### Background
Research registries and repositories are used to **collect**, **maintain**, and **distribute** data and/or human biological specimens (blood, tissues, cells, DNA, etc.) for some future research purpose. Some are created and maintained explicitly for research purposes. Others are created and maintained for non-research purposes (such as medical care, education, normal operations) but may be accessed later for research uses. The purpose of establishing a formal research registry/repository is to give the investigator the authority and responsibility for distributing data and/or specimens from a registry or repository and to define future uses in a manner that protects the rights of research participants, supports scientific inquiry, and complies with Federal regulations. (45 CFR 46; 45 CFR 160-164; 21 CFR 50, 56, 812)

### Purpose
The purpose of this policy is to outline IRB procedures for establishing, maintaining, and closing a research registry or repository at Florida Atlantic University (FAU).

### General Statement
- This policy **applies** to human subject research registries or repositories established by 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 routine clinical care or hospital procedures (for example, blood banks, pathology, disease surveillance, or quality assurance) **unless they are stored for future research**.
• While most references in this policy speak to clinical care or procedures, the general philosophy and procedures also apply to data of a non-medical/non-clinical nature and/or are collected and maintained in non-clinical settings for future research use. (e.g., from social/behavioral studies)

IV. Policy
A. All research registries and repositories at FAU require review and approval by the IRB.

B. The collection and storage of data/specimens (see definition of “specimens” below) becomes a research registry/repository when there is a specific intention for the data/specimens to be maintained for future research or shared with other investigators. NOTE: The prospective collection and storage of data/specimens for defined research purposes (including holding samples to “batch” them for assays), as part of a single IRB-approved protocol is not considered a “repository.”

C. If the PI has no explicit plan to destroy the data/specimens when an original research project ends, the investigator may maintain the data/specimens under continued IRB approval for uses that were approved in the original protocol. Once a use is desired beyond the primary research goals of the original protocol, the PI must establish an IRB-approved research registry/repository for any future research uses or submit data/specimens into an existing IRB approved registry or repository.

V. Definitions

Registry: In general, a registry is a collection of information elements or databases containing names, contact information, and personal records (medical, educational, attitudinal, etc.) of people who are willing to consider participation in research studies and share their data for research. While data may also be analyzed as part of the registry, the primary intention is as a recruitment resource for researchers.

Repository: A research repository provides a way for researchers to store human biological specimens (for example, blood, urine, tissue specimens obtained from biopsies, and tissues or organs removed during surgery) and related medical information for future research studies. A repository can also be used to store non-medical data elements for future research purposes.

*Note: for purposes of this policy, definitions of registry and repository apply to the intended use rather than the type of material (data, specimens, etc.) to be stored.

Coded: This term refers to specimens or data whose identifying information (such as name or social security number) has been replaced with a number, letter, symbol, or combination of these elements. Often there is a mechanism or “key” to decipher the code. Deciphering the code would enable someone to link the data or specimen or dataset to identifying information which could reveal the donor of the data or specimen.

Gatekeeper: A person(s) who has primary control of data and/or specimens and maintains the registry/repository. This person may be delegated by the Principal Investigator; however the PI retains ultimate responsibility for the oversight of the registry/repository.
Specimens: For purposes of this policy, specimens are human biological materials that range from subcellular structures and cell products such as DNA, to cells, tissue (e.g., blood, bone, muscle, connective tissue and skin), organs (e.g., liver, bladder, heart, kidney, placenta), secretions, and waste (e.g., hair or nail clippings, urine, feces, sweat, etc.).

Material Transfer Agreement: An agreement between FAU and another institution that allows one institution to share materials with another (e.g. tissues, etc.). This agreement protects the investigator and institution by notifying the recipient regarding materials that are patented and any limits on the use of samples and associated information.

Submittal Agreement: An agreement that attests that data/specimens collected were obtained with written informed consent of the subjects utilizing an informed consent document approved by the local IRB or under an IRB approved waiver of informed consent.

Usage Agreement: An agreement that details the conditions for receipt and future use of data and/or specimens from a registry/repository.

VI. Accountability

The Principal Investigator (PI) will be responsible for:
- Submitting the appropriate IRB protocol for his/her registry/repository; developing standard operating procedures (SOPs) for maintenance of the registry/repository; appointing a gatekeeper for the registry/repository; and ensuring the proper disposition of the registry/repository.

