

## **SOP 304: DOCUMENTATION, DOCUMENTS, AND DATA MANAGEMENT**

### **1. POLICY**

The IRB shall document determinations required by applicable laws, regulations, codes, and guidance. The IRB office shall maintain IRB files in a manner that contains a complete history of all IRB actions and determinations related to review and approval of New Studies, Continuing Reviews, Modification, Unanticipated Problems involving risks to participants or others, Protocol Deviations, Human Research Determinations, Protocol Developments, and miscellaneous items.

The IRB Office shall maintain and retain study documents related to research project submissions pursuant to applicable federal, state, and local regulations, collaborating institution requirements, and University policies and procedures. IRB research project documents will be provided to sponsors, collaborating institutions, or funding entities according to the terms of the study-specific research agreement. IRB research project documents may be made available for inspection and copying by authorized representatives of regulatory agency and University auditors at reasonable times and in a reasonable manner.

The IRB Office shall maintain IRB records related to IRB and Privacy Board proceedings and determinations pursuant to applicable federal, state, and local regulations and University policies and procedures. These records may be made available for inspection and copying by authorized representatives of the sponsor, collaborating institutions, funding department or agency, regulatory agency, and institutional auditors at reasonable times and in a reasonable manner. Requests for documents or IRB records by other individuals will be processed according to SOP 307: Copy and Record Requests.

### **Specific Policies**

#### **1.1 Document Retention**

The IRB office shall retain all records **on site** regarding a research project (regardless of whether it is not approved, active, or inactive) for as long as possible or as space allows **on site**. All IRB paper records are permanently stored in an off-site location approved by the University for storage of PHI when space is no longer available in the IRB office. All electronic records are maintained in the IRB's electronic information system.

The IRB office shall retain on site or electronically, all records regarding research projects that are submitted for at least three (3) years after completion of the research or after the non-approval.

The HSC HRPP office shall retain on behalf of the Privacy Board all records related to the HSC Privacy Board, in the same manner as described above.

#### **A. Study-related Documents**

Adequate study-related documentation of each IRB activity is prepared and maintained in a secure location. These documents may include paper or electronic copies of:

Research project proposals (including grant applications as applicable)

- Investigator brochures (if applicable)
- Scientific evaluations (if applicable)
- Participant recruitment materials and data collection instruments
- Consent documents
- Progress reports submitted by Researchers
- Research Privacy forms
- DHHS-approved sample consent documents
- Continuing review reports and records of continuing review activities
- Reports of any complaints or injuries received from participants
- Reports of unanticipated problems involving risks to participants or others, reports of injuries to participants, and/or protocol deviations
- Monitoring reports and site visit reports
- Modifications to previously approved research
- Documentation of non-compliance with applicable regulations
- Statements of any significant new findings provided to participants
- Correspondence between the IRB and the Investigators
- Documentation of determinations required by the regulations and protocol-specific findings supporting those determinations
- For VA research:
  - All correspondence between the IRB and the VA Research and Development Committee
  - Correspondence between the IRB and Researchers
  - Serious and unexpected adverse events submitted to the IRB reported on the Unanticipated Problem report form, including internal serious adverse events
  - Protocol violations/deviations submitted to the IRB
  - A resume for each IRB member
  - All previous membership rosters
  - Copies of regulatory audits and any correspondence related to the audit.

## **B. VA Research Records Access**

Records for VA Research, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are according to the VHA Records Control Schedule (RCS 10.1).

The VA Research and Development Committee shall have access to all VA-related IRB records. All IRB records will be accessible to appropriate

VA personnel for inspection as requested. (A confidentiality agreement must be signed by the VA prior to the latter.)

### **C. Privacy Board Documentation**

The IRB staff maintains a restricted location for adequate documentation of the Privacy Board activities. These documents include copies of all original Research Privacy Forms submitted for review.

### **D. Department of Defense**

Department of Defense-sponsored research may require the IRB to submit records to the Department of Defense for archiving.

## **1.2 IRB Administration Documents**

The IRB office shall maintain on site or electronically all records regarding IRB administrative activities that affect research project review for at least three (3) years or as space allows.

1.2.1 All IRB paper records are stored in a warehouse when space is no longer available in the IRB office. On site, electronic or archived documents may include:

A. Rosters of IRB members identified by name, earned degrees, representative capacity, scientific/nonscientific status, affiliation status (whether the member or an immediate family member of the member is affiliated with the organization), employment or other relationship between each IRB member and the organization, and indications of experience sufficient to describe each member's chief anticipated contribution to the IRB deliberations.

B. Alternate members including the member for whom the alternate substitutes.

C. Records of any employment or other relationship between each IRB member and IRB and/or the University (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

Current and obsolete membership rosters remain in the IRB Office and are archived according to University policy in an approved University storage location for permanent storage. The roster of IRB members is submitted to OHRP. Any changes in IRB membership are reported to OHRP. Reports submitted to OHRP are maintained on site. See SOP 202: Management of IRB, for detailed information pertaining to IRB Rosters.

