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. This guideline has been updated to incorporate the NIH Data Management and Sharing Policy (effective January 25, 2023; revised by NIH Notice NOT-OD-26-046, issued February 25, 2026, with updated DMS Plan requirements effective for applications due on or after May 25, 2026), NIH guidelines on tissue sharing and research resources, Texas HB 130 (Texas Genomic Act of 2025, with TAMUS compliance guidance effective February 2026), and other pertinent regulatory updates.

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 Federal research regulations, Texas A&M System Guidelines, A&M-SA IRB policies, and local considerations. Research involving tissue collection and genomic data must comply with the Texas Genomic Act of 2025 (effective September 1, 2025) and the NIH Data Management and Sharing Policy (effective January 25, 2023). Effective for NIH applications with due dates on or after May 25, 2026, investigators must use the updated DMS Plan format as required by NOT-OD-26-046.

III. SCOPE

This guideline applies to all research conducted where the A&M-SA IRB serves as the Reviewing IRB, including research involving tissue collection, storage, and genomic sequencing.

IV. PROCEDURE

Investigators will be asked to respond to the following questions:

A. Personal Health Information and Sample Identification

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.).

Is the sample de-identified?

'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 personal information. For clinical samples, investigators must use good clinical judgment and exercise caution when selecting groups of patients based on accompanying information. The IRB will consider whether the proposed use of such information could create potential harm to a race or ethnic group being studied. When needed, legal counsel should be consulted before approving the use of such information."

Coded Samples and Linking Information

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. Investigators must specify:

- Whether a code or link exists to re-establish the identity of the sample
- Who created the code
- Who has access to the code
- Security measures in place to protect coded information

B. 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

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:

1. 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 involves tissue banking, refer to NIH Guidelines for Human Tissue Repository (NHLBI) and ensure compliance with NIH Research Resources Sharing Policy (revised April 2024).
- 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 and comply with Texas HB 130 (Texas Genomic Act of 2025).

2. 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:

- 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?
- Will the data be shared in accordance with the NIH Data Management and Sharing Policy (2023)?

Waiver of Consent
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 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.

Methods to Account for Authorization
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 with data use agreement
- De-identified data set

C. Compliance with Texas HB 130 (Texas Genomic Act of 2025)
Effective September 1, 2025, Texas HB 130 (Chapter 174, Health and Safety Code, Texas Genomic Act of 2025) requires annual certification of compliance for organizations that conduct research on or testing of the human genome or perform human genome sequencing. Whether certification is required must be determined based on the specific research activities involved.

RESEARCH ACTIVITIES EXCLUDED FROM HB 130 (NO CERTIFICATION REQUIRED): Per TAMUS Research Compliance Office guidance (February 2026), the following are excluded from the Act's definition of human genome sequencing: protein sequencing; metabolite sequencing; RNA sequencing when cDNA is not created; any plant or animal genomic sequencing; human genome sequencing where every sample can be confidently identified as a non-Texas resident.

RESEARCH ACTIVITIES INCLUDED — CERTIFICATION REQUIRED: The following activities are subject to HB 130: (1) sequencing the human genome, including samples from Texas residents or samples where Texas residency cannot be ascertained (e.g., de-identified samples, commercially available samples, or samples sequenced as a commercial external service); and (2) creation of cDNA following RNA sequencing, thereby reconstructing the human genomic sequence.

Key requirements include:

- PROHIBITED EQUIPMENT AND SOFTWARE: Facilities may not use genome sequencers or software produced by or on behalf of foreign adversaries (as defined by 15 C.F.R. Section 791.4(a)), state-owned enterprises of foreign adversaries, or entities domiciled within foreign adversary countries.
- DATA STORAGE REQUIREMENTS: Genome sequencing data of Texas residents may not be stored within the borders of a foreign adversary country. Exception: Data collected as part of clinical trials or biomedical research subject to 28 C.F.R. Part 202.
- DATA SECURITY: Facilities must ensure security of genome sequencing data using reasonable encryption methods, restriction on access, and other cybersecurity best practices.
- ACCESS RESTRICTIONS: Genome sequencing data of Texas residents (other than open data) must be inaccessible to any person located within the borders of a foreign adversary country.
- ANNUAL CERTIFICATION: Organizations conducting research on or testing of the human genome or performing human genome sequencing (as defined above), must certify compliance annually to the Texas Attorney General by December 31. Extensions may be requested when necessary. Simply existing as a research organization or performing research related solely to plant or animal genomics, does not require certification. Institutions must determine whether certification is required based on their specific research activities.

