J. Repository Staff Responsible for Processing and Annotation:
Indicate the personnel responsible for processing and annotation tasks identified in this section.

K. Specimen Storage
Be sure to construct SOPs specific to each type of specimen to be collected.

L. Types of Specimens in Storage:
Specify the types of specimens.

M. Storage Techniques:
Specify how specimen storage will be accomplished.

N. Freezer Maintenance and Backup:
Specify storage will be maintained and plan for a back-up should primary source fail.

O. Quality Control, Auditing and Standardization for Specimen Storage:
Specify how quality control, auditing and standardization for specimen storage will be accomplished.

P. Repository Staff Responsible for Storage Tasks:
Indicate the personnel responsible for storage tasks identified in this section.

Q. 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.

UPLOAD to eIRB+ – Biosafety Approval and evidence of Biosafety Training AND agreement(s) (MTAs) which govern the transfer of specimens, if applicable.

3.2 DATA Collection Procedures

In this section specify how data collection will be accomplished.
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 data, 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.

A. Types of Data to be Collected
Research Data Bank: i.e., lab reports, counseling records, intake forms, etc.

B. Collection & Collection Locations

Outline collection procedures and identify collection locations. 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 data chain of custody. Append examples of log forms to be used, as applicable.

C. Repository Staff Responsible for Data Collection:

Indicate the personnel responsible for collection tasks identified in this section.

D. Eligibility Criteria

List the inclusion and exclusion criteria for subject participation in the research data bank and provide a justification for same. Data collected should reflect the demographic characteristics and diversity of the population appropriate to the scientific goals of the research data bank outlined in the Purpose of Operation.

E. 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.).

F. Recruitment Plan

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

G. Non U.S. Data Sources

If data 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 data.

H. Data Storage

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 data to identifiers will be destroyed.

Identify the software platform(s) that will be used to track all phases of data 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.

I. 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.

J. 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.

4.0 Retention and Destruction

A. Research Biological Materials (specimens) and / or Data Destruction Requests

Include procedures that respect subjects' wishes to have their samples and/or data removed or destroyed and document such removal/destruction.

B. Retention

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

C. Contingency Plan(s) for the Transfer and/or Destruction of Samples and Data in the Event of the Dissolution of the Research Biological Materials (specimens) OR data Bank and Notification to Subjects (as applicable):

Indicate plan(s) for the Transfer and/or Destruction of Samples and Data in the Event of the Dissolution of the Research Biological Materials (specimens) OR data Bank and Notification to Subjects (as applicable)

5.0 Specimen and/or Data Distribution

A. Researcher Requests:
Specify how researchers will request specimen and/or data from the repository.

B. Researcher Access Qualifications and IRB Requirements:
Describe who may have access to specimens and/or data. Outline what procedures are in place to assure individual research projects will only be conducted with prior IRB review and approval.

C. Repository Staff Responsible for processing specimen and/or data Requests:
Indicate the personnel responsible for processing request from researchers.

D. Distribution to Researchers:
Specify how specimen and/or data from the repository will be transferred to the researchers. Include shipment and tracking procedures.

E. Repository Staff Responsible for distributing specimen and/or data:
Indicate the personnel responsible for distribution tasks identified in this section.

F. Fees:
Indicate the fees that will be charged to researchers (if applicable).

6.0 Agreements and Honest Brokers

A. 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.

B. Data Use Agreements
Data Use Agreements outline the terms and conditions under which the research biological materials (specimens) 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/

C. 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

D. Certificate of Confidentiality

Certificates of Confidentiality, (if applicable) 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.

7.0 Consent Process

Disregard the sections on consent, assent and surrogate consent if specimens and data will be de-identified by the sending entity/organization/collection location prior to receipt by the research biological materials (specimens) OR data bank.

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 biological materials (specimens) OR data banks that lead to research studies. Consent information should describe the nature, purpose and activities of the research biological materials (specimens) 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 biological materials (specimens) 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 data are consistent with the documented wishes of the subjects.

A. Consent and HIPAA Authorization (when applicable)

Outline how, where and by who informed consent will be obtained from subjects providing specimens and/or data. 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.

B. 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.

C. Surrogate Consent and HIPAA Authorization (when applicable)

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 biological materials (specimens) OR data from persons who have surrogate representation, please see https://orra.rutgers.edu/hrpp-guidance-toolkit for further information about protections and consent procedures for persons unable to consent on their own behalf.

D. Waiver of Consent and / or Waiver of HIPAA Authorization (when applicable)

If consent will not be obtained for the collection, storage and distribution of specimens and/or data, 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.

E. 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 data 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 (as applicable):

- 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.

F. Community Education

Outline any community education efforts planned to inform and educate the general community about biological materials (specimens) and/or data bank collection and use activities as well as the scientific value of its use, especially if specimen and/or data collection will occur without subjects' knowledge or consent (such as, thru collection of de-identified biological materials (specimens) 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.

8.0 Other Considerations

A. Other Liability Issues:

Indicate other liability issues.

B. Applicable Federal, State, Local Regulations and Statutes Applicable International Regulations:

Indicate any applicable laws and / or regulations that you will adhere to.

C. Applicable License and Certifications:

List any applicable licenses and certifications.

IRB Review – Submit your application for IRB Review of your proposed Research Biological Materials (specimens) or Data Bank via eIRB+.