Human Research Protection Program Departmental Policy and Procedure

8.3 Recordkeeping

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: June 12, 2026

I. Policy

a. This policy describes documentation requirements, storage and maintenance of records for the Human Research Protection Program Department HRPPD.

b. The HRPPD maintains a physical and electronic filing system (hybrid) for protocol and other IRB records.

II. Scope

a. This policy and procedures applies to HRPPD who maintains IRB records in accordance with applicable federal, state and local regulations with regard to access, storage and retention.

III. Procedures For Policy Implementation

a. Access to Records

i. The HRPPD secures all paper and electronic IRB records and limits access to the IRB Chair, IRB members, Assistant Vice President for Human Research Administration (AVPHRA), IRB Director (IRBD), HRPPD staff, Institutional Official (IO), and other authorized affiliated institution representatives, and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies. IRB records are accessible for inspection and copying by authorized representatives of federal agencies or departments in reasonable times and in a reasonable manner.

1. HRPPD staff may grant other UTSW employees access to the records on an as- needed basis for official UTSW business. Investigators or

their authorized study personnel have reasonable access to files related to their research activities. HRPPD staff limits all other access to IRB records to those who have legitimate need for them, as determined by the AVPHRA, IRBD, or designee, and/or when submitted through state open records statutes UTSW Legal Counsel).

2. Individual permissions to access electronic files are submitted to Academic Information Systems (AIS)
3. Individuals with access to electronic HRPP files will submit a signed Acknowledgement of Confidentiality Policy Related to Human Research to the HRPPD

ii. Access Security

1. The electronic IRB system is a closed, centrally managed system that utilizes unique user IDs, passwords, and system authentication. Additionally, the electronic IRB system utilizes role-based access to authorized users only and maintains an activity history and audit trail.
2. When the HRPPD receives a request for IRB records, HRPPD staff checks to see whether the request is from a PI or his/her authorized personnel. If the person requesting the record is listed as study personnel contact on the record requested, the HRPPD staff may copy record for that person to pick up or may fax, mail, or e-mail the pertinent parts of the record.
3. If the individual requests a substantial amount of material, HRPPD staff allows access to the record and a scanner or computer in the HRPPD for use by the person requesting the material.
    a. If the person requesting the record is not listed as study personnel on the record requested, the AVPHRA or designee makes a determination before releasing any records as to whether the request is from appropriate accreditation bodies, institutional

officials, administrators, or regulatory agencies that should have access. Unless the individual states a reason for not informing the PI of the request for a record, HRPPD staff informs the PI that HRPPD has received a request for access to the applicable protocol.

b. Storage of protocol records

   i. At the time of conversion in May 2010 the legacy IRB number was recorded in the electronic system for historical purposes. The active protocol legacy paper records for each protocol prior to electronic conversion are maintained in secure but physically accessible access restricted storage until the study is closed in the electronic system. These records are stored according to the state of Texas Retention Schedule.

   ii. Records must be identifiable, concise, accurate, timely, complete, relevant, organized and secured.

   iii. For research involving genomic sequencing or genomic data from Texas residents, recordkeeping must include documentation demonstrating compliance with Texas genetic-information security requirements, including evidence of U.S.-based data storage, verification of permitted genomic sequencing equipment/software, and records of access-control measures preventing access from foreign-adversary countries. These records must be maintained with the protocol file for the duration required under HRPP and applicable law.

   iv. Records should not be corrected after they are written. If modification is necessary because of error, the original must be legible, the reasons for the modification should be clear and the modification must be signed/initialed and dated as appropriate by the person who made the correction. (Substantive changes must be communicated to the IRB and the PI.)

v. The official protocol record as of May 1, 2010 is the electronic file. Prior to that date, the paper record is the official record and the electronic files represent a hybrid shadow file plus current status. The paper record for electronically converted legacy protocols should not be the sole reference.

vi. The electronic IRB system has a server-based filing system that allows electronic storage of individual protocol documents.

