

SOP: 304
DOCUMENTATION, DOCUMENT,
AND DATA MANAGEMENT

1. POLICY

The IRB office shall maintain IRB files in a manner that contains a complete history of all IRB actions related to review and approval of protocols, continuing reviews, amendments, unanticipated problems involving risks to participants or others, protocol deviations, and miscellaneous items.

The IRB Office shall maintain documents related to study protocols as well as to IRB and Privacy Board proceedings pursuant to federal, state, and local regulations, sponsor requirements, and organizational policies and procedures. All records regarding a study submission (regardless of whether it is approved) shall be retained in an appropriate manner as required by law and/or institutional policy.

Records shall be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, regulatory agency, and institutional auditors at reasonable times and in a reasonable manner.

Required documents shall be submitted to the appropriate funding entity as required.

Specific Policies

1.1 Document Retention

The IRB office shall retain all records **on site** regarding an application (regardless of whether it is approved or cancelled without participant enrollment) for as long as possible or as space allows **on site**. All IRB records are permanently stored in a warehouse when space is no longer available in the IRB office.

The IRB office shall retain on site, all records regarding research that is approved and initiated for at for at least three (3) years after completion of the research or as space allows. The HRPP office shall retain on behalf of the Privacy Board all records related to the Privacy Board, in the same manner as described above.

A. Study-related Documents

Adequate study-related documentation of each IRB activity is prepared, maintained and retained in a secure location. These documents may include:

- Copies of all original research protocols reviewed, scientific evaluations (if any), approved consent documents, DHHS-approved sample consent documents, amendments, continuing review reports, and reports of unanticipated problems involving risks to participants or others, reports of injuries to participants, protocol deviations and miscellaneous items.
- Copies of grant applications/research proposals and investigator brochures that have been submitted to the IRB for review.
- Records of continuing review activities.
- Copies of all submitted participant recruitment materials, survey instruments, and questionnaires.
- Agendas and minutes of all IRB meetings.

- Copies of all submitted monitoring reports, site visit reports, and other continuing review activities.
- Copies of all correspondence between the IRB and the Investigators.
- Statements of any significant new findings provided to participants.
- Reports of any complaints received from participants.
- A resume for each IRB member.
- Documentation of determinations required by the regulations and protocol-specific findings supporting those determinations.
- Documentation of non-compliance with applicable regulations.
- Approved Research Privacy forms.
- For VA research:
 - All correspondence between the IRB and the VA Research and Development Committee.
 - Serious and unexpected adverse events submitted to the IRB reported on the Unanticipated Problem report form.
 - Protocol violations submitted to the IRB.

B. VA Research

Records for VA research shall be retained for a minimum of five (5) years after completion of the study, in accordance with VHA's Records Control Schedule.

The VA Research and Development Committee shall have access to all IRB records.

C. Privacy Board Documentation

The IRB staff prepares, maintains, and retains in a secure location adequate documentation of the Privacy Board activities. These documents shall include copies of all original Research Privacy Forms that are submitted for review.

1.2 IRB Administration Documents

The IRB office shall maintain and retain on site, all records regarding IRB administrative activities that affect review activities for at least three (3) years or as space allows. All IRB records are stored in a warehouse when space is no longer available in the IRB office. These documents may include:

See SOP 202, Management of IRB for detailed information pertaining to IRB Rosters.

- A. Current and obsolete copies of the Policies and Standard Operating Procedures, Investigator Manuals, Oklahoma City Campus: In-house Program Reference Manual "OUHSC Human Subject Protection in Research" are maintained.
- B. Documentation of the IRB Chair's delegation of specific functions, authorities, or responsibilities.

1.3 IRB Records for Initial and Continuing Review by the Expedited Procedure, to Include:

- The specific permissible category.
- Description of actions taken by the 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 are to Include:

- The specific category of exemption.

1.5 Destruction of Copies

All material received by the IRB that is considered confidential and is not required original documentation, as well as appropriate controlled forms, shall be collected at the end of each meeting and destroyed by an appropriate records destruction facility.

1.6 Archiving

All documents and materials germane to IRB determinations shall be retained on site for three (3) years or as space allows and archived according to University policy. Archiving policies of the University require that archived records must be retained permanently in an approved University storage facility.

1.7 Data Management

The database shall be managed to contain records of all IRB activities, facilitate correspondence with all researchers, and provide access to reports and data needed for internal and external business functions.

2. SCOPE

The policies and procedures apply to all documents used in the submission, initial review, and continuing review of research submitted to the IRB.