- PROHIBITION ON SALE IN BANKRUPTCY: Facilities may not sell or transfer genomic sequencing data of Texas residents to foreign adversaries, their state-owned enterprises, or related entities as part of bankruptcy proceedings.
- CIVIL PENALTIES: Violations carry civil penalties of $10,000 per violation, with enforcement by the Attorney General.
- PRIVATE CAUSE OF ACTION: Texas residents harmed by violations may bring private actions for actual damages or statutory damages up to $5,000 per violation, plus attorney's fees.

Investigators conducting genomic research must include in their IRB application a statement of compliance with Texas HB 130 and describe measures taken to ensure compliance.

Note: The certification form required by the Texas Attorney General may include information beyond the strict scope of HB 130. For questions regarding foreign adversaries, export controls on sequencing equipment, and other Research Security matters, contact the TAMUS Research Security Office.

D. NIH Data Management and Sharing Policy (2023, updated 2026 per NOT-OD-26-046)

Effective January 25, 2023, NIH-funded or NIH-conducted research that generates scientific data must comply with the NIH Data Management and Sharing Policy, regardless of funding level. This policy applies when tissue collection, genomic, or other studies generate scientific data. As of February 25, 2026, NIH issued Notice NOT-OD-26-046, which updates the required DMS Plan elements and mandates a new format page for applications with due dates on or after May 25, 2026. This notice supersedes NOT-OD-21-014. Key requirements include:

- DATA MANAGEMENT AND SHARING PLAN (DMSP): All NIH grant applications generating scientific data must include a plan using the required NIH format page describing how data will be managed and shared throughout the funded period.
- SCIENTIFIC DATA DEFINITION: "Recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings." This does NOT include laboratory notebooks, preliminary analyses, case report forms, or physical specimens.
- PLAN ELEMENTS:
- Effective for applications with due dates on or after May 25, 2026, DMS Plans must use the updated NIH format page and address the following elements: (1) Will there

be maximum appropriate sharing of scientific data underlying publications? [YES/NO]; (2) Will data be shared by the time of publication or end of performance period? [YES/NO]; (3) Will shared data be made available for at least as long as required by repository/journal policies? [YES/NO]; (4) If "no" to elements 1-3, or if sharing will be otherwise limited, describe the limitations and the ethical, legal, or technical factors [300 words maximum]; (5) If data from human participants will be shared, will privacy, rights, and confidentiality be protected per NOT-OD-22-213, including use of access controls? [YES/NO]; (6) A table [100 words maximum] listing key data types anticipated (including species and modality, e.g., "human genomic data") and the repository where data may be managed and shared. For studies subject to the NIH Genomic Data Sharing (GDS) Policy, two additional elements are required: whether large-scale human genomic data will be shared in a NIH-designated repository per GDS timelines [YES/NO/Not Applicable]; and whether Institutional Certification expectations will be met [YES/NO/Not Applicable]. Applications submitted before May 25, 2026 should continue using the elements in NOT-OD-21-014.

- BUDGETING: Direct costs to support data management and sharing activities may be included in the budget and are allowable costs.
- MAXIMIZING SHARING: NIH expects investigators to maximize scientific data sharing while acknowledging that ethical, legal, or technical factors may necessitate limiting sharing to some extent.
- REPOSITORIES: Data should be deposited in well-established repositories. NIH maintains a list of recommended repositories.
- HUMAN SUBJECTS PROTECTION: When sharing data from human subjects research, investigators must ensure appropriate de-identification and privacy protections, including consideration of informed consent for data sharing.
- COMPLIANCE REPORTING: Starting in 2024, investigators must report on compliance with their approved DMS plan in their Research Performance Progress Reports (RPPRs). Plans must be updated throughout the life of the project as appropriate, and shared data should adhere to FAIR (Findable, Accessible, Interoperable, and Reusable) principles.

For research subject to both the Genomic Data Sharing Policy and the DMS Policy, a single integrated plan may be submitted. Investigators should consult with their funding NIH Institute or Center for specific guidance.