vii. The electronic files are secured, maintained and backed up by Academic Information Systems (AIS)

viii. The records must be identifiable by using the PI name and the IRB tracking number

ix. The records must be concise, by containing all essential information and when possible, avoiding duplication of documents

x. The records must be accurate, by ensuring all applicable information is located within the documents and all items are verifiable

xi. The records must be timely, by being completed and filed in an appropriate time frame

xii. The records must be complete, by all applicable documentation within the files. The following documents will be filed in the IRB record (paper and/or electronic record):

1. Protocol Files

    a. The protocol and any request to revise or amend the protocol;

    b. Any scientific evaluations provided to the IRB;

    c. Consent documents including DHHS-approved sample consent documents (as applicable);

    d. Progress reports and records of continuing review activities (including DSMB report summaries);

e. Reports of unanticipated problems (e.g., unexpected serious adverse events that are possibly related to the research or other injuries that meet the UPIRSO criteria);

f. All correspondence between the IRB and investigators;

g. Significant correspondence between the HRPPD and investigators;

h. All correspondence between the IRB and institutional officials;

i. Statements of significant new findings provided to participants;

j. Reports of noncompliance;

k. Complaints;

l. Requests to inactivate IRB approval (Notice of Study Closure);

m. Notices or approval letters from other committees (e.g., Radiation Safety Committee);

n. Drug or device information (including Investigator's Brochures, as applicable)

o. Recruitment materials

2. Other HRPPD Records – In addition to protocol files, the HRPPD maintains the following information and records: HRPPD staff organizes and stores records in files or binders or in electronic documents as appropriate, which include, but are not limited to, the following categories:

   a. Policies and procedures

   b. IRB membership rosters (including resumes or CVs for each member)

   c. Documentation of IRB Actions (See 8.1 IRB MINUTES)

   d. Federalwide Assurance

e. Memorandums of Understanding where applicable, with Affiliated Institutions (e.g., Parkland, Children's, etc.)

f. Other IRB correspondence

g. Alleged noncompliance case records

h. Federally mandated reports and, where responses to those reports require IRB review for potential determinations, results of review of such responses by the convened IRB

i. Electronic records documenting completion of mandatory IRB training for study personnel, IRB members, and HRPPD staff

j. Communications to and from the IRB

k. Budget/Accounting information for the department of the HRPP

l. The records must be relevant, by including only information needed

m. The records must be organized, by filing documents within the appropriate categories

c. Retention

i. The HRPPD retains all records (with or without participant enrollment) for six years after closure or cancellation, which is sufficient to meet federal, state, and local regulations, sponsor requirements, and organizational policies and procedures

ii. Physical Files

1. As necessary, physical files of inactivated protocols are sent to the University long term storage

2. The files to be archived are logged into an electronic database (which tracks the box number for each file) and the boxes containing the files are sealed.

3. A request to store the files is generated with a destruction date (six

years after the inactivation date of the last study in the box which was inactivated).

4. The request is sent to the for transport of the files and storage.
5. Files are destroyed after 6 years per the request of the HRPPD. Destruction eligibility is confirmed by HRPPD and communicated to the file caretaker who then proceeds with the destruction.

iii. Electronic Files

1. Electronic files of inactivated protocols are stored indefinitely in the electronic system. The electronic system study status will display “closed.”
2. The electronic record remains intact in the “closed” state and viewable to authorized individuals as described above.

IV. Definitions

See glossary of human research terms

V. References

a. 21 CFR 50: Protection Of Human Subjects
b. 45 CFR 46: Protection Of Human Subjects
c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)
d. 21 CFR 56: Institutional Review Boards

VI. Revision and Review History

a. Revision Date: June 2026; Author: HRPP; Description: Adding information about research involving genomic sequencing
b. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

c. Revision Date: July 2018; Author: HRPP; Description: Reference changed to RSO from SHUR

d. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

e. Revision Date: March 2012; Author: IRB Office; Description: IRB Written Procedures