1. PURPOSE

1.1. The establishment and management of repositories that collect and store human specimens and/or data for research purposes requires review and continuing oversight by the University of Georgia Institutional Review Board (UGA IRB). This policy applies to human subject research repositories established by UGA investigators for the purpose of storing data and/or specimens for future research purposes. This policy does not apply to data/specimens that are collected and stored as part of standard educational or programmatic procedures, or of routine counseling or clinical care. However, it applies to data/specimens from these sources if these will be stored for future research. Repository activities involve three components, the collection, storage, and distribution of biological specimens/data, which are all described in this policy.

2. DEFINITIONS

2.1. **Research Repository**: For the purpose of this policy, a research repository is a collection of any human biological specimens and/or data that are individually identifiable and intended to be used for research. The terms tissue/specimen or bank, data bank, registry, or library are all considered “repositories” for IRB purposes if it involves the accumulation, storage and later distribution of data and/or biological specimens for future research.

2.2. **Human biological specimens and data** that may be deposited in a research repository include, but are not limited to the following:

- **2.2.1. Biological products** (organs, tissues, bodily fluids, cells, and other body specimens) obtained through intervention or interaction with a living individual for the purpose of research.
- **2.2.2. Discarded tissues** such as surgical/pathology specimens, organs, tissues, bodily fluids, cells, and other bodily specimens.
- **2.2.3. Private information** (e.g., clinical/treatment notes and related medical information) that can be identified with an individual subject. This includes private information provided for specific purposes by an individual subject, which the individual can reasonably expect will not be made public.
- **2.2.4. Specimens/data** obtained from voice, video, digital or image recordings.
2.2.5. Data obtained from surveys, interviews, focus groups, program evaluations, quality assurance/improvements.

2.3. **Repository PI:** The principal investigator responsible for oversight of a research repository.

3. **POLICY**

3.1. The establishment and operation of all research repositories will require review and approval by the UGA IRB.

3.2. The IRB does not consider prospective collection and storage of data/specimens for very specific or well-defined research purposes as part of a single IRB-approved protocol as a research repository.

3.3. Research repositories must comply with applicable federal, state, and university regulations and policies.

3.4. Adequate provisions must be in place to protect the privacy and confidentiality of the subjects and their specimens and/or data.

3.5. Specified uses of the repository will be respectful of the subjects, meaning that informed consent must be obtained from subjects to whom the data/specimens pertain for the storage in the repository and for the intended future use of the data/specimens.

3.5.1. Minors Who Reach Legal Age of Consent:

In some repositories, the subjects were minors at the time the specimens/data were initially collected. Unless the IRB determines that the requirements for obtaining informed consent can be waived (see Policy and Procedure: Informed Consent Waivers), the investigators will seek and obtain the legally effective informed consent for the now-adult subject for the continued inclusion of identifiable specimens/data in the repository.

See [http://www.hhs.gov/ohrp/researchfaq.html#q18](http://www.hhs.gov/ohrp/researchfaq.html#q18). When determining if consent can be waived in these circumstances, the IRB may also consider:

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

3.6. **Research Repository** study team members must comply with the institution’s human subject research training requirements.
3.7. If the **repository** will include protected health information (i.e., individually-identifiable physical and mental health 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.

3.7.1. Although research involving specimens/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.

4. **PROCEDURES: Researchers**

4.1. The researcher must complete the submission form through the IRB’s electronic application system. The description of the research design must indicate that the submission contains a repository component or is for the sole purpose of creating a repository.

4.2. A **Repository** Supplement that contains specific information for the administration of a research repository must be included. See Repository Supplement Application.

4.2.1. The description of the operations of the repository must include the following:

4.2.1.1. Mission/purpose of the repository

4.2.1.2. General description of specimens/data that will be included in the repository including:

- if/how the specimens/data are identified
- if existing, whether the specimens/data were obtained with the IRB-approved informed consent of the subjects or under an IRB-approved waiver of informed consent
- the plan for prospective collection of specimens/data to be included in the repository (with informed consent of subjects or under a waiver)

4.2.1.3. Types of research to be conducted (be as specific as possible) using the data/specimens in the repository

4.2.1.4. If specimens/data were/will be included with the informed consent of the subjects, the consent process must contain all the basic elements of informed consent. Specifically, the following issues need to be addressed 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 specimens/data that will be deposited in the repository, and how these will be collected. Brief description of the operation of the repository. If data/specimens will be released to outside investigators, the conditions under which these will be released (e.g., with direct or indirect identifiers, or
stripped of any identifiers) and with whom the data/specimens may be shared, 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.
- Procedures to protect **confidentiality** and **privacy**
- Information regarding ownership of data/specimens and whether use of data/specimens may lead to new discoveries or commercially-valuable products, and whether subjects will receive any financial benefits from these discoveries/products.
- Describe if the subjects can have their sample(s) destroyed or all personal identifiers removed if he or she decides to withdraw from the research.

### 4.2.1.5. Duration of storage of sample(s); if indefinite, provide a justification.

### 4.2.1.6. Procedures for storage (i.e., where repository will be housed) and for protecting the privacy of subjects and maintaining the confidentiality of specimens/data. Since breach of confidentiality is the major risk for stored repository specimens/data, there must be adequate plan for protecting the security and confidentiality of the repository specimens/data and prevent accidental or inappropriate release of information. At a minimum, the following measures need to be in place:

- **A method of coding the specimens/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 specimens/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 specimens/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, see http://grants1.nih.gov/grants/policy/coc/.

### 4.2.1.7. If outside researchers (i.e., those who are not members of the repository team) will be allowed to receive/access repository data/specimens, the submission should include documentation that the researcher receiving the specimens and/or data has
IRB review for each specific research study that requests specimens/data from the repository.

4.2.1.8. If the specimens and data collected for the research repository will be made available to non-UGA researchers, the repository Principal Investigator (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 specimens and data for research. A Specimens/Data Use Agreement may also be required.

4.2.1.9. 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 specimens/data will cease operation.

5. PROCEDURES: Institutional Review Board

5.1. The IRB will review the submission to determine if it involves creating a research repository.

5.2. If this involves a research repository, the IRB will make an initial determination of the required level of review (Non-Committee or Committee Review).

5.3. For research eligible for Non-Committee Review, IRB staff will determine if review by a Subject Matter Expert or a Consultant is required.

5.3.1. The Subject Matter Expert will assess anticipated risks and will determine if the submission meets criteria for Non-Committee Review or needs Committee Review at a convened meeting.

5.4. For Non-Committee Review, IRB staff will offer the investigator the opportunity to provide additional information/specimens and/or to revise the submission in appropriate review correspondence.

5.5. For Committee Review, IRB staff will offer the investigator the opportunity to provide additional information/specimens and/or to revise the submission in appropriate review correspondence that describes missing information or required modifications.

5.6. IRB Staff will document information pertaining to determinations that the requirements of this policy have been met in the review history for Non-Committee Review, or in the meeting minutes by recording the motion to approve for Committee Review.

6. MATERIALS

6.1. Repository Supplement Application
7. REFERENCES

7.1. Policy and Procedure: Determination of Human Subjects Research

7.3. Policy and Procedure: Informed Consent Process
7.4. Policy and Procedure: Informed Consent Waivers
7.5. Policy and Procedure: Engagement