Policy on Records Retention

Effective date: 9/20/2019

I. Background
Retention of research records is an increasingly important task to allow for transparency and replication of results. Federal regulations and UC Policy require researchers and IRB administration to retain records for specified periods.

II. Principal Investigator and Research Team
a. Identifiable data: To protect confidentiality, especially for more sensitive data, identifiers should be removed as soon as possible.
b. Retention period:
   1. OHRP: For research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), the Office of Human Research Protections (OHRP) in the Department of Health and Human Services requires human research study records to be kept for a minimum of 3 years after the close of the study.
   2. HIPAA: Any records pertaining to protected health information (PHI) must follow HIPAA Privacy Rule retention period of 6 years after close of study.
   3. The sponsor may inform the principal investigator (PI) of additional record retention requirements.
c. Study records to maintain: Records the PI must retain include but are not limited to:
   1. Initial submission, Continuing reviews, Modifications/Amendments, Event Reports, Request to Review/Rely forms.
   2. All IRB approval letters, notifications, and correspondence.
   3. Copy of all IRB-approved versions of the consent form and parent permission and assent form (if applicable).
   4. Copy of all IRB-approved versions of any recruitment materials.
   5. Signed copies of informed consent documents if applicable.
   6. Blank copies of all data collection forms, questionnaires, and/or study instruments.
   7. Any personnel training documents and certificates.
   8. 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.).
   9. Grant proposals, contracts, and progress reports if externally funded.
10. HIPAA authorizations or approved waivers as applicable.

III. Office of Research Compliance Administration (ORCA)

a. Retention period: OHRP and UC Records Retention policies require ORCA (the IRB administrative office) to retain their business records. 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 study. This includes studies with no subjects enrolled.

b. IRB Records to Maintain: Records the IRB administrative office must retain include but are not limited to:

a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

b. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

c. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.

d. Copies of all correspondence between the IRB and the investigators.

e. A list of IRB members and training records.

f. Written procedures for the IRB.

g. Statements of significant new findings provided to subjects.

h. 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.

i. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance.

IV. Storage

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