HRPP Policy Number: 2801 Version: 3.0 Effective Date: 08/14/25	Human Tissue and Data Repositories for Research Use	Supersedes Document Dated: 11/18/17, 07/26/19
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HRPP POLICY 2801 Human Tissue and Data Repositories for Research Use

28.1 Applicability

A human tissue or data repository is a collection of tissue samples or data with the intent of establishing a relatively large collection of data or tissue that will be accessed by other investigators who may or may not be located at the University. This section does not apply to principal investigators (PI) who collect biological fluids or other types of human tissue for analysis as a part of a specific research project.

28.2 Review and Oversight

The U.S. Department of Health & Human Services (HHS), Office of Human Research Protections (OHRP) requires operation of data and tissue repositories be overseen by an IRB. The IRB must review, approve the procedures and conditions under which data and/or tissue specimens are collected, stored, and shared, and ensure that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. As part of its oversight responsibility, the IRB must review and approve a tissue and/or data collection protocol, or section of a protocol, and an informed consent document relating to the collection of the tissue specimens and/or data. For specific OHRP guidance, refer to **http://www.hhs.gov/ohrp/policy/reposit.html**.

28.3 Considerations and Requirements

28.3.1 IRB Review

Collection of data or tissue for storage in a repository must be reviewed and approved by the IRB. The IRB is familiar with the particular circumstances of the local research setting and must weigh considerations like local professional and community standards, institutional policies and resources, and the needs of differing subject populations. An IRB application must be submitted and, along with the standard requirements, address 1) what data or tissue is being collected; 2) a description and location and operation of the repository; 3) the type(s) of research that will be conducted using the data or tissue; 4) the conditions under which data and/or specimens will be released to recipient-investigators; and 5) the procedures to be used by during collection, storage, and release of the data or tissue for protecting the privacy of subjects and maintaining the confidentiality of data.

28.3.2 Informed Consent Documentation

Written documentation of informed consent (consent form) should be obtained from each donor subject.

1. Included among the basic elements of informed consent should be a clear description of 1) the operation of the cell repository; 2) the specific types of research to be conducted; 3) conditions under which data and specimens will be released to recipient-investigators; and 4) procedures for protecting the privacy of subjects and maintaining the confidentiality of data. Informed consent information describing the nature and purposes of the research should be as specific as possible. Where human genetic research is anticipated, informed consent information should include information about the consequences of DNA typing, and the consent form should also include a section for the participant to choose whether or not to allow the specimen to be used in genetic research.

2. Informed consent documents may not include any exculpatory language through which subjects are made to waive or appear to waive any legal rights.

3. The informed consent document should also contain an acknowledgement that collector-investigators and the repository are prohibited from providing recipient investigators with access to the identities of donor-subjects or to information through which the identities of donor-subjects could be readily ascertained.

28.3.3 Submittal Agreements

A written submittal agreement for tissue collectors should require written informed consent of the donor-subjects utilizing an informed consent document approved by the local IRB. It should also contain an acknowledgment that collectors are prohibited from providing recipient-investigators with access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained.

28.3.4 Usage Agreements

Investigators are encouraged to obtain a written usage agreement from recipient investigators that states the following: “Recipient acknowledges that the conditions for use of this research material are governed by the IRB overseeing the repository in accordance with HHS regulations at 45 CFR 46. Recipient agrees to comply fully with all such conditions and to report promptly to the repository any proposed changes in the research project and any unanticipated problems involving risks to donor-subjects or others. Recipient remains subject to applicable State or local laws or regulations and institutional policies that provide additional protections for human subjects.”

28.3.5 Certificate of Confidentiality

It is highly recommended that, for federally funded projects, a **Certificate of Confidentiality** is obtained to protect the confidentiality of repository specimens and data.

28.4 Repository Requirements

1. The research material may be utilized only in accordance with the conditions stipulated by the IRB overseeing the repository. Any additional use of this material requires prior review and approval by the IRB overseeing the repository, and where appropriate, by an IRB at the recipient site.

2. Recipient investigators may never be given information that would allow

identification/re-identification of specimens or data to a specific donor.

3. A covered entity's use or disclosure of PHI to create a research database or repository, and the use or disclosure of the PHI from the database or repository for a future research purpose, are each considered as a separate research activity under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. In general, the Privacy Rule requires authorization for each activity unless an IRB waives or alters the authorization requirement. A single authorization can cover uses and disclosures for multiple activities of a specific research study, including the collection and storage of data and or tissue specimens. However, a compound authorization is not allowed where the provision of research-related treatment, payment, or eligibility for benefits is conditioned on only one of the authorizations and not the other. For example, if an investigator conducts a clinical trial that also involves the collection of tissues and data (PHI) for storage in a central repository for future research use, the actual future research use would require the investigator to obtain a separate authorization for use and disclosure of PHI or a waiver of the requirement for IRB authorization.