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
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