Institutional Review Board

GUIDELINE # 6: REVIEW PROCESS FOR TISSUE COLLECTION AND USE

I. PURPOSE

The IRB must review all research involving human tissue collection that meets the criteria for Human Subjects Research and make a determination if the research is Exempt.

II. STATEMENT

All human subjects research, irrespective of the source of funding, conducted by A&M- SA faculty, staff and students must be submitted and reviewed in accordance with the Federal research regulations, Texas A&M System Guidelines, A&M-SA IRB policies and local consideration.

III. SCOPE

This guideline applies to all research conducted where the A&M- SA IRB serves as the Reviewing IRB.

IV. PROCEDURE

Investigators will be asked to respond to the following questions:

1. **What personal health information will accompany the sample for use in the proposed research?**
   Personal health information can accompany a sample, including identifying information. The type of information will depend on what the investigator is allowed to have access in line with IRB approval, consent and tissue source restrictions (e.g., lab sources, repository sources, etc.).

2. **Is the sample de-identified - i.e. will the investigator be able to identify the participant using the accompanying personal health information?**
   'De-identified' means that there are no participant identifiers accompanying the sample, such as
   - name
   - medical record number
   - social security number
   - date of birth
   - address
   - telephone number

'De-identified' also means that the sample cannot be linked to a specific group or family, based on the characteristics of the sample, such as genetic makeup.
Other participant information may accompany the sample and still be considered 'de-identified.' Information that may accompany the sample includes, but is not limited to the following:

- approximate date of collection (month/year)
- approximate date of surgery (month/year)
- type of specimen
- diagnosis (*some exceptions)
- stage of disease
- gender
- age
- treatment status
- outcome
- race or ethnic group

*when the diagnosis is rare and individuals are potentially identifiable by naming the condition.

The IRB will also review the information that will be included with the samples, and assess how appropriate and necessary the information is to the research study proposed. The IRB recognizes that any combination of general information may provide a link to the personal information.

For clinical samples, investigators must use good clinical judgment and exercise caution in using information when it comes to selecting groups of patients. The IRB will determine whether there may be potential harm to the race or ethnic group being studied. If there is a question as to the use of certain information, the IRB should consult legal counsel for advice prior to the use of such information.

3. **If the sample is de-identified, does a code or link exist to re-establish the identity of the sample? If yes, who created the code and who has access to the code?**
A sample may be de-identified, however, a code or link may still exist between the sample and the identity of the participant. It is important for the IRB to know if such a link exists and who has access to this link.

4. **Consent and Authorization for Tissue Collection and Use**

Informed consent and authorization (for samples collected within the covered entity) must be accounted for in one of the following ways:

- Full informed consent and authorization (for samples collected within the covered entity)
- Waiver of consent plus a method to account for authorization

Full informed consent and authorization must be obtained from participants or their legally authorized representatives for use and/or banking of their samples, except where waivers or non-human subject determinations apply. Consent and authorization documents should include the following information:

- **Tissue use description**
  The consent form must describe how the sample will be collected and used for the proposed research.
    - For use that does not require tissue banking, the consent form must specify when the sample will be destroyed.
    - For use that involved tissue banking, see the Tissue Repositories [1]
    - If use of the sample involves genetic testing, the investigator must also include language regarding the disclosure of results as outlined in the IRB guidance on Genetic Research
- **Authorization language for use and disclosure of information**
  Authorization determines who can have access to the personal health information of the participants. Some important considerations are as follows:
    - What protected health information (identifiable or non-identifiable) will accompany the samples?
    - Who will be allowed to receive the samples with the accompanying health information - only individuals within A&M-SA and its covered entity, or others from outside entities and institutions?
- **A waiver of consent** may be requested for the use of tissues. Per A&M system guidance only specimens collected with informed consent can be used in teaching or research. The IRB will approve a waiver if the study meets the following 4 criteria, as outlined in 45 CFR 46.116(d):
    - The research involves no more than minimal risk.
    - The waiver will not adversely affect the rights and welfare of the participants.
    - The research could not practicably be conducted without the waivers.
    - When appropriate, the participants will be provided with additional pertinent information.
- **A method to account for authorization** must be used in conjunction with a waiver of consent. The following methods may be used:
    - Waiver of authorization
    - Limited data set[2]

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[1] **Samples from Repository**
The use of samples from a tissue repository typically requires the submission of a new study application to the IRB, disclosing the proposed use of the tissues, according to the requirements for tissue use. Samples may be held under IBC holding protocol and may not be released until final IRB approval has been issued.
The use and disclosure of information and tissues from a repository are determined by the (a) IRB responsible for oversight of the repository, and (b) the IRB responsible for research at the site where the information and tissues are used.
The A & M- SA IRB is responsible for any research repository maintained at the A & M- SA. Information and tissues from the repositories may be accessed, used, shared, or disclosed in accordance with the IRB-approved repository protocol, informed consent and authorization document, and any additional conditions stipulated by the IRB. Once provided to investigators outside of the A & M- SA, use and disclosure of the information and tissues must also comply with any additional requirements of the recipient institution and it's IRB.