E. NIH Research Resources Sharing Policy (Updated April 2024)

NIH considers sharing of unique research resources (research tools) an important means to enhance the value of NIH-sponsored research. When biological materials and other research resources are developed with NIH funds and the associated research findings have been accepted for publication, they should be made readily available for research purposes to qualified individuals within the scientific community. Key principles include:

- Research resources should be made available after publication or after they have been provided to NIH.
- Recipients may elect and retain title to inventions developed with federal funding pursuant to the Bayh-Dole Act.
- NIH allows funding recipients to retain and license biological materials for which patent protection might not be pursued.
- Agreements must reflect the objectives of the Bayh-Dole Act and ensure inventions are used to promote free competition without unduly encumbering future research.
- Tissue repositories distributing materials require an IRB that establishes conditions under which tissue will be shared.
- A committee must evaluate each request for samples to ensure consistency with IRB conditions and informed consent.

F. NIH Policy on Human Fetal Tissue (Updated January 2025)

As of January 2025, NIH funds may no longer be used to support research involving human fetal tissue from elective abortions. This policy applies across all NIH Intramural Research Programs and NIH-supported extramural research, including grants, cooperative agreements, and contracts. Investigators are encouraged to utilize alternative research approaches including organoids, tissue chips, computational biology, and other cutting-edge platforms.

G. 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 the 1960s) 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.

H. 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.

I. Publicly Available Tissue Samples

There are 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.

Limited Data Sets

A limited data set may contain the following identifiers:

- Dates of birth and, if applicable, death
- Age (including age 90 or over)
- 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
- 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.

J. Sharing Samples with Other Institutions

Sharing specimens involves 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.
- A Materials Transfer Agreement (MTA): All MTAs 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

A. Federal Regulations

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:

- The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals. AND
- 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.
- There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

B. 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.

C. Texas State Law

Research facilities in Texas must comply with the Texas Genomic Act of 2025 (HB 130), effective September 1, 2025. See Section IV.C for detailed requirements. Institutional determination of whether HB 130 certification is required should be made in consultation with the TAMUS Research Compliance Office, referencing the TAMUS Guidance for

Institutions Regarding HB-130 Certifications and Compliance (Version 2, February 2026).

VI. REFERENCES

1. 45 CFR Part 46 - Protection of Human Subjects (Common Rule)

2. HIPAA Privacy Rule, 45 CFR Part 160 and Part 164

3. NIH Policy for Data Management and Sharing (Effective January 25, 2023), Notice Number NOT-OD-21-013. Available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html. [As updated by NOT-OD-26-046, effective May 25, 2026; supersedes NOT-OD-21-014.]

4. NIH Guidelines for Human Tissue Repository, National Heart, Lung, and Blood Institute. Available at: https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/guidelines-for-human-tissue-repository

5. NIH Research Resources Sharing Policy (Revised April 2024). Available at: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm

6. NIH Genomic Data Sharing Policy. Available at: https://sharing.nih.gov/genomic-data-sharing-policy

7. Texas Health and Safety Code, Chapter 174 - Security of Genetic Information (Texas Genomic Act of 2025), H.B. No. 130, 89th Legislature, effective September 1, 2025

8. 15 C.F.R. Section 791.4(a) - Definition of Foreign Adversary

9. 28 C.F.R. Part 202 - Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern

10. Executive Order 14117 - Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern

11. NIH Announcement: Policy Shift to End Use of Human Fetal Tissue in NIH-Supported Research (January 2025). Available at: https://www.nih.gov/news-events/news-releases/nih-announces-major-policy-shift-end-use-human-fetal-tissue-nih-supported-research

12. VA Tissue Banking Guidelines. Available at: https://www.research.va.gov/programs/tissue_banking/default.cfm

13. Office for Human Research Protections (OHRP) Guidance on Research Involving Coded Private Information or Biological Specimens

14. Genome.gov - Protecting Human Research Subjects Guide. Available at: https://www.genome.gov/protecting-human-research-subjects-guide

15. NIH Notice NOT-OD-26-046. Updated Elements of an NIH Data Management and Sharing Plan. Released February 25, 2026. Supersedes NOT-OD-21-014. Effective for applications with due dates on or after May 25, 2026. Available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-046.html

16. Texas A&M University System Research Compliance Office. Guidance for Institutions Regarding HB-130 Certifications and Compliance. Version 2, reviewed by RCO & OGC February 16, 2026.

17. NIH Notice NOT-OD-22-213. Protecting Privacy when Sharing Human Research Participant Data. Available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-213.html

VII. Revisions

Guideline: # 6	**Version: V.2**
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