

## UNIVERSITY OF GEORGIA INSTITUTIONAL REVIEW BOARD GUIDANCE ON TISSUE AND DATA REPOSITORIES

### I. Background

The establishment and management of repositories that collect and store human materials and/or data for research purposes requires review and continuing oversight by the University of Georgia Institutional Review Board (UGA IRB). A *research repository* is a collection of any human biological materials and/or data that are individually-identifiable and intended to be used for research purpose(s). Repository activities involve three components: the collection, storage, and distribution of materials/data. The terms tissue/specimen bank, registry, and data bank are all considered **repositories** for IRB purposes if:

- Materials/data collected prospectively or retrospectively are contributed by multiple investigators or sources
- Materials/data are maintained over time
- Controlled access to and use of materials/data by multiple, outside investigators (i.e., *those who are not members of the repository team*) and/or for multiple future research purposes

No specific research study will usually occur when a repository is created. The collection and storage of materials/data for very specific or well-defined research purposes as part of a single IRB-approved protocol is not considered a repository. Materials/data that were initially collected by individual investigators not originally intended to be part of a repository may subsequently be submitted to a repository if these have been stripped of any direct and indirect identifiers.

The IRB shall ensure that research repositories comply with federal, state, and university regulations, guidance, and policy; that adequate provisions are in place to protect the privacy and confidentiality of the donor-subjects and their materials and/or data; and, collection and future use will be respectful of the donor-subjects.

Human participant materials and data that may be deposited in a research repository include, but are not limited to the following:

- Biological products (organs, tissues, bodily fluids, cells, and other body materials) obtained through intervention or interaction with a living individual for the purpose of research.
- Discarded tissues such as surgical/pathology specimens, organs, tissues, bodily fluids, cells, and other body materials. If the samples are de-identified (i.e., *when any direct or indirect identifiers or codes linking the data to the individual donor-subjects are removed/destroyed*), the standard surgical or medical treatment consent documents may suffice if there is a statement that describes the future use of the materials for

research. Otherwise, a project specific IRB approved research consent document is required.

- Private information (e.g., clinical/treatment notes and related medical information) that can be identified with an individual donor-subject. This includes private information provided for specific purposes by an individual donor-subject, which the individual can reasonably expect will not be made public.
- Materials/data obtained from voice, video, digital or image recordings.
- Data obtained from surveys, interviews, focus groups, program evaluations, quality assurance/improvements, etc.

## II. IRB Oversight

Some repositories are established and maintained explicitly for research purposes. Others are established and maintained for non-research purposes, but may be accessed for research. Regardless of their intended purpose, such resources often hold information of value for research. When the purpose of the repository includes research, its collection and storage activities are considered *human subjects research* and require IRB oversight. When information or tissues from a repository will be used/accessed for research purposes, the research use must adhere to the applicable IRB and privacy policy requirements, regardless of the purpose for which the repository was created.

## III. Procedures for Collection, Storage, and Distribution of Data and Materials

Researchers shall obtain IRB approval for the establishment and operation of research repositories of human materials and/or data that are managed and operated by UGA. The principal investigator responsible for oversight of a research repository (repository PI) shall submit an IRB application with a clear description of the operation of the repository. At a minimum, the IRB shall require a description of the following:

- Mission/purpose of the repository.
- Repository PI and staff (include evidence of IRB training [see *Training, Section VI*] and experience in relevant procedures).
- The types of materials/data that will be collected and stored.
- Procedures for collection of materials/data.
- Types of research to be conducted (be as specific as possible).
- Procedures for storage (i.e., *where repository will be housed; procedures for protecting the privacy of subjects and maintaining the confidentiality of materials/data*).
- If outside researchers (i.e., *those who are not members of the repository team*) will be allowed to receive/access repository, describe who the future researchers will be and for what specific research purposes.
- Conditions under which data and materials will be released to recipient-investigators and procedures for protecting the privacy of subjects and maintaining the confidentiality of materials/data.

- Duration of storage of materials/data; if indefinite, provide a justification. Address fate of repository for scenarios like (a) repository PI leaving the institution or will no longer be the responsible person, and (b) agency collecting/storing the materials/data will cease operation.

## A. Collection of Materials and Data

The IRB shall require the repository to have policies specifying that researchers interacting with human subjects with the intent to eventually submit their materials/data to the repository obtain the informed consent and authorization of the donor-subjects (or their legal representative) prior to the collection of materials/data to be deposited and stored in a repository for future research, unless a waiver of informed consent has been granted by the IRB (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>). When informed consent will be obtained, the consent form must contain all the basic elements of informed consent (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>). Specifically, the following need to be addressed/described in the consent form:

- Purpose of the repository.
- All type(s) of research that will, or may, be conducted, including whether genetic analysis will be performed. This should be as specific as possible.
- Specific materials/data that will be deposited in the repository, and how these will be collected. Brief description of the operation of the repository.
- Describe if data/materials will be released to outside investigators and conditions under which these will be released (e.g., with direct or indirect identifiers, or stripped of any identifiers), or if there will be no secondary/future use. Subjects must be given an option of consenting to any secondary/future use. Inform subjects that they may be re-contacted to seek additional consent for secondary/future use, or give subjects option to indicate if they are willing to be re-contacted.
- With whom the data/materials may be share, if known.
- Potential risks of disclosure of the information, such as negative effects on insurance coverage, employment status, emotional discomfort, familial strife, or even harm to a cultural group.
- The potential benefits, including whether any results will be provided to the research participant.
- Procedures to protect confidentiality and privacy during collection, storage, and distribution of data and materials.
- Indicate if their data/materials will eventually be made anonymous and if so, how and when.
- Information regarding ownership of data/materials, and whether use of data/materials may lead to new discoveries or commercially-valuable products, and whether donor-subjects will receive any financial benefits from these discoveries/products.
- Describe if the donor-subjects can have their sample(s) destroyed or all personal identifiers removed if he or she decides to withdraw from the research.

