

HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

2.9 REPOSITORY POLICY AND PROCEDURE

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD)

EFFECTIVE DATE: June 7, 2021

I. POLICY STATEMENT

- A. The collection, storage, and distribution of human data and/or tissue/biospecimens for future research purposes are separate “repository operations”. In most cases, these repository operations constitute “human research” and requires Institutional Review Board (IRB) approval.
- B. The operation of a human data management center (e.g., data centers, data banks, or database) or human biospecimen repository (e.g., registry, bank, or library) for research purposes by UTSW employees or agents must be approved by an IRB if the activity meets the definition of human subjects research.
 - 1. The repository Principal Investigator (PI) has primary responsibility for the collection, storage and distribution of data and/or biospecimens.
 - 2. The repository operation must comply with all applicable policies regarding establishment, maintenance and use of databases containing personal identifiers including IRB approval. In addition, the operation of the repository must be capable of:
 - a) Identifying when the material is originally received and whether the person from whom the material was obtained signed a legally effective consent/gave authorization under HIPAA (unless consent and/or authorization were waived by the IRB).
 - b) Identifying data/samples for which consent has been withdrawn and ensuring no future use.
 - 3. The security and confidentiality of the materials are protected by providing the following minimum measures:
 - a) Coding. A method to code the data/biospecimens, including a process to protect/maintain the key to the code and limit access to the key. The coding system must be adequate to reduce the possibility of re-identification by unauthorized individuals.
 - b) Controlled access to the data/biospecimens - access to the un-coded data/biospecimens must be restricted to a limited number of repository staff. Accountability for controlling and monitoring access must be provided.
 - c) Security procedures - a method to limit access to the coded data/biospecimens (including computer security and biospecimen storage security measures) must be provided.

d) A Certificate of Confidentiality is recommended, but not always required by the IRB, as an additional protective measure.

4. Distribution of data/biospecimens from a UTSW repository.

a) Repositories will not (generally) provide access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained to individuals or entities outside of the repository investigators and staff (with the exception of 4b).

b) Repositories will require proof of IRB review for each specific research study (from researchers outside of the repository team) that requests identifiable data/biospecimens from the repository or will generate identifiable data/biospecimens from de-identified data/biospecimens from the repository. Each study utilizing or generating identifiable data/biospecimens is a research activity that is separate from the data center/repository itself.

c) In the situation where the recipient investigator is also a member of the repository team, there must be a process to either:

(1) prevent this person from being able to access the identifiable information; or

(2) allow access but restrict activities to only involve the use of repository materials, if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; and this is an IRB approved distribution activity under the repository protocol.

d) Repositories may require a signed agreement from the recipient-investigator stating (as applicable):

(1) that use of repository materials is governed by an IRB,

(2) only biospecimens or data that are not otherwise identifiable to the recipient may be provided by a UTSW repository (except those with IRB approval to do so),

(3) the recipient agrees not to attempt to re-identify the materials (except those with IRB approval to do so),

(4) if identifiable materials are distributed, they may only be utilized in accordance with the conditions stipulated by an IRB, and

(5) any additional use of the materials requires prior review by the repository and an IRB (if identifiable).

e) Tracking. Repositories must include a plan to track the distribution of materials to recipient investigators. This tracking should include (as applicable):

(1) Name of recipient,

(2) title of protocol,

(3) type of materials distributed (data, blood samples, tumor samples, etc.),

(4) whether the materials were provided with/without identifiers, and

(5) confirmation that IRB approval was received (for identifiable material distribution)

- C. The collection of materials (data or biospecimens) for inclusion in a research data center or repository by UTSW employees/agents must be submitted to the UTSW IRB.
 - 1. The data center or repository may be either local or external.
 - 2. Collection of materials (data/specimens) must be authorized by obtaining the legally effective informed consent and authorization of the subject or the subject's legally authorized representative (unless consent and authorization were waived by the IRB).
 - 3. Prior consent and authorization for collection and use of materials in future research may be waived only if the criteria for a waiver of consent and HIPAA authorization are met, and:
 - a) The protocol includes a plan for allowing subjects to opt-out of the repository or certain aspects of the repository, or
 - b) It involves materials (data, documents, records, or biospecimens) that have been collected, solely for non-research purposes such as medical treatment or diagnosis, or
 - c) It involves existing materials (data, documents, records, or biospecimens) that have been collected for research purposes under another IRB-approved research study, however consent and authorization for future research use could not/cannot be obtained.

