1.0 Purpose:

1.1 The Hartford HealthCare Human Research Protection Program (HHC HRPP) maintains a complete set of materials relevant to the Institutional Review Board (IRB) review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, sponsor requirements, and organizational policies and procedures.

1.2 IRB records should be organized to allow a reconstruction of a complete history of all IRB action related to the review and approval of a protocol, this includes, but is not limited to copies of report of injuries to subjects, data and safety monitoring reports, if any, and significant new findings.

1.3 HRPP policies govern document retention that follows legal, regulatory, and sponsor requirements, as well as institutional policies.

1.4 The method of record retention should allow access by authorized personnel and ensure that documents are kept safely and confidentially.

2.0 Definitions:

3.0 References:

3.1 45 CFR 46.115(a)-(b)

3.2 21 CFR 56.115(a)-(b)

3.3 ICH-GCP 4.9.5

4.0 Procedure:

4.1 Maintenance and Retention of IRB Records

4.1.1. The HHC HRPP office will prepare and maintain documentation related to IRB review of all study materials for expedited and full reviews (for expedited reviews, this will include justification for the expedited review), including initial submissions, continuing reviews, and modifications. These may include, but are not limited to:

- submission forms
- protocols and amendments
- consents, authorizations, and waivers
- recruitment and other patient materials
- progress reports and records of continuing review activities
- scientific or other evaluations submitted by a consultant/ad hoc member that are not otherwise incorporated into the minutes
- data and safety monitoring reports
- reports of unanticipated problems, complaints, deviations, non-compliance, or significant new findings
- reports of injuries to subjects
- significant new findings

- checklists pertinent to the reviews
- correspondence between the IRB and researchers related to review of such items

These will be kept for a minimum of 6 years after completion of a study at Hartford HealthCare.

Investigator Brochures and reports of adverse events and DSMB findings will be kept for a minimum of 3 years after completion of a study at HCC.

4.1.1.1. Materials submitted for research activities that would require IRB review, but that are withdrawn or otherwise inactivated prior to review by the IRB, will be maintained for a minimum of 1 year from submission.

4.1.1.2. Records for research activities that are reviewed by the IRB, but are disapproved, will be maintained for a minimum of 3 years after the review.

4.1.1.3. Records for research activities that are reviewed by the IRB, but are not given final approval (either by the IRB or for other reasons), will be maintained for a minimum of 3 years after the review.

4.1.1.4 Records for research activities receiving IRB approval, but closed by the investigator without subject enrollment will be maintained for a minimum of 3 years after closure.

4.1.2. The HHC HRPP office will maintain records related to exempt studies, including justification for the exemption, for a minimum of 3 years after completion of the study.

4.1.3. The HHC HRPP office will maintain copies of agendas and complete sets of minutes for a minimum of 6 years after a meeting. In addition, minutes documenting initial and continuing reviews and discussion of major revisions pertinent to individual research activities will be retained with the project until it is discarded.

4.1.4. The HHC HRPP office will maintain documentation related to IRB membership, including attendance at convened meetings, rosters, and curricula vitae, and records relating to financial disclosures and training requirements completed by IRB members or consultants for a minimum of 3 years.

4.1.5. Other records maintained by The HHC HRPP office include HRPP Policies and Procedures, Federalwide Assurance and IRB registrations, and reports of inspections.

4.2. Investigator Responsibilities for Record Retention

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period

however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained

4.3. Storage and Accessibility

4.3.1. Paper study materials are stored in lockable file cabinets in the Research Administration wing, which is accessible only with a work-force identification badge.

4.3.2. Electronic copies of study materials are stored in files on a secure hospital network. Access is restricted by users / user groups. Applications and other supported documentation are submitted through an online forms tracking system using SSL Secure Sockets Layer protocols. All data submitted is stored securely on site with backup plans in place.

4.3.3. All requests to view or copy any part of a file by anyone other than documented study personnel must be authorized by the principal investigator in writing or in person (e.g., via telephone). A log will be kept of any such requests, including date, files viewed, name of reviewer, and reason for review.

4.3.4. Any confidential paper records to be discarded, including protocol-related documents, are placed in one of the hospital's locked confidential waste containers. Once project records are discarded, the corresponding electronic files are deleted.

4.3.5. All records will be made accessible for inspection and copying by authorized representatives of the FDA and DHHS and other appropriate agencies at reasonable times and in a reasonable manner.

5.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	SMH	7/1/11	Conversion to new policy template; general expansion of policy
02	CLB	7/22/15	Clarification of documents to be retained, addition of retention requirement for trials closed without subject enrollment
03	CLB	3/15/20	General review and administrative changes

Element II.5.A

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