3. RESPONSIBILITY

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

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

The IRB Business Analyst is responsible to maintain, archive, and support the IRB access database system of the IRB electronic files.

The HRPP and IRB staff is responsible for the proper disposal of Board member packages following the meetings.

The IRB staff is responsible to enter study information into the database, upon receipt of a new study.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 115

21 CFR 56.115

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 202, Management of IRB

6. ATTACHMENTS

304-A State Universities and Colleges General Records Disposition Schedule

7. PROCESS OVERVIEW

The following process overview describes the requirements for document management.

7.1 Document Retention

The IRB office shall retain on site all records regarding an application (regardless of whether it is approved) for at least three (3) years. The IRB office shall retain on site, all records regarding research that is approved and initiated for at for at least three (3) years after completion of the research or as space allows. All IRB 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.

7.1.1 Study-related documents:

The HRPP Director oversees the maintenance of adequate documentation of IRB activities in a secure location. These documents may include:

- Copies of all original research protocols reviewed, scientific evaluations, if any, approved consent documents, DHHS-approved sample consent documents, amendments, progress reports, and reports of unanticipated problems involving risks to participants or others, reports of injuries to participants, and reports of deviations from the protocol.
- Copies of grant applications/research proposals and investigator brochures that have been submitted to the IRB for review.
- Records of continuing review activities.
- Copies of all submitted participant recruitment materials, survey instruments, and questionnaires.
- Agendas and minutes of all IRB meetings.
- Copies of all submitted monitoring reports, site visit reports, and other continuing review activities.
- Copies of all correspondence between the IRB and the Investigators.
- Statements of any significant new findings provided to participants.
- Reports of any complaints received from participants.
- A resume for each IRB member.

- Documentation of determinations required by the regulations and protocol-specific findings supporting those determinations.

The HRPP Director maintains IRB records for at least three (3) years after cancellation if a protocol is cancelled without participant enrollment.

The HRPP Director retains records for VA research for a minimum of five years after completion of the study, in accordance with VHA's Records Control Schedule.

The HRPP Director provides access to all IRB records to the VA Research and Development Committee to all IRB records.

The HRPP Director oversees maintenance of adequate documentation of the Privacy Board activities. These documents may include:

- Copies of all original Research Privacy Forms that are submitted for review.

7.2 IRB Administration Documents

7.2.1 The HRPP Director oversees the on-site 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 records are stored in a warehouse when space is no longer available in the IRB office.

The HRPP Director oversees the on-site retention of all records regarding IRB administrative activities that affect review activities for least three (3) years. These 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 facility for permanent storage. The roster of IRB members is submitted to OHRP. Any changes in IRB membership is reported to OHRP. Reports submitted to OHRP are maintained on site.

On appointment of unaffiliated IRB members, it is determined whether any of their immediate family members are affiliated with the University. If so, they are changed to affiliated member. 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.

7.2.2 The HRPP Director maintains current and obsolete copies of the Standard Operating Procedures, Investigator Manuals, Policies and Procedures, and Investigator Education Manual.

7.2.3 The HRPP Director is responsible for maintaining delegation records of specific functions, authorities, or responsibilities of the IRB Chair in writing.

7.3 Destruction of Copies

All material received by the IRB, that is considered confidential and in excess of the required original documentation, as well as appropriate forms, is collected at the end of the convened meeting by the IRB staff and stored in locked bins. The IRB staff contacts the records destruction facility for collection and destruction as needed.

7.4 Archiving and Destruction

The IRB Business Analyst oversees the archiving of inactive study files, retained on site for three (3) years according to institutional policy. All IRB records are stored in a warehouse when space is no longer available in the IRB office. The IRB Business Analyst provides reports for archiving to the IRB staff. The IRB Business Analyst consults with the HRPP Director as necessary to resolve any related problems. Files are moved and retained permanently in an off site, approved storage facility. The IRB Business Analyst or HRPP Director maintains records of permanently archived study files.

7.5 Data Management

The IRB Business Analyst trains all IRB staff members on the proper use of all electronic systems used to document study review and compliance activities, maintains the database manual as a reference document for staff to assure consistency of operations, and oversees the security of the electronic system by conducting appropriate reviews of electronic data and audit trails at designated time periods. The IRB Business Analyst maintains appropriate security methods, such as issuance and revision of ID/passwords, to limit access to secure areas. If user ID/password combinations are used, they are changed at appropriate intervals. Invalidated, stolen, lost or otherwise compromised user ID/password combinations are replaced with a new combination.

The database is backed up every 60 minutes during the day at the HSC Campus and once each night at the Norman Campus.

APPROVED BY: _____

DATE: 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012