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
5.1. The RSRB office is responsible for maintaining (paper and/or electronic) records of RSRB activities and 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. The RSRB office will maintain the following records (paper and/or electronic files) indefinitely:
   6.1.1. For each study’s initial and continuing review, the RSRB research project records will generally include the following RSRB specific material, as applicable to either full 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 determinations for a consent procedure that waives or alters some or all of the elements of informed consent.
  o Protocol-specific findings supporting determination to waive requirement to obtain 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 other vulnerable populations (e.g., decisionally impaired adults). [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]
• Continuing review report form 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.

Additionally, expedited and exempt status review project records include the following 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.

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

6.3. 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.)

6.4. 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.
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Appendices:
None

Revision History:
February 2016: Sect 4.2 hyperlinks added to references

Supersedes Date:
10/07/2013

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