

**Policy on Records Retention****Date of Last Revision: 9/20/2019; 4/19/2021****I. Background**

- (a) Retention of research records is an increasingly important task to allow for transparency and replication of research results. Federal regulations and UC Policy require investigators and IRB administration to retain records for specified periods.

**II. Principal Investigator and Study Team**

- (a) Identifiable data: To protect confidentiality, especially for more sensitive data, identifiers should be removed as soon as possible, based on the need of the research.
- (b) Retention period:
  - (1) For research funded by any Common Rule department or agency, the Office of Human Research Protections (OHRP) in the Department of Health and Human Services requires human subjects research study records to be kept for a minimum of 3 years after the close of the study, including studies in which no subjects were enrolled. To find funding agencies to which the regulations apply see [Common Rule Departments and Agencies](#) and [HHS Agencies & Offices](#).
  - (2) Any records pertaining to protected health information (PHI) must follow HIPAA Privacy Rule retention period of 6 years after the close of the study.
  - (3) A sponsor may inform the Principal Investigator (PI) of additional record retention requirements.
- (c) Study records, the PI must retain include, but are not limited to:
  - (1) Initial Submission for review of proposed human subject research and all related documentation.
  - (2) Modification Submissions for IRB-approved/exempt certified studies and all related documentation.
  - (3) Renewal Submissions and all related documentation. This includes annual administrative check-ins (for studies that qualify) and requests for continuing review of IRB approved studies.
  - (4) Incident Submissions and all related documentation. This includes reports of unanticipated problem involving risk to subjects or others (UPRs), protocol deviation reports, adverse event reports, reports of subject complaints, etc.
  - (5) All IRB approval/exempt determination letters, notifications, and correspondence.
  - (6) Copies of all IRB-approved versions of study informed consent documents. This includes consent forms, parent permissions forms, adolescent assent forms and child assent forms (as applicable based on the study).
  - (7) Copies of all IRB-approved versions of study recruitment materials.
  - (8) Signed copies of informed consent documents, if applicable.

- (9) Blank copies of all data collection forms, questionnaires, and/or study instruments.
- (10) Copies of study team member training documents/certificates (e.g., human subjects research training, responsible conduct of research training, etc.).
- (11) Raw study data (e.g., screening logs, eligibility checklists, enrollment logs, completed study instruments whether in paper form, transcribed or collected electronically, compensation logs, etc.).
- (12) Grant proposals, contracts, and progress reports if externally funded.
- (13) HIPAA authorization forms or documentation of approved waiver(s), as applicable.

### **III. Office of Research Compliance Administration (ORCA)**

- (a) OHRP and UC Records Retention policies require ORCA (the IRB administrative office) to retain their business records.
- (b) Retention period: While OHRP only requires IRB records to be retained for 3 years after close of study, UC requires IRB records to be retained 10 years after close of the study, including studies in which no subjects were enrolled.
- (c) Records the IRB administrative office must retain include, but are not limited to:
  - (1) Copies of all human subjects research studies reviewed.
  - (2) Scientific evaluations, if any, that accompany the Initial Submissions
  - (3) Approved study consent documents.
  - (4) Modification Submissions, and all related documentation.
  - (5) Renewal Submissions, and all related documentation. This includes annual administrative check-ins (for studies that qualify) and requests for continuing review of IRB approved studies.
  - (6) Incident Submissions and all related documentation. This includes reports of unanticipated problem involving risk to subjects or others (UPRs), protocol deviation reports adverse event reports, reports of subject complaints, etc.
  - (7) Minutes of IRB meetings, which shall be in sufficient detail to show:
    - (i) attendance at the meetings,
    - (ii) actions taken by the IRB,
    - (iii) the vote on these actions including the number of members voting for, against, and abstaining,
    - (iv) the basis for requiring changes in or disapproving research; and
    - (v) a written summary of the discussion of controverted issues and their resolution.
  - (8) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.
  - (9) Copies of all correspondence between the IRB and study investigators.
  - (10) A list of IRB members and copies of training records/certificates of completion.

- (11) Written procedures for the IRB.
- (12) Statements of significant new findings provided to subjects.
- (13) The rationale for an expedited reviewer's determination that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
- (14) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance.

#### **IV. Storage**

- (a) Records may be stored in hard copy, electronically, or both. Storage of identifiable data must follow UCSC ITS security standards. See [Confidentiality of Electronic Research Data](#) for more information.

#### **V. References**

- (a) [Investigator Responsibilities FAQs | HHS.gov](#)
- (b) [45 CFR 46.115](#)
- (c) [UC Records Retention Schedule](#)
- (d) [Disposal of Protected Health Information | HHS.gov](#)