1.16 ORA Record Keeping Requirements

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for maintenance of documentation of IRB and ORA activities. Retention of records by the investigator is described in HRPP policy 1.17 (Retention of Research Records).

2.0 Policy

It is the policy of the Organization that the ORA will maintain documentation of all IRB activities in accordance with 45 CFR 46.115 and 21 CFR 56.115 as applicable. Records for each protocol will be organized to allow a reconstruction of a complete history of all IRB actions related to the review and approval of the protocol.

3.0 Procedures

- 3.1. Format of Protocol Files: In accordance with 45 CFR 46.115 and 21 CFR 56.115, the ORA will maintain, in paper or electronic format:
  - 3.1.1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, records of protocol modifications, and reports of injuries to subjects.
  - 3.1.2. 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.
  - 3.1.3. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).
  - 3.1.4. Copies of all correspondence between the IRB and the investigators.
  - 3.1.5. A list of IRB members in the same detail as described in §46.108(a)(2).
  - 3.1.6. Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).
  - 3.1.7. Statements of significant new findings provided to subjects, as required by§46.116(c)(5).
  - 3.1.8. The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
  - 3.1.9. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).
- 3.2. Records of protocol related activities submitted electronically through RSS are maintained indefinitely in RSS.
- 3.3. Records of protocol related activities submitted on paper are maintained in UNMC storage in either CD-ROM or paper format. Files will be maintained by the ORA as described in HRPP 1.17 (Retention of Research Records).
- 3.4. Records of protocol related activities will be retained by the investigator as described in HRPP 1.17 (Retention of Research Records).
- 3.5. Copies of IRB agendas, minutes, IRB member Curriculum Vitae, and IRB membership rosters are maintained within RSS or as electronic or paper documents within the ORA.
- 3.6. Copies of all educational items given to the IRB members are maintained within RSS, or as electronic or paper documents within the ORA.
- 3.7. Copies of HRPP policies are maintained on the UNMC website, accessible directly or thru a link in RSS.

4.0. Availability of IRB and ORA records

All IRB records are accessible for inspection and copying at reasonable times and in a reasonable manner in accordance with 45 CFR 46.115 and 21 CFR 56.115.

DOCUMENT HISTORY:

? Written: 4/7/2016 (Approved: 4/7/2016) - original author not recorded

? Revised: 2/2/2018 - revision not documented

? Revised: 10/11/2022 - typo corrected in 3.2.27.2/3.2.27.3 - rational to rationale {by Robert Lewis, IRB Assoc}

? Revised: 7/22/2022 - Extensive revisions; removed list of items to be retained, and substituted appropriate regulatory language; specified location of retained records; clarified duration of retention of paper records (per HRPP 1.17). {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/10/2022

? Revised: 01/17/2024 – Modified 3.1.1 to specify that records of protocol modifications will be retained along with other documents. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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