SECTION I. GUIDANCE FOR THE DEVELOPMENT OF STANDARD OPERATING PROCEDURES FOR A RESEARCH [TISSUE OR DATA] BANK

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.

ROADMAP: In what follows the reader will find Section I offers a glossary of selected concepts; Section II lists sources used to develop this model SOP Manual; and Section III provides a sample Table of Contents for a Research [Tissue or Data] Bank Standard Operating Procedures complete with a brief description of what (types of) information should be outlined under each heading. Additionally, in some sections, we recommend some elements the reader should consider depending on the scope and purpose for which the tissue and/or data will be collected, and the unique ethical considerations that may exist as a result.

SECTION I: GLOSSARY

Human Biological Materials – include the full range of specimens, from subcellular structures like DNA, to cells, tissue (e.g., blood, bone, muscle, connective tissue and skin), organs (e.g., liver, bladder, heart, kidney, placenta), gametes (i.e., sperm and ova), fetal tissues, and waste (e.g., hair or nail clippings, urine, feces, and sweat, that often contain shed skin cells) (Note: This part of the definition is taken from the 1999 report of the National Bioethics Advisory Commission Report referenced below.). The definition also includes breast milk, or other biological material. The terms tissue, specimens, and samples are synonymous in this context. However, in order to aid participants’ comprehension, use only the terms tissue and/or sample in the consent document, where appropriate. PLEASE NOTE: Collection of and/or research on embryos or embryonic stem cells raises special issues that are outside the scope of this template.*Contact HSPP office to discuss projects involving embryos or embryonic stem cells.
Existing Clinical/Research Tissue Samples: Existing samples are biological materials that were collected for clinical or research purposes and are no longer needed for the original purpose. Any research conducted using tissue or data from this bank constitutes a secondary use of the collected samples and/or data.

Research Tissue or Data Bank: An entity that collects, stores and/or distributes human biological materials or personal health data expressly for use in research. The terms bank and repository are synonymous in this context. However, in order to aid participants’ comprehension, please only use the term bank throughout the consent document. PLEASE NOTE: The collection and storage of specimens or data to be used for defined research purposes as part of a single IRB-approved protocol is NOT considered a research tissue or data bank. Neither does the phrase refer to specimens and data that are collected and stored as part of routine clinical care or hospital procedures, such as blood banks, pathology or autopsy.

Data: Individual facts, statistics or items containing participant information, or data from analyses.

Database: Any combination of paper and/or electronic files that store participant information and/or information derived from research on human biological materials.

Genetic research: Involves the analysis of DNA, RNA, chromosomes, proteins, or certain metabolites which might act as or identify markers associated with a known or suspected predisposition to disease or behavior. Usually genetic research involves the collection of human biological material such as blood, skin or other tissues, nail clippings or hair. Genetic research also may include the construction of pedigrees (maps of the distribution of a particular trait or condition among related individuals or family medical histories). Although gene transfer is another form of genetic research, this document does not address issues of gene transfer.

Lay language: To ensure comprehension by the greatest number of people, please write the consent for readers with a modest education (6th - 8th grade reading level) and no background in health-related sciences. An application within Microsoft Word, called “readability statistics”, can assist you to assess and modify your consent document to improve lay readability and comprehension. [If using Microsoft Word Version 97-2003, you will find the application at the top of the screen in “Tools”. If using Microsoft Word Version 2007, you will find the application in the “Word Options” Box when you click on the “Office” Logo in the upper left-hand side of the screen.]

Personal Identifiers: Personal identifiers are any data collected that may directly or indirectly identify a unique individual (or the relatives, employers, or household members of an individual). Personal identifiers are listed below:

- name
- all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
(a) the geographic unit formed by combining all zip codes with the same three initial digits containing more than 20,000 people; and (b) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

- all elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of date (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
- telephone numbers
- fax numbers
- electronic mail addresses
- social security numbers
- medical records numbers
- health plan beneficiary numbers
- account numbers
- certificate/license numbers
- vehicle identifiers and serial numbers, including license plate numbers
- device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- biometric identifiers, including finger and voice prints
- full face photographic images and any comparable images
- any other unique identifying characteristics

Protected Health Information: Protected health information is information that is linked to personal identifier(s) making it possible to determine the identity of the individual. It includes information about:

- an individual’s physical or mental health;
- health care; or
- payment for health care.

If identification is possible, the information must be protected from unauthorized uses (see HIPAA Privacy Rule in reference section)

Directly identifiable samples or data: Specimens or data are labeled with information that directly identifies the person from whom the material or information was obtained.

Unidentified samples or data: Sometimes termed “anonymous”, specimens or data for which identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved.
Coded samples or data: Samples or data are labeled with a code that links or is linkable to personal information in such a way that the person from whom the material or information was obtained could be identified by name, patient number, or other information.

Unlinked samples or data: Otherwise termed “anonymized”, samples or data that lack codes that can link them to identified specimens or particular individuals either because the existing link or code to the identity of an individual was destroyed (de-identified sample) or because a link or code was never created (non-identifiable sample). Non-identifiable specimens or data lack all 18 personal identifiers listed above (see HIPAA reference below)

Traditionally-used identifying information: refers to identifying information that is collected through traditional methods of conversations with, observation of, or recorded from a participant’s medical record. It does not include identifying information intrinsic to human biological material (such as DNA) that is retrieved through non-traditional methods (such as through the power of technology).

SECTION II: REFERENCES & RESOURCES:

A. Developing a Tissue Bank: A number of publications outline best practices for the development of quality research tissue banks. A few are listed below for your convenience.


B. Key Regulatory and Ethics Guidance:


C. **Other Readings of Interest:**


SAMPLE TABLE OF CONTENTS FOR A

RESEARCH [TISSUE OR DATA] BANK STANDARD OPERATING PROCEDURES

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.

Newark Link: http://rehs.rutgers.edu/

New Brunswick Link: http://rwjms.rutgers.edu/research/orsp/index.html

(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://privacyruleandresearch.nih.gov/research_repositories.asp](http://privacyruleandresearch.nih.gov/research_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/](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 Office of Technology Transfer and Business Development for instruction on how to develop Rutgers-approved Material Transfer Agreements.
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 http://www.rbhs.rutgers.edu/hsweb/guidance.

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 http://www.rbhs.rutgers.edu/hsweb/forms/surrogate.html 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 waiver; 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.