1.17 Retention of Research Records

1.0 Purpose

The purpose of this policy is to describe the requirements for retention of research records by the investigator.

2.0 Policy

It is the policy of the Organization that all research records must be maintained and stored securely, in accordance with Nebraska State Law, for at least seven years beyond the termination of the study or longer as required by sponsors.

- **2.1.** All records associated with non-exempt human subject must be retained securely, for at least seven years beyond the termination of the study or longer as required by sponsors. If records include subject identifiers, those identifiers must be retained with the research records.
- **2.1.** All records associated with exempt human subject research must be retained securely for at least three years beyond the termination of the study.

3.0 Required Records

- **3.1.** Research records include:
  - **3.1.1.** All applications, other forms, communications, reports and other documents created in, or stored in, RSS. For the purposes of this policy the presence of this information within RSS constitutes retention.
  - **3.1.2.** Subject files including original signed consent documents, case report forms, laboratory results and other applicable information.
  - **3.1.3.** All communications between the investigator and the sponsor or funder, or, for multisite studies, between the local investigator and other investigators or coordinating center(s).
- **3.2.** For applications and reports generated within RSS (for example, the IRB Application, Request for Change, Continuing Review, Report of Protocol Deviation), a paper copy may be printed an retained as above, or the presence of the information within RSS constitutes “retention” of the record for the purpose of this policy.

4.0 Department Retention of Records

- **4.1.** If the PI resigns or otherwise departs from the Organization before the end of the designated retention period, the PI's department or college maintain the research records.
  - **4.1.1.** If the research is conducted by a student, the faculty advisor is responsible for assuring retention of records as above.
  - **4.1.2.** If the PI is volunteer faculty then the Dean or other person taking responsibility for assuring the PI fulfills his/her responsibilities (as described in HRPP 1.26 {PI Qualifications and Responsibilities}) must maintain the research records.
- **4.2.** The PI may request a copy of the research records in accordance with applicable Organizational policies

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ADDENDUM

Under the HIPAA Privacy Rule, subjects have the right to ask the Organization for an accounting of certain disclosures of their identifiable health information for a period dating 6 years from the date of the last covered disclosure. To ensure that the Organization can meet this accounting requirement, investigators must retain study records, along with records of all disclosures of study information, for at least 7 years after either of the following (whichever is later) (1) the last subject has completed his or her participation in the study; or (2) the date of the last disclosure of identifiable health information from study records, if disclosures continue after all subjects have completed the study. {45 CFR 164.528}

DHHS regulations require that, "records relating to research which is conducted shall be retained for at least 3 years after completion of the research." {45 CFR 46.115(b)}

FDA requires that sponsors and investigators participating in research subject to IND regulations retain "records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified." {21 CFR 312.57(c)} FDA requires that sponsors and investigators participating in research subject to IDE regulations retain the records "for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated of 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." {21 CFR 812.140(d)}

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? Revised: 6/30/2022 - revised to state that records associated with exempt research only need to be retained for three years; added statement regarding records retention for volunteer faculty (section 4.1.2) {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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