TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Repositories: Banking of Identifiable Specimens or Data**	
	Section III: IRB Protocols	
	Number	Date
	IRB III-018	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process for TAMUK investigators to follow when collecting and storing human biological specimens or data that can be linked to individuals.

1.2. The banking of specimens/data refers to the creation of banks and/or database repositories to collect, store, and distribute human biological specimens and data for future research purposes. Repository activities involve three components: (1) Collection of specimens/data; (2) storage and management of the specimens/data; and (3) distribution of specimens/data to recipient investigators for use in a future research project.

1.3. The SOP begins when the Institutional Review Board (IRB) has determined that storage of identifiable specimens/data is the intent of the investigator and/or research site designee.

1.4. The SOP concludes when the IRB determines that the policy should no longer be observed or the repository is no longer in use and the IRB has been formally notified.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. Non-Research Repositories:

3.1.1. If specimens or data were originally collected for non-research purposes AND were added to a non-research repository/database without any identifiable private data or information or links (codes, pathology numbers, record numbers) to identifiable private data or information, it is a non-research repository/database. If this criteria for non-research repository/database is not met, this SOP applies in full as written.

3.2. Research Repositories:

3.2.1. If human specimens or data were collected for research purposes, it is a research repository. Collection of specimens/data, repository storage or data management and use of specimens or disclosure of data are all considered research activities and require IRB review and approval.

3.2.2. Human specimens/data repositories may include two kinds of specimens/data: a) those collected with the express purpose of distribution to other investigators, and b) those collected by individual investigators, and not originally intended to be shared with others, but which are subsequently shared as part of a repository.

3.2.3. Any collection which contains human specimens or data that are potentially identifiable (i.e. directly or indirectly with a code or link) and are distributed to someone other than

the original named investigator(s) creating the collection, regardless of the original intent, may be considered to be a repository requiring IRB oversight.

3.2.4. If the original named investigator(s) wishes to use the potentially identifiable human specimens or data for any future use that is not part of the original IRB approved protocol, then the subsequent use will also require IRB approval and oversight.

3.3. Collection of human specimens/data for a repository:

3.3.1. Investigators collecting human specimens/data that are directly/indirectly identifiable are required to request an IRB review and approval prior to initiating the collection. In most cases, written informed consent from the subject is required, along with HIPAA Authorization when applicable. The informed consent documentation must include a clear explanation of the repository in which the specimens or data will be stored; the conditions under which the specimens or data may be shared with other investigators or entities; and whether the specimens or data will be retained for future research beyond the scope of the current study

3.4. Confidentiality risks associated with research participation may extend beyond the duration of the subject's direct involvement in research. This is relevant when identifiable records or samples are retained by the investigator. These confidentiality risks and/or new disclosure concerns are important to consider during study planning and oversight.

3.5. Advances in genetic analysis, including the ability to re-test samples containing accessible DNA, have increased the likelihood that retained samples may yield significant scientific, personal, or ethical implications that were unforeseen at the time of initial collection. Investigators should destroy identifiers to their samples/data when possible.

3.6. In regard to storing data/specimens outside of TAMUK, if the repository is located at an external institution or organization, the investigator must submit to the TAMUK IRB a copy of the external site's IRB approval letter for operation of the repository at that institution or organization.

3.7. The IRB at the institution where the repository is located must approve and maintain oversight of a protocol that: (a) specifies the conditions under which data and specimens may be accepted and shared with other investigators/designees and (b) ensures adequate privacy and confidentiality protections for subjects contributing to the repository.

3.8. Any "research" specimens/data repository that distributes materials/data requires IRB approval prior to the distribution. The investigator must follow the conditions under which the specimens/data will be shared in the IRB initial application.

3.9. These conditions must consider the privacy of the individuals from whom the tissue came, what the informed consent permitted, and the intent of the person to whom the tissue is sent. The recipient of the tissue samples must abide by the conditions specified in the initial approved IRB application.

3.10. A gatekeeper or repository director, established under the IRB guidelines and pursuant to the IRB approval for the repository, should evaluate each request for sample access to see if the request is consistent with the IRB's conditions for sharing samples, with the original informed subject consent, and the repository's policies.

3.11. The transfer of any data (including de-identified data) to outside collaborators or to external repositories requires a Data Use Agreement or other types of agreements/contracts between the parties involved. All agreements need to be signed by an authorized agent of TAMUK.

3.12. The transfer of materials to outside collaborators requires the use of Material Transfer Agreements (MTAs).

3.13. Research Administration under the Office of Research and Innovation coordinates the completion of MTAs. MTAs need to be signed by an authorized agent of TAMUK.

4. RESPONSIBILITIES

4.1. The investigator should ensure these procedures are carried out to ensure safe and proper usage of repositories and banking of specimens/data.

5. PROCEDURE

5.1. The following procedure should be followed when establishing a repository at TAMUK.

5.1.1. The investigator is to develop written policies and procedures on operating and managing the repository. The policies and procedures are to be provided to the IRB as part of the initial application. No human specimens or data may be collected or stored prior to IRB approval.

5.1.2. The following information must be included with the IRB application.

5.1.2.1. Purpose of the repository

5.1.2.2. Specimen and data collection procedures

5.1.2.3. Specimen and data storage/retention

5.1.2.4. Specimen derivation and processing

5.1.2.5. Specimen and data distribution

5.1.2.6. Obtaining informed consent

5.1.2.7. Procedures for protecting privacy and confidentiality (for example, anonymization of specimens/data, coding of specimens/data, encryption, limited access/secure storage)

5.1.2.8. Confidentiality measures

5.1.2.9. Procedures for return of research results (if and under what conditions)

5.1.2.10. Repository oversight

5.1.2.11. Model informed consent(s) for subjects contributing to the repository

5.1.2.12. Model agreement(s) for investigators collecting tissues for the repository and for investigators receiving tissues from the repository. These agreements should address use of specimens/data, human subject protections, sharing of

specimens with third parties, commercial use of specimens, biohazards, and indemnification.

5.1.2.13. A plan for the disclosure of clinically relevant results/incidental findings, including the mechanism for evaluating whether the results of research testing are clinically relevant and might warrant disclosure to the research participants and a mechanism for disclosure to participants of clinically relevant results/incidental findings.

5.1.2.14. A Certificate of Confidentiality, if needed. Certificates of Confidentiality are issued by the National Institutes of Health to protect identifiable research information from forced disclosure. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Additional information is available at the NIH Certificate of Confidentiality Kiosk website.

5.1.3. If the experimental design allows it, all identifiers should be stripped from the stored samples or data, such that they can never be traced to the individual.

5.1.4. If the experimental design requires that the specimens/data be linked back to an individual subject, retention creates a durable confidentiality risk that must be both controlled and disclosed.

5.1.5. Storage with easily traceable identifiers such as patient names, initials, social security numbers, or medical record numbers is almost never appropriate. An additional safeguard for maintaining confidentiality while retaining a link is to use a code in place of identifiers and retaining a safeguarded master list that provides a key to the code.

6. REFERENCES

6.1. NIH Certificate of Confidentiality Kiosk web site

6.2. OHRP-Guidance on Research Involving Coded Private Information or Biological Specimens (2008)

6.3. OHRP- Issues to Consider in the Research Use of Stored Data or Tissues. (1997)

6.4. 45 CFR 46.116

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