Recordkeeping
Policy and Procedure

Table of Contents
Policy
Procedure
   Access to and Storage of Records
   Storage of Protocol Records
   Retention
References

I. Policy. The Office of the IRB (OIRB) maintains records in accordance with applicable federal, state and local regulations with regard to access, storage and retention.

A. Access to Records

   1. The OIRB secures all paper and electronic IRB records in the OIRB and limits access to the IRB Chair, IRB members, IRB Director, Associate Director, OIRB staff, Associate Vice President for Research Operations (AVPRO), authorized South Texas Veterans Health Care System (STVHCS) 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.

   2. OIRB staff may grant other UTHSCSA employees access to the records on an as-needed basis for official UTHSCSA business. Investigators or their authorized study personnel have reasonable access to files related to their research activities. OIRB staff limits all other access to IRB records to those who have legitimate need for them, as determined by the IRB Director, Associate Director, and/or when submitted through state open records statutes UTHSCSA Legal Counsel).

   3. Individual permissions to access electronic files are submitted to Information Management Client Support Services (IMCSS)

   4. Individuals with access to electronic IRB files will submit a signed Acknowledgement of Confidentiality Policy Related to Human and Animal Research Records to the OIRB.

B. Storage of files

   1. The OIRB staff maintains a physical and electronic filing systems (hybrid) for protocol and other IRB records.

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

   3. 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.)
4. 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 shadow file and should not be the sole reference.

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

6. The electronic files are secured, maintained and backed up by Information Management Client Support Services (IMCSS).

C. Retention - The OIRB retains ALL records (VA research and non-VA research; 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. In the event the VA policy on record retention exceeds the UTHSCSA IRB policy on retention, IRB records for VA research studies will be transferred to the VA for retention in accordance with the VA policy.

II. Procedures

A. Access to and Storage of Records

1. Access Security

   a) When the OIRB receives a request for IRB records, OIRB 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 OIRB staff may copy record for that person to pick up or may fax, mail, or e-mail the pertinent parts of the record.

   b) If the individual requests a substantial amount of material, OIRB staff allows access to the record and a scanner or computer in the OIRB for use by the person requesting the material.

      (1) If the person requesting the record is not listed as study personnel on the record requested, the OIRB Director or the Associate Director 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, OIRB staff informs the PI that OIRB has received a request for access to the applicable protocol.

2. Storage of protocol records

   a) OIRB maintains hybrid records about individual protocols for which a research application was reviewed by the IRB up to protocol number ‘HSC20100428H – paper records storing was discontinued after that protocol; subsequent protocols only maintain electronic records.

   b) The records must be identifiable by using the PI name and the IRB tracking number

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

   d) The records must be accurate, by ensuring all applicable information is located within the documents and all items are verifiable
e) The records must be timely, by being completed and filed in an appropriate time frame.

f) 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 OIRB and investigators;

(h) All correspondence between the IRB and institutional officials (e.g., STVHCS R&D Service or Committee);

(i) Statements of significant new findings provided to participants;

(j) Reports of noncompliance;

(k) Complaints;

(l) Requests to inactivate IRB approval (final report);

(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 OIRB Records – In addition to protocol files, the OIRB maintains the following information and records: OIRB 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)
Institutional Review Board

Recordkeeping Policy and Procedure

Page 4 of 5

(c) Documentation of IRB Actions (See IRB Minutes Policy and Procedure)

(d) Federalwide Assurance

(e) Memorandums of Understanding where applicable, with Affiliated Institutions (e.g., STVHCS)

(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 OIRB staff

(j) Communications to and from the IRB

(k) Budget/Accounting information for the department of the IRB

The records must be relevant, by including only information needed

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

1. Electronic files

(a) Exterior protocol folders should be appropriately labeled as YY-NNNL PI Name.

(b) Interior electronic files should be created from the documents submitted via email attachments, CD or other modality from the PI at submission and consistently named as per Example Folder for Electronic Files.

(c) All subfolders within the Example Folder for Electronic Files should be copied and placed within the Exterior protocol folder at time of creation of electronic file.

(d) Large paper items (i.e., Sponsor Protocol, Investigator Brochure) may be kept electronically on the Share Drive with the first page of the document showing document type and date to avoid large documents in the paper files.

2. Physical files

(a) OIRB staff maintain records utilizing the above policy, and the Protocol Records Index at http://library.uthscsa.edu/rrs/recordrrs.php.

(b) Exterior folder is labeled with IRB tracking number and the name of the Principal Investigator (at the time of initial approval).

(c) Interior folders are labeled with IRB tracking number (using modified tracking number format: YY-NNNL (two digit fiscal year-last three digits of assigned number, and type of study letter.)
(d) All paper protocol records are filed in reverse chronological order.

(3) Other OIRB Records

(a) As other non-protocol-specific documents are created or received, OIRB staff categorize and file

3. Retention

a) Physical Files

(1) Quarterly, physical files of inactivated protocols are sent to the warehouse for storage (files for VA research studies are filed in separate boxes than non-VA research studies)

(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) For Non-VA research, 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) For VA research, a request to store the files is generated without a destruction date. The boxes will be recalled (at the end of the UTHSCSA retention period) for transfer to the VA or destruction depending upon the VA retention policy at that time.

(5) The request is sent to the warehouse, whose staff transports the files and stores them.

(6) Files are destroyed after 6 years per the request

b) Electronic Files

(1) Quarterly, electronic files of inactivated protocols are stored on an external hard drive.

(2) The files to be archived are logged into an electronic database (which tracks the month/year the files were archived and the anticipated destruction or transfer to VA date).

(3) The date of destruction (or transfer for VA research in accordance with VA policy) is calculated by adding six years to the last day of the quarter in which the study was inactivated.

(4) A query will be run quarterly to identify protocols that have reached their destruction/transfer date and those files will be (transferred to VA if applicable, and) permanently deleted from the hard drive.

III. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)