



POLICY: IRB Records

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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

- 2.3. 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. DHHS-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. DHHS-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 reviewer
- 2.3.15.3. Any findings required by law

- 2.3.16. For exemption determinations the specific category of exemption.
- 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. <Non-Viable Neonates>
- 2.3.17.5. <Prisoners>
- 2.3.17.6. <Children>
- 2.3.17.7. <Wards>
- 2.3.17.8. Adults lacking capacity
- 2.3.17.9. <Significant Risk Device>/<Non-significant Risk Device> determinations



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- 2.3.18. For each study's initial and continuing review, the frequency for the next continuing review
- 2.3.19. 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.
- 2.3.20. 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.
 - 2.3.20.1. 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.
- 2.3.21. IRB Records are retained indefinitely.

3. REFERENCES

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