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 for a minimum of three years after study completion or 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, as applicable:

6.1.1. For each study's initial and continuing review (when required), the RSRB records will generally include the following materials, as applicable to either convened board or expedited review:

- RSRB application form(s);
- Scientific evaluations that accompany the proposal, as applicable;
- Copies of research protocol(s);
- 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, law, codes, guidance, and applicable regulations including (as applicable),
  - Protocol-specific findings supporting determination to waive the requirement to obtain informed consent.
  - Protocol-specific findings supporting determinations for a consent procedure that waives or alters some or all of the elements of informed consent.
  - Protocol-specific findings supporting determinations for federally funded research involving pregnant women, fetuses, and neonates. [HHS 45 CFR 46 Subpart B]
  - 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]
  - Protocol-specific findings supporting determinations for federally funded research involving prisoners. [HHS 45 CFR 46 Subpart C]
  - Protocol-specific findings supporting determinations for federally funded research involving children. [HHS 45 CFR 46 Subpart D]
  - 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)]
  - 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 form submitted for continuing review and related materials;
- Modifications to previously approved research and related materials, if any;
- Reports of new information – initial reports and follow up reports, if any, including but not limited to reports of injury to subjects and unanticipated problems involving risks to subjects or others;
- Pertinent protocol specific correspondence between the RSRB, Investigators, study team, or others;
- Approval and expiration dates for initial and continuing reviews, when applicable;
- 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, modifications required to secure approval) for initial or continuing review;
- Frequency of next continuing review, if applicable;

- Rationale for an expedited reviewer's determination that research appearing on the expedited review list (OHRP Expedited Review Categories) is more than minimal risk;
- All other protocol related documents as necessary.

6.1.1.1 Expedited and exempt status review project records include the following additional RSRB information:

- 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, including rationale for the requirement of continuing review of research that otherwise would not require continuing review [45 CFR 46.109(f)(1)].

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.

6.1.5. Reliance agreements describing the responsibilities of the relying organization the RSRB to ensure compliance with requirements of the Common Rule [HHS 45 CFR 46].

6.1.6. Resume for each RSRB member.

6.1.7. All RSRB membership rosters, current and prior.

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.

6.3.1. Records that document compliance (or non-compliance) with Department of Defense (DoD) regulations will be accessible for inspection and copying by authorized DoD representatives 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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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
01/2019: Updates for Revised Common Rule and AAHRPP standards; removed T. Gommel as signatory; editorial changes
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Kelley A. O'Donoghue
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Director, OHSP

Date

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