II. SCOPE

This policy applies to human subject research repositories established for the purpose of storing data and/or human biospecimens for future research purposes.

This policy does not apply to data/human biospecimens that are collected and stored solely as part of routine clinical care or hospital procedures, such as blood banks, pathology, surveillance, or quality assurance. However, it does apply to data/human biospecimens from these sources that are then stored for future research.

III. PROCEDURES FOR POLICY IMPLEMENTATION

- D. Submission for a **local repository** involving **collection, storage, and distribution** of human data and/or tissue/specimens.
 - 1. A repository application is submitted for IRB review. The package includes a completed repository protocol, repository consent form or waiver request, and other supporting documents as appropriate.
 - 2. If the local repository will accept biospecimens/data from other IRB approved research studies, the consent form (or waiver) used in the collection of biospecimens/data from the other studies must be included in the repository application. The Repository PI may either:

- a) Add the individual collector-investigator(s) (from the other study) as a repository team member(s) and utilize the consent approved for the repository to collect biospecimens/data from subjects enrolled in the other research study, or
 - b) Add the entire study staff of the contributing study to the study personnel list and the study staff will use the consent form approved under the repository protocol. The personnel role will be “collector-investigators.”
3. The IRB will consider exceptions to the consent requirement for studies which are contributing existing data/biospecimens where consent for banking has already been obtained.
- E. Submission procedures for repository activities limited to **local collection** of materials to be sent to a separate repository (either internal or external repositories).
1. An IRB application is submitted for review. The information related to the local collection of materials for inclusion at a separate repository which should be submitted are:
 - a) For repository studies only collecting and contributing to a separate (external) repository:
 - (1) A UTSW IRB Application,
 - (a) Provide information about collection of materials
 - (b) If you will maintain a link (code) to the identifiers, information about the coding plan must also be provided
 - (2) UTSW Repository consent form (current version)
 - (3) A copy of the external institution’s IRB approval for the storage/distribution operations of the repository, and
 - (4) other supporting documents as appropriate.
 - b) For research studies that will also collect and contribute to separate repositories:
 - (1) The repository sponsor’s protocol or study’s research description providing information on collection activities and transport of materials to the repository,
 - (2) Repository consent form (current version) or research consent with added information about the repository and an opportunity for subjects to opt in to the repository or a copy of the external repository consent form,
 - (3) A copy of the IRB/ethics committee approval for the storage/distribution operations of the repository (if applicable), and
 - (4) Other supporting documents as appropriate,
 - (5) The new contributing protocol must be added to the repository protocol collection plan for internal repositories,
- F. Procedure common to all repository submissions

1. The HRPPD staff conducts an administrative review of the submission (see 1.1 RECEIVING, ROUTING, AND ADMINISTRATIVE REVIEW OF IRB SUBMISSIONS POLICY AND PROCEDURE).
2. The submission is forwarded to the appropriate review team (convened board or expedited review) and is reviewed by the IRB (expedited reviewer or convened board) following guidance provided in the 6.2 IRB APPROVAL OF RESEARCH POLICY AND PROCEDURE AND 2.1 INITIAL REVIEW OF RESEARCH POLICY AND PROCEDURE.
3. Following approval by the appropriate review procedure, the determinations are reported in accordance with the 8.2 REPORTING POLICY AND PROCEDURE.

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
January 2019	HRPP	Revision to reference 2019 common rule
June 2018	HRPP	New Policy