Issuing Department: Human Subjects Protection Program
Policy Number: 2011-024.0
Policy Title: File Requirements & Record Retention Requirements

Purpose

The purpose of this policy is to set forth record retention requirements that the Institutional Review Board (IRB) and Principal Investigators (PI) must follow.

Definitions

Policy

IRB Files & Retention: IRB files and documentation are considered privileged information. Every effort will be made to maintain confidentiality and non-disclosure of this information.

The IRB staff will maintain records for each convened meeting, including the minutes, agenda and roster. IRB minutes will document required determinations.

In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of a protocol, the IRB staff will maintain complete files of all active studies on site either in paper or electronic format. Study files will contain all documentation submitted by the PI for IRB initial review, continuing review, review of modifications, and review of problem reports that may constitute an unanticipated problem involving risk to subjects or others, serious non-compliance or continuing non-compliance. Documentation contained in files, as applicable to a study, includes:

- Protocols or research plans.
- Recruitment materials.
- Consent documents.
- Progress reports submitted by researchers.
- Records of continuing review activities.
- Data and safety monitoring reports, if any.
- Modifications to previously approved research.
- Documentation of non-compliance,
- Correspondence between the IRB and the PI,
- Reports of unanticipated problems,
- Reports of injuries to subjects,
- Statements of significant new findings provided to participants
- Investigator brochures,
- Grant applications,
- Results of scientific reviews
- Audit reports, and
- DHHS-sample consents and protocols.
- If applicable, rational for determining that research appearing on the expedited review list is more than minimal risk

When the expedited procedure is used, the IRB file will also contain the reviewer's determination that the submission qualified for expedited review, the category(ies) under which it qualifies, the action taken by the reviewer, and documentation by the reviewer that required determinations have been met.

When a submission qualifies for exemption, the file will also contain the reviewers determination that the submission qualifies for exemption and the category(ies) under which it qualifies.

In accordance with Federal regulations, IRB staff will retain IRB study records for at least three years beyond the completion of a study or study cancellation without subject enrollment. Connecticut currently has no required retention period for IRB records.

A designated member of the IRB staff arranges to have closed paper study files moved to a location off-site for archiving. The IRB staff person maintains a master index of the files archived. Files are retrievable within approximately 48 hours for future reference to allow for inspection and copying by regulatory agencies, including the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP), at reasonable times and in a reasonable manner.

Investigator Records & Retention: OHRP and the IRB require investigators to maintain research records for 3 years beyond the completion / cancellation of the study.

Per FDA regulations for investigational new drugs investigators must retain records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it was investigated; or, if no application is to be filed or if the application is not approved for such indications, until 2 years after the investigation is discontinued and the FDA is notified.

Per FDA regulations for investigational devices an investigator or sponsor shall maintain the study records during the investigation and for a period of 2 years after the latter of the following two dates: the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. An investigator or sponsor may withdraw from the responsibility to maintain records for the period required and transfer custody of the records to any other person who will accept responsibility for them. Notice of a transfer must be given to FDA not later than 10 working days after transfer occurs.

Per the HIPAA regulation, investigators are to retain documents relating to uses and disclosures, authorization forms, business partner contracts, notices of practice, responses to requests to amend or correct information, a patient's statement of disagreement, or a complaint from an individual for 6 years from the date of creation or the date when it last was in effect, whichever is later. (See 64 Fed. Reg. 59994)

Investigators are responsible for meeting any additional record retention requirements set forth in clinical trial agreements with sponsors.

Procedure

IRB File Procedures:

- The electronic IRB submission system will house study specific files and all associated documents. For studies that began before implementation of the system the study may have both a paper file and electronic file associated with it. The paper file will be retained in chronological order until such time as the study closes at which point it may be archived. IRB minutes and agenda will be maintained within the electronic submission system and will also be exported to store in electronic format on a secure shared drive.

- The IRB roster will also be stored on the secure shared drive.

IRB - Record Retention/Archiving:
Upon closure of a study designated IRB staff will archive the paper IRB study folders off site for at least the required retention period.

- staff will record the contents being archived (e.g. IRB numbers) and the identification of the archive box on the master archive index
- after the required retention period has been met, designated staff may request that records be destroyed by filing a records destruction request form with facilities management who in turn coordinate the request with the off-site storage facility.

Electronic files may be periodically purged from the system after the retention requirements have been met.

Investigator Study Files

- Investigators are responsible for satisfying record retention requirements and must confirm in the IRB application that they will do so.

Related Policies

2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

45 CFR 46
31 CFR 312
21 CFR 812
45 CFR 164

Document Attributes

Date Created: 9/26/2017

Replaced Version: 8/20/2013

Reviewed and Approved By:

Richard H. Simon *9/26/2017*

Richard Simon, MD **Date**
Director Human Subjects Protection Program