



POLICY: IRB Records

Document No.:	Edition No.:	Effective Date:	Page:
HRP-023	1.0	01/21/2019	Page 1 of 2

1. PURPOSE

- 1.1. This policy describes the contents of IRB records.

2. POLICY

- 2.1. Documents in a study file are to record the history of IRB actions related to the review.
- 2.2. IRB files are to include:
 - 2.2.1. Study files
 - 2.2.2. IRB meeting minutes
 - 2.2.3. A resume or curriculum vitae for each IRB member
 - 2.2.4. Current and previous versions of IRB member rosters
 - 2.2.5. Current and previous versions of controlled document
 - 2.2.6. Correspondence to and from the IRB related to human research
 - 2.2.7. <Reliance Agreements>
- 2.3. Study files are to include the following information when it exists:
 - 2.3.1. Correspondence and submissions to and from the IRB related to the study
 - 2.3.2. Protocols or research plans
 - 2.3.2.1. HHS-approved sample protocol
 - 2.3.3. Investigator brochure
 - 2.3.4. Scientific evaluations, when provided by an entity other than the IRB
 - 2.3.5. Recruitment materials
 - 2.3.6. Consent documents
 - 2.3.6.1. HHS-approved sample consent document and protocol
 - 2.3.7. Progress reports submitted by investigators
 - 2.3.8. Reports of injuries to subjects
 - 2.3.9. Records of continuing review activities
 - 2.3.10. Data and safety monitoring reports
 - 2.3.11. Modifications
 - 2.3.12. <Unanticipated Problems Involving Risks to Subjects or Others>
 - 2.3.13. Documentation of <Noncompliance>
 - 2.3.14. Significant new findings and statements about them provided to subjects
 - 2.3.15. For initial and continuing review by the expedited procedure:
 - 2.3.15.1. The specific permissible category
 - 2.3.15.2. Description of action taken by the <Designated Reviewer>
 - 2.3.15.3. Any findings required by law
 - 2.3.15.4. For the research subject to <Revised Requirements>:
 - 2.3.15.4.1. If continuing review is not required by "WORKSHEET: Criteria for Approval (HRP-400)", but the IRB requires continuing review, the IRB's rationale for requiring continuing review.
 - 2.3.15.4.2. If the research falls into a category in "WORKSHEET: Expedited Review (HRP-424)" allowing initial review by the expedited procedure, but the <Designated Reviewer> determines that the research involves greater than <Minimal Risk> to subjects, that rationale for the determination that the research involves greater than <Minimal Risk> to subjects.
 - 2.3.16. For exemption determinations, the specific category of exemption



POLICY: IRB Records

Document No.:	Edition No.:	Effective Date:	Page:
HRP-023	1.0	01/21/2019	Page 2 of 2

- 2.3.17. Required determinations and study-specific findings supporting those determinations for research involving:
- 2.3.17.1. Waiver or alteration of the consent process
 - 2.3.17.2. <Pregnant Women>
 - 2.3.17.3. <Neonates of Uncertain Viability>
 - 2.3.17.4. <Nonviable Neonates>
 - 2.3.17.5. <Prisoners>
 - 2.3.17.6. <Children>
 - 2.3.17.7. <Wards>
 - 2.3.17.8. <Significant Risk Device>/<Non-significant Risk Device> determinations
- 2.3.18. For each study's initial and continuing review, the frequency for the next continuing review or that continuing review is not required
- 2.4. Records for FDA-regulated research are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.
- 2.5. Records for research conducted, supported, or otherwise subject to regulation by a Federal department or agency are to be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.
- 2.5.1. Records maintained that document compliance or <Noncompliance> with Department of Defense (DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.
- 2.6. Upon request, the [Organization] makes IRB records available to clients provided they are relevant to the client. Such records may be excerpted and/or redacted to comply with the [Organization's] obligations to maintain confidentiality.

3. REFERENCES

- 3.1. 21 CFR §56.115
- 3.2. 45 CFR §46.115