- Duration of storage of sample(s); if indefinite, provide a justification.
- Fate of their samples if PI leaves or repository center ceases operation.

## **B. Storage - Security and Confidentiality Measures**

Since breach of confidentiality is the major risk for stored repository materials, there must be adequate plan for protecting the security and confidentiality of the repository materials and prevent accidental or inappropriate release of information. At a minimum, the following measures need to be in place:

- A method of coding the materials/data, including a process to protect/maintain the key to the code and limit access to the key. The coding system must be adequate to reduce the possibility of re-identification. If the repository must have individual identifiers, the IRB will require extensive electronic protections, such as multiple firewalls or passwords, for accessing the repository.
- Access to the code and individually-identifiable materials/data must be restricted to authorized individuals who are trained about the repository and human research protections, including the preservation of confidentiality.
- A Certificate of Confidentiality is recommended as an additional protective measure, especially if the repository includes collection of genetic materials/information or sensitive data. If a Certificate of Confidentiality will be obtained, a copy of the certificate should be provided to the IRB once this becomes available. For information on Certificate of Confidentiality, visit <http://grants1.nih.gov/grants/policy/coc/>.

## **C. Distribution of Materials/Data from a Repository**

The IRB Application must include detailed provisions for the distribution of materials and/or data to outside researchers to ensure the protection of the privacy and confidentiality of donor-subjects. At a minimum, the Application should address the following:

- Describe if data/materials will be released to outside investigators and conditions under which these will be released (e.g., with direct or indirect identifiers, or stripped of any identifiers), or if there will be no secondary/future use.
- Repository will require a signed Materials/Data Use Agreement from the recipient-investigator.
- Documentation that the researcher receiving the materials and/or data has IRB review for each research study that requests materials/data from the repository.
- The IRB recommends that the repositories, when allowing access to outside investigators, not contain the direct identities of donor-subjects or information through which the identities of donor-subjects may readily be ascertained. If this is not possible, the recipient-investigator may be required to obtain a signed informed consent from each participant prior to accessing the repository for a proposed research activity when the extracted data/materials will contain direct or indirect personal identifiers. In

certain justified situations, the IRB may approve a waiver of the requirement to obtain a signed informed consent, or approve a consent procedure which does not include or which alters some or all of the elements of informed consent, or approve a waiver of the requirement to obtain informed consent.

- If an investigator will access materials/data from a repository that is not directly or indirectly linked to individual donor-subjects (i.e., *no identifiers or codes*), the study may qualify as *not human subjects research* or meet criteria for exemption from IRB approval and informed consent requirements. However, only the IRB may determine which activities meet the regulatory definition of *not human subjects research* or qualify for an exempt review. The Office for Human Research Protections (OHRP) *Guidance on Research Involving Coded Private Information or Biological Specimens* will be used to determine need for IRB review. The link to this guidance is <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>.

#### **IV. Non-UGA Researchers**

In addition to the requirements of Section III.C above, if the materials and/or data collected for the research repository will be made available to non-UGA researchers, Repository PI is responsible for ensuring that non-UGA investigators meet their institution's requirements for local IRB review of the research project. Investigators at other sites should also check their institutional policies regarding the transfer of materials/data for research. A Materials/Data Use Agreement is also required.

#### **V. Minors Who Reach Legal Age of Consent**

The IRB shall advise the PI the need to obtain informed consent from donor-subjects, who were minors at the time the materials/data were initially collected for the repository reach the legal age of consent, in accordance with OHRP's guidance for research involving children (<http://www.hhs.gov/ohrp/researchfaq.html#q18>). Unless the IRB determines that the requirements for obtaining informed consent can be waived, the investigators should seek and obtain the legally effective informed consent for the now-adult subject for any continued analysis of materials/data for which the subject's identity is readily identifiable to the investigator(s). Among the factors the IRB will consider when making this determination are:

- The ability of the researchers to locate and contact the donor-subjects.
- Whether the collection of materials/data is ongoing or a one-time donation.
- Whether the materials/data continues to meet the regulatory definition of *human subjects research*.
- The nature and sensitivity of the research being done with the materials/data in the repository.
- If assent was obtained from the minors at the time materials/data were collected for the repository.

## **VI. Personnel and Training Requirements**

The repository must have a UGA employee designated as the Principal Investigator (Repository PI). The Repository PI has primary responsibility for the collection, storage, and distribution of data and/or materials. Training on the protections of human subjects is required of Repository PI and others who are considered *engaged in the conduct of human subjects research*.

The link to UGA IRB training is <http://www.ovpr.uga.edu/compliance/hso/training/>.

For guidance on engagement in human subjects research, see <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>

## **VII. Privacy Rule/HIPAA Compliance**

If repository will obtain and use/access protected health information (i.e., *individually-identifiable physical and mental health/medical information created or maintained by a covered entity which may only be used/disclosed to researchers in certain circumstances and under certain conditions*), the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies.

For information about HIPAA, see <http://www.hhs.gov/ocr/privacy/index.html>. *Note: Although research involving materials/data from deceased individuals no longer meets the regulatory definition of human subjects and is not subject to IRB review, decedents' protected health information is subject to the Privacy Rule.*

## **VIII. Questions or Assistance**

For questions or assistance, please contact the Institutional Review Board at 706.542.3199 or [irb@uga.edu](mailto:irb@uga.edu).