1. PURPOSE
   1. This SOP establishes a process for the banking of identifiable specimens (human biological materials)/data by TAMU investigators. The banking of specimens/data refers to the creation of banks and/or databases (“repositories") to collect, store, and distribute human biological materials (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.
   2. The SOP begins when the Institutional Review Board (IRB) has determined that the banking of identifiable specimens/data is intended by an investigator, and/or research site designee.
   3. The SOP ends when the IRB determines that the policy should no longer be observed or the repository is no longer in use and the IRB is notified.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. SOP STATEMENT
   1. Non-Research Repositories:
      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 links are included, this policy section (3.1.1) does not apply.
   2. Research Repositories:
      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.
      2. Human specimen/data repositories may include two kinds of specimens/data: a) those collected with the expressed 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. Any collection which contains human specimens/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) making the collection, regardless of the original intent, may be considered to be a repository requiring IRB oversight.
      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. Collection of Human Specimen/data for a Repository:
      1. Investigators who collect directly or indirectly identifiable human specimen/data must request IRB review and approval of the activity. Under most circumstances, written informed consent and when applicable HIPAA Authorization from the subject is required and should include information about the repository, the conditions under which the specimens/data will be shared with others and if the specimen/data will be store for future use beyond the current research.
   4. Confidentiality risks of research participation may extend beyond the duration of the subject’s direct participation in research. This is common when records or samples with identifiers are retained by the investigator. These confidentiality risks and/or new disclosure concerns are important to consider.
   5. The ability to re-test samples containing extractable DNA has made it possible that retained samples may contain information that cannot be foreseen at the time of initial collection, but that may eventually be of great importance or sensitivity. Investigators should destroy identifiers to their samples/data when possible.
   6. In regards to storing data/ specimens outside of TAMU, if the repository is located at an external institution or organization, the investigator must submit (to the TAMU IRB) a copy of the external site’s IRB approval letter for operation of the repository at that institution or organization.
   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 or designees and (b) ensures adequate privacy and confidentiality protections for subjects contributing to the repository.
   8. Any “research” specimen/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 as described in the IRB initial review application.
   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.
   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 samples to see if the request is consistent with the IRB's conditions for sharing samples and with the original informed consent and the repository’s policies.
   11. The transfer of 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 TAMU.
   12. The transfer of materials to outside collaborators requires the use of Material Transfer Agreements **(**MTAs). MTA protects the intellectual and other property rights of the provider and generally addresses:
       1. Limits on the use of the research materials, inventions, and results
       2. Prohibitions on the redistribution of the material
       3. Conditions of use, including prohibitions of use in animals or humans
       4. Conditions for publication, usually with provisions that the manuscript must be seen by the donor before submission for publication
       5. A hold-harmless cause, meaning that the donor has no liability resulting from the use of the material
       6. The return of unused materials.
   13. Research Administration under the Division of Research, coordinates the completion of MTAs. MTAs need to be signed by an authorized agent of TAMU.
4. RESPONSIBITIES
   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
   1. The following procedure should be followed when establishing a repository at TAMU.
      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.
      2. The following information must be included with the application ).
         1. Purpose of the repository
         2. Specimen and data collection procedures
         3. Specimen and data storage/retention
         4. Specimen derivation and processing
         5. Specimen and data distribution
         6. Obtaining informed consent
         7. Procedures for protecting privacy and confidentiality (for example, anonymization of specimens/data, coding of specimens/data, encryption, limited access/secure storage)
         8. Confidentiality measures
         9. Procedures for return of research results (if and under what conditions)
         10. Repository oversight
         11. Model informed consents for subjects contributing to the repository
         12. Model agreements 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.
         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. A mechanism for disclosure to participants of clinically relevant results/incidental findings to be included.
         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 web site.
      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
      4. If the experimental design requires that the specimens/data be referable back to an individual subject, retention creates a durable confidentiality risk that must be both controlled and disclosed.
      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 master list that provides a key to the code.
6. MATERIALS
   1. IRB electronic Application
7. REFERENCES:
   1. NIH Certificate of Confidentiality Kiosk web site
   2. AAHRPP II.3.E