[2] **Limited Data Set:** A limited data set could include the following (potentially identifying) information:

- Admission, discharge, and service dates;

- De-identification

Samples Collected for Non-Research Purposes (Pathology Samples)

Samples that have been collected or will be collected solely for non-research purposes, such as pathology samples, may be used and stored for research. Since antique tissue or body samples (e.g. those collected before 1960's) are not collected with proper consent process they cannot be included in research or teaching. The investigator must either obtain full consent and authorization from participants or provide justification for the use of a waiver of consent and other method to account for authorization. The IRB will often request that these samples be de-identified without a link to identifiers to protect the privacy and confidentiality of the participants.

a. Autopsy Samples

According to the Common Rule, deceased individuals do not meet the definition of a human subject; however, the IRB is still responsible for assuring HIPAA regulations are followed and must review research involving specimens collected from postmortem individuals. The IRB will also consider ethical issues concerning potential harm to the decedents' families or other associated groups (e.g. race, sect, etc.).
Typically, consent is not required to use and store autopsy specimens; however, if the research involves genetic testing of these samples for heritable traits, a consent form signed by the responsible family member(s) may be required. Written consent from the responsible family member(s) should be gained in conjunction with or following the autopsy consent process. Collection of autopsy specimens may not occur without IRB approval.

b. Publicly Available Tissue Samples

There are a few opportunities for tissue samples to be publicly available, but there may be limited circumstances of tissue samples being made available to qualified researchers for valid research purposes at a reasonable cost. Publicly available samples must be characterized as de-identified samples. If the identity of the sample is known, the identity must be recognizable in the public domain and not entitled to a presumption of anonymity.

- Dates of birth and, if applicable, death;
- Age (including age 90 or over); and
- Five-digit zip code or any other geographic subdivision, such as state, county, city, precinct and their equivalent geocodes (except street addresses).

Covered entities must condition the disclosure of the limited data set on execution of a "data use agreement," which

- establishes the permitted uses and disclosures of such information by the recipient, consistent with the purposes of research, public health, or health care operations;
- limits who can use or receive the data; and
- requires the recipient to agree not to re-identify the data or contact the individuals.

In addition, the data use agreement must contain adequate assurances that the recipient will use appropriate physical, technical and administrative safeguards to prevent use or disclosure of the limited data set other than as permitted by HIPAA and the data use agreement, or as required by law.

C. Sharing Samples with Other Institutions

Sharing specimens involve two components:

- Samples sent to other institutions/entities/investigators (including sponsors) from A&M-SA Covered Entity.
- Samples received by the A &M- SA covered entity from other institutions/ entities/ investigators.

Identifying information can only be shared between institutions if the participant has been given authorization to do so. The consent and authorization document must specify which outside institutions/entities/investigators the identifying information will be shared with. If the receiving institutions/entities/investigators are not listed in the authorization, the identifying information cannot be shared.
If use of the samples is approved under a method other than full consent and authorization, the samples must be de-identified before they are shared. The samples may or may not have accompanying medical information. If a code exists to link the samples and the identity of the participants, it should remain with the home institution or entity and not be made available to the other institutions/entities/investigators.
Rules and procedures defining the handling, storage, and disposal of samples should be developed by the investigators and the process for the return of the tissue sample to the original requestor or the process of destruction of the sample(s) should be clearly defined.

IRB review must be conducted for both institutions before the data and samples are shared. The IRB requires all external IRB approvals to be submitted as part of the IRB application. One of the following agreements outlining tissue use and transfer must also be signed by officials representing each institution or entity before the transfer of data and samples may occur:

- A sponsor contract: All contracts must be signed and approved through the Office of Research and Sponsored Programs (ORS) or similar entity.
  OR
- A Materials Transfer Agreement (MTA): All MTA's must be signed and approved through the Office of Vice President for Research & Graduate Studies or Designee before the IRB will issue final approval for a study.

V. APPLICABLE REGULATIONS AND GUIDELINES

OHRP does not consider research involving specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals.
   AND
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.

Examples of acceptable conditions:

- The key to decipher the code is destroyed before the research begins.
- The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased.
- There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
- There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Veteran's Administration (VA) Policies for Tissue Collection

The Veteran's Administration (VA) designates human subject research to include both living and deceased individuals. Therefore, research involving human tissues from an autopsy or postmortem sampling requires full IRB approval as well as a signed informed consent document by a responsible family member that meets VA requirements.
Human biological specimens, as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, must be maintained at VA-approved tissue banks. All tissue used for VA samples will follow the appropriate VA guidelines.

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