**Instructions:**

* Keep an electronic copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, and policies, can be found on the IRB website.
* **Remove all instructions in italics so they are not contained in the final version of your protocol.**
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A”. Do not deletethe section headers.
* *When you save and upload this document, add the protocol version date to the title.*

*Definition:*

*A research [tissue OR data] repository is defined as an entity that receives, stores, processes and/or disseminates [specimens and/or health information/data], as needed, for future research. It includes the physical location as well as the full range of activities associated with its operation.*

**REPOSITORY TITLE:**

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY SUMMARY:**

*Please provide a brief summary of the study in the table below.*

|  |  |
| --- | --- |
| **Research Site** |  |
| **Purpose/Objective** |  |
| **Specimen/Data Collected** |  |
| **Study Population** |  |
| **Type of Consent** |  |
| **Registry Size** |  |
| **Ownership** |  |
| **Funding Source** |  |

**REVISION HISTORY:**

***\*This table should only be used during submission of an Amendment application to the IRB.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Version #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**OBJECTIVES/PURPOSE OF OPERATION:**

*State the specific details surrounding the objectives in creating your registry/repository/ database; broad objectives are acceptable – try to predict all possible future uses.*

* *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*
* *Identify which, if any, samples are pre-existing—tissue collected solely for clinical purposes that are no longer needed for patient care, and/or any tissue in a pre- existing research tissue bank, and/or whether any samples are from deceased persons.*

*Objectives should not include specific research aims and analyses. Studies using data or biospecimens collected from this protocol will require a separate IRB submission.*

**BACKGROUND AND RATIONALE:**

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

**REPOSITORY PLAN OF OPERATIONS:**

*Outline the operations of the research repository 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 repository. 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).*

*Include a plan for continuing repository operations in the absence (or departure) of the principal investigator (as applicable).*

**[Specimen and/or Data] Collection**

*In this section specify how [specimen or data] collection will be accomplished. Will it be obtained by direct interaction with participants from a clinical or hospital site, or via chart review? Outline collection procedures for each type of specimen collected.*

**[Specimen and/or Data] Sources**

*Research Tissue Repository: i.e., patients, deceased persons, preexisting samples, etc.*

*Research Data Repository: 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.*

**EligibilityCriteria**

*List the inclusion and exclusion criteria for subject participation in the research repository and provide a justification. [Specimens and/or data] collected should reflect the demographic characteristics and diversity of the population appropriate to the scientific goals of the research repository 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 repository. Itemize specific consent procedures in the Consent section.*

**SPECIMEN PROCESSING AND ANNOTATION:**

*Skip this section if you are developing a Research Data Bank.*

*Specify how specimen processing and annotation will be accomplished.*

*Indicate the personnel responsible for processing and annotation tasks identified in this section.*

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

**SPECIMEN STORAGE:**

*Skip this section if you are developing a Research Data Repository.*

*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*

* *Number and Types of Specimens in Storage*
* *Storage Techniques*
* *Freezer Maintenance and Backup*
* *Quality Control, Auditing and Standardization for Specimen Storage*

**[SPECIMEN AND/OR DATA] DISTRIBUTION:**

*In this section specify how [specimen and/or data] 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.*

*Discuss any limits on data/specimens’ intended future use (e.g., for cancer research only).*

**Researcher Access Qualifications and IRB Requirements**

*Describe who may have access to specimens and/or data.*

*Describe how identifiers will be handled.*

*Describe procedures to verify IRB Approval Documentation, if recipient researchers will be given data/biospecimens with any HIPAA identifiers attached.*

*Identify research team members who will evaluate requests for use of data/biospecimens.*

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

*Describe shipment and tracking procedures of specimens and/or data to researchers.*

**Fees**

*Describe any fees associated with the registry.*

**BIOSAFETY:**

*Skip this section if you are developing a Research Data Repository.*

*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.*

**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 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.*

**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 data] chain of custody.*

*Include methods for tracking participants’ decisions regarding data/specimen use.*

*Attach examples of log forms to be used, as applicable.*

**Data Storage Techniques**

*All sensitive data and data that contains HIPAA identifiers, when electronic, should be stored on storage media that is encrypted – not solely password-protected or kept in a locked office.*

*Provide a description of where and how [specimens and/or data] 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 data] acquisition, processing, storage, handling, QA/QI, 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 Withdrawal/Destruction Requests**

*Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.*

*Include procedures that respect subjects’ wishes to have their [samples and/or data] 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. 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 & Material Transfer 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.*

*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.*

*Identify the position/person assigned to work with the IRB/research office to execute data use and/or material transfer agreements. Outline the policies and procedures in place.*

**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.*

**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 repository.*

*Informed consent 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 repositories that lead to research studies. Consent information should describe the nature, purpose and activities of the research [tissue or data] repository and should be as specific as possible.*

*If consent will be obtained, not by agents/employees of your research repository, 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 registry 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.*

**Consent**

*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.*

**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), as applicable.*

**Surrogate/Legally Authorized Representative 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.*

**Waiver of Consent**

*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 repository activities cannot practicably be carried out without the wavier; and*
* *Outline community education efforts planned to otherwise inform the targeted community about repository 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 data], outline permissible reasons for re-contact and how and when re-contact would or might occur.*

*Skip this and go on to Community Education if you are creating a Research Data Bank.*

**Incidental Findings**

*Based on the nature of the research expected to be done with the data/specimens, determine if any expected or incidental findings should ever be shared with participants.*

*Keep in mind that when a registry/repository will be used broadly for many types of future research, it will be hard to predict what kinds of findings might result.*

*Return of results should be based on at least the following factors:*

* *Whether data/specimens will be shared with any identifiers (if not, including no study ID, then sharing results will be impossible)*
* *Whether findings could be medically actionable*
* *Whether findings can be reproducible via CLIA lab tests*

*Include information about how findings will be shared in the informed consent form, if applicable.*

**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., HIPAA Privacy Officer, FDA, NIH, or other IRBs) require notification of such events, as applicable.*

**RESOURCES AVAILABLE:**

*Describe the resources available to conduct the research:*

* + - *Describe the time that you will devote to conducting and completing the repository.*
    - *Describe your facilities.*
    - *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

**REFERENCES:**

*Add references*