On appointment of unaffiliated IRB members, it is determined whether any of the members' immediate family members are affiliated with the University. If so, they are changed to affiliated members. Each unaffiliated IRB member is polled annually to determine whether any of their immediate family members are affiliated with the University and if so they are changed to affiliated member. Documentation of the initial and annual poll is retained in the member's file.

- 1.2.2 The HRPP Director or designee maintains copies of current and obsolete SOPs, Investigator Manuals and the “OUHSC Human Subject Protection in Research” and Investigator Education Manual.
- 1.2.3 The HRPP Director or designee is responsible for maintaining written records of delegation of specific functions, authorities, or responsibilities of the IRB Chair.

**1.3 IRB Records for Initial Review, Continuing Review and Modifications by the Expedited Procedure shall include:**

- The specific permissible category.
- Description of actions taken by the IRB reviewer.
- Any determinations required under the regulations, along with protocol-specific findings supporting those determinations.
- Note regarding the frequency for the next continuing review.

**1.4 IRB Records for Exempt Determinations shall include:**

- The specific category of exemption.
- Description of actions taken by the IRB reviewer.
- Any determinations required under the regulations, along with protocol-specific findings supporting those determinations.

**1.5 Destruction of Copies**

All paper materials received by the IRB that are considered confidential and are not original documents that need to be retained in the study-records, as well as confidential materials distributed to the IRB members, shall be collected by the IRB staff at the end of each IRB meeting and destroyed by an authorized records destruction agent.

**1.6 Archiving**

All documents and materials related to IRB activities shall be retained on site or electronically for three (3) years or as space allows and archived according to University policy. University policy is governed by a state statute that requires files containing applications submitted by faculty, students and staff to conduct research projects involving human subjects, correspondence relating to review of applications, and federal guidelines regarding the uses of human subjects in research projects to be retained permanently in a in an office maintained by the University. Any IRB files that contain PHI will be stored at a location approved by the University for storage of PHI.

**1.7 Data Management**

The IRB's electronic information system shall be managed to contain records of all IRB activities, facilitate correspondence with investigators, and provide access to reports and data needed for internal and external business functions.

## **2. SCOPE**

This SOP applies to all documents submitted to the IRB.

## **3. RESPONSIBILITY**

The HRPP Director is responsible for maintaining complete files on all research projects submitted to the IRB and for all applicable regulatory compliance requirements.

The HRPP, IRB staff, and IRB members are responsible for the maintenance and confidentiality of the IRB files.

The Compliance Applications and Technology Office is responsible to maintain, archive, and support the electronic information system.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.103, 115

21 CFR 56.115

Veteran's Health Administration Handbook 1200.05 § 26 - 29

VHA RCS 10.1

## **5. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 202: Management of IRB

SOP 307 Copy and Data Request

## **6. ATTACHMENTS**

304-A State Universities and Colleges General Records Disposition Schedule

VHA RCS

## **7. PROCESS OVERVIEW**

The following process overview describes the requirements for document management.

### **7.1 Document Retention**

The IRB office shall retain on site or electronically all records regarding a research project (regardless of whether it is not-approved, approved or inactivated) for at least three (3) years after completion of the research or after non-approval. All IRB paper-based records are stored in a warehouse when space is no longer available in the IRB office. The HRPP Office retains on behalf of the Privacy Board all records related to the Privacy Board, in the same manner as described above.

Study-related documents: The HRPP Director oversees the maintenance of adequate documentation of IRB activities in a secure location. These documents include those described in Section 1.1 of this policy.

## **7.2 IRB Administration Documents**

The HRPP Director oversees the retention of all records regarding protocols that are approved and the research initiated for at least three (3) years after completion of the research. All IRB paper records are stored in a warehouse when space is no longer available in the IRB office.

The HRPP Director oversees the maintenance of adequate documentation of IRB Administrative activities in a secure location. These documents include those described in Section 1.2

## **7.3 Destruction of Confidential Materials**

The IRB staff is responsible for collecting at the end of each IRB meeting all confidential materials that were used by the IRB members. These materials will be destroyed by an authorized records destruction agent.

## **7.4 Archiving**

The HRPP Director or designee oversees the archiving of inactive study files, retained on site for three (3) years according to University policy. The paper IRB records are moved and stored in an off-site location approved by the University for storage of PHI. The HRPP Director maintains records of study files permanently as required by state statute.

## **7.5 Data Management**

All HRPP staff members shall be trained on the proper use of the IRB electronic information system used to document study review and compliance activities. The HRPP Director or designee maintains appropriate security methods, such as reviewing and processing requests to access the IRB's electronic information system by researchers at affiliated institutions and to limit access to secure areas. The IRB's electronic information system shall be backed up daily.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/09/2016

**NEXT ESTABLISHED REVIEW DATE:** AUGUST 2018