POLICY

1. Purpose
   Describe the requirements and procedures for maintaining adequate documentation of RSRB activities.

2. Scope
   This policy applies to the RSRB and RSRB office staff.

3. Definitions
   None.

4. References
   4.1. HHS 45 CFR 46 Subparts B – D
        HHS 45 CFR 46.115
        FDA 21 CFR 56.115
        FDA 21 CFR 812 Subpart D
        US Code 42 USC 289g-1/g-2
   4.2. Policy 302 RSRB Membership and Composition
         Policy 402 RSRB Meetings

5. Responsibilities
   The RSRB office is responsible for maintaining (paper and/or electronic) records of RSRB activities for at least three years and records pertaining to the review of human subject research while a project is active and for a minimum of three years after study completion or after study cancellation [45 CFR 46.115; 21 CFR 56.115].

6. Requirements
   6.1. When the RSRB is the Reviewing IRB, the RSRB office will maintain the records (paper and/or electronic files) listed below:
       6.1.1. For each study’s initial and continuing review, the RSRB records will generally include the following materials, as applicable to either convened board or expedited review:
              • RSRB application form(s);
              • Copies of approved research protocol(s);
              • Scientific evaluations that accompany the proposal, as applicable;
              • Consent/permission/assent document(s), when applicable;
              • HHS-approved sample consent document and protocol, when they exist;
              • Questionnaires, recruitment materials and Investigator’s brochure, when applicable
              • Reviewer’s written comments or assessments;
- Findings required under local policy and applicable regulations including (as applicable),
  o Protocol-specific findings supporting determination to waive the requirement to obtain informed consent.
  o Protocol-specific findings supporting determinations for a consent procedure that waives or alters some or all of the elements of informed consent.
  o Protocol-specific findings supporting determinations for federally funded research involving pregnant women, fetuses, and neonates. [HHS 45 CFR 46 Subpart B]
  o Protocol-specific findings supporting documentation for research involving use of or transplantation of fetal tissue. [HHS 45 CFR 46 Subpart B; 42 USC 289g-1/g-2]
  o Protocol-specific findings supporting determinations for federally funded research involving prisoners. [HHS 45 CFR 46 Subpart C]
  o Protocol-specific findings supporting determinations for federally funded research involving children. [HHS 45 CFR 46 Subpart D]
  o Protocol-specific findings supporting determinations for federally funded research involving subjects who may be vulnerable to coercion or undue influence (e.g., decisionally impaired adults, economically or educationally disadvantaged). [HHS 45 CFR 46.111(b)]
  o Protocol-specific findings supporting documentation of the rationale for Significant/Non-Significant Risk determinations for research devices. [FDA 21 CFR 812 Subpart D]
- Progress report submitted for continuing review and related materials;
- Amendment application form and related materials, if any;
- Reportable events – initial reports and follow up reports, if any;
- Pertinent protocol specific correspondence between the RSRB, Investigators, study team, or others;
- Approval and expiration dates for initial and continuing reviews;
- Data and safety monitoring reports, if any;
- Statements of any significant new findings provided to subjects;
- Documentation of non-compliance, if applicable;
- A description of the action taken by the reviewer (approval, approval contingent upon minor changes) for initial or continuing review;
- Frequency of next continuing review, if applicable;
- All other protocol related documents as necessary.

6.1.1.1 Expedited and exempt status review project records include the following additional RSRB materials:
- An indication of the specific permissible category for expedited review or exempt status;
• Any findings required under HHS regulations;
• Any justifications deemed to be necessary.

6.1.1.2 When the RSRB is reviewing for a multi-site study the following additional records may be maintained:
• Model Informed Consent(s)
• Participating site’s consent form(s)
• Participating site’s IRB questionnaire/documentation of the institutional review

6.1.2. Approved meeting minutes with applicable documentation required for the type of review (see Policy 402 RSRB Meetings, Appendix 2 for sample meeting minutes).

6.1.3. Emergency use reports.

6.1.4. Written procedures for the RSRB.

6.2. When the RSRB is the Relying IRB, the RSRB office will maintain records (paper and/or electronic files) consistent with the required institutional review and applicable Reliance Agreements.

6.3. Records will be accessible for inspection by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

6.4. The RSRB office will maintain current membership information including notification of appointment and re-appointment from the Institutional Official that includes the member’s terms of service. Membership information is updated as changes occur. (Refer to Policy 302 RSRB Membership and Composition, Appendix 6, for a sample roster.)

6.5. The RSRB office maintains records confirming that RSRB members, as well as researchers and study staff, have completed the human subjects protection required training and education requirements.

6.6. For studies receiving convened board or expedited review, records will be maintained for 20 years from the date of study closure. For studies receiving a not human subject research or exempt determination, records will be maintained for 20 years from the date of initial determination.
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Appendices:
None

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02/2016: Sect 4.2 hyperlinks added to references
01/2018: Sect 5 minimum period of time added; Sect 6.1 Reviewing IRB language added;
Sect 6.1.1.2, Sect 6.2 and Sect 6.6 added; editorial changes

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