- Coordinating with Environmental Health and Safety and related units, as appropriate, regarding appropriate storage, maintenance, and destruction of specimens.

- Coordinating with IRB and information technology staff, as appropriate, re: appropriate storage, security, and destruction of data.

The Institutional Review Board will be responsible for:
- Reviewing and approving any request to create, or request data from, a data/specimen registry or repository in accordance with this policy.

The Research Integrity office will be responsible for:
- Advising researchers on the appropriate submission process for establishing, maintaining, and closing a data/specimen registry/repository.

- Coordinating with related FAU compliance units as needed.

VII. Procedures

Creating a New Research Registry or Repository
1. First determine the category of approval you are seeking for your research registry/repository. (see Quick Guide on IRB Review Type for Registries/Repositories)
• **Non-Human Subjects (NHS) Research:** This is an activity that doesn't meet the regulatory definition of human subject or research. In this category the specimens or data kept in the registry/repository must not have any data that could identify the subject (See Protected Health Information Determination Form) nor a code in which the key to the code is kept by anyone on the study staff. Research projects that are originally deemed NHS research and converted to a registry/repository can be considered for this category. In addition, data or specimens that are de-identified as part of the original research protocol can likely be deemed “NHS.” Data or tissues from another IRB approved research protocol that originally contains identifiers, cannot be de-identified and placed in an NHS registry/repository if both the originating study and the registry/repository have the same P.I. The IRB must make the determination that a registry/repository meets the definition of “not human subjects research.”

• **“Exempt” Review:** If a registry/repository meets the regulatory definition of being exempt, continuing oversight by the IRB is not required. All data/tissue in an exempt registry/repository must exist at the time of IRB submission. A registry or repository will likely NOT be exempt if the data/specimens are collected after the date of the original IRB submission.

• **"Expedited" or "Full Board Review:"** This category applies to registries/repositories that have greater risk in terms of confidentiality and privacy issues. A research registry approved under expedited or full board review requires continued oversight by the IRB.

2. Next, submit the IRB protocol via IRBNet.
   a. Use the protocol format for Registries & Repositories and attach all requested information.
   b. Include either a consent OR a request for waiver of consent by the IRB. (see “Quick Guide” below) NOTE ABOUT CONSENT: Federal regulations (45 CFR 46.116) require researchers to describe the nature and purposes of the research as well as both reasonably foreseeable and unforeseeable risk of participation. Accordingly, informed consent for a registry/repository must be as clear as possible about the range and types of future uses envisioned without being vague and open-ended. Researchers should be sensitive to the concerns of special populations, issues surrounding genetic research, and issues surrounding long term storage of data on sensitive behaviors that could cause stigma or affect the reputation, employability, or legal status of a research participant.
   c. If data or specimens are to be collected by or received from a “covered entity” under HIPPA regulations, include the HIPPA authorization form that will be signed by participants for the storage and future research use of their data or specimens. (OR submit the Waiver of HIPAA authorization request form)
      Note: Only certain FAU components are covered by HIPAA requirements; check with Research Integrity or see Guidance on HIPAA and Research if you are unsure.

3. The IRB will review the registry/repository protocol to ensure it adequately specifies the conditions under which data and tissues may be accepted into the registry/repository, how they will be securely stored, and the procedures under which they will be shared to protect the privacy of subjects, maintain the confidentiality of
the data, and preserve the integrity of specimens. Once these and other standard review concerns are addressed, approval will be issued.

**Maintaining a Research Registry/Repository**

4. The registry/repository must be maintained according to the protocol and SOPs submitted to and approved by the IRB. As with all IRB protocols, any amendment to a registry or repository protocol must be approved by the IRB before they are implemented.

5. If the PI of an FAU registry/repository receives a request from an investigator to **distribute** identifiable or de-identified data/specimens from an existing research registry/repository, he/she must obtain a copy of that investigator’s IRB approval (if applicable) and confirmation that the investigator will comply with the registry/repository’s terms of usage. (If applicable, the recipient-investigator may be asked to sign a Material Transfer Agreement; consult Technology Development Office or General Counsel)

6. At each continuing review, the PI of an FAU research registry/repository will be required to provide a summary report to the IRB of all collections, distributions, or destruction of data/specimens from the registry/repository.

