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

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 University 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 University's obligations to maintain confidentiality.

3. REFERENCES

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