7. When a PI no longer wishes to operate the registry/repository for future research, or if the data/specimens are being transferred to another registry/repository, he/she should submit a request for closure to the IRB. The closure request must include the disposition of the data and specimens, including details on the transfer, donation or destruction of data/specimens in a secure way. Any inactive registry/repository should be responsibly closed after 5 years. If a PI wishes to transfer the repository to another PI, a request for amendment should be submitted with the credentials of the new PI and endorsement of the College Departmental Chair or Dean.

**Contributing to a Non-FAU Research Registry/Repository**

If an FAU investigator wishes to contribute data/specimens to a registry or repository outside of FAU, the IRB must review, at a minimum, the IRB protocol used to collect the data/specimens, the consent process and the submittal agreement (see definition above). This allows the IRB to confirm that the data/specimens are authorized to be shared and used beyond the intent of the original research protocol. **Note:** Not all submissions to a research repository meet the federal definition of being engaged in human subjects research. Contact the IRB office for further clarification.

**Requesting Data/Specimens from a Research Registry/Repository**

When an FAU investigator wishes to request coded or identifiable data from an established registry or repository, he/she should submit a request to the IRB either via a new protocol application or as an amendment to an existing study. The FAU IRB must review, at a minimum, the protocol, data collection tools, the usage agreement, consent process (most likely a waiver), and obtain the IRB approval number of the registry/repository from which the request is being made.

If the investigator wishes to request **anonymous** (and some coded) data, he/she may submit a request to the IRB for Determination of Non-Human Subjects Research using Form 6.

**Note:** Certain registries or repositories may require the recipient to obtain a more stringent IRB review, even if the data appears to be de-identified. For example, if the repository contains “microdata” that is anonymous but rich in indirect identifiers, or data on sensitive or criminal behavior, the gatekeeper of the repository may request expedited or full IRB review because the likelihood of the data causing harm in the event of a breach is great, even if the likelihood of the breach occurring is rare.
### Quick Guide on IRB Review Type for Registries/Repositories

- **Data/Specimens Obtained PROSPECTIVELY** *(e.g., after IRB approval granted)*
- **Data/Specimens Obtained ONLY For Research** *(not part of normal operations or clinical care)*

<table>
<thead>
<tr>
<th>Status of Donor Identity</th>
<th>Type of IRB Review and Consent</th>
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<tbody>
<tr>
<td></td>
<td>Genetic Studies</td>
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<tr>
<td></td>
<td>Type of IRB Review</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Full Board or Expedited</td>
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<tr>
<td>Known to Principal Investigator</td>
<td>Full Board</td>
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<tr>
<td>Known to 3rd Party (such as the repository gatekeeper)</td>
<td>Full Board</td>
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*For example, additional blood draw or biopsy.*

### Specimens Obtained PROSPECTIVELY
- **Specimens Left Over from Clinical Procedures and Would Normally Be Discarded**

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<tbody>
<tr>
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<td>Genetic Studies</td>
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<tr>
<td></td>
<td>Type of IRB Review</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Not Human Research</td>
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<tr>
<td>Known to Principal Investigator</td>
<td>Full Board</td>
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<tr>
<td>Known to a 3rd Party (such as the repository gatekeeper)</td>
<td>Full Board</td>
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*For example, excess blood from routine blood draw or leftover biopsy material.*

### Data/Specimens Obtained RETROSPECTIVELY
- **Data/Specimens Were Previously Collected for Either Clinical or Research Purposes**

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<tr>
<td>Known to a 3rd party (such as the repository gatekeeper)</td>
<td>Expedited</td>
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</tbody>
</table>

*ALL specimens needed for the study are already stored, for example, in a laboratory or registry/repository.*
VIII. **Guidance Renewal Date**  
August 15, 2017

IX. **References**  
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens  
(http://www.hhs.gov/ohrp/policy/cdebiol.html)

Response of the Department of Health and Human Services to NBAC’s Report Research Involving Human Biological Materials: Ethical Issues and Policy Guidance  
(http://aspe.hhs.gov/sp/hbm/hbm.pdf)

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**POLICY APPROVAL**

*Initiating Authority*

Signature:  
Date:  
Name: Daniel C. Flynn, Ph.D., Vice President for Research

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*Executed signature pages are available in the Initiating Authority Office(s)*