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:

- Study files
- IRB meeting minutes
- A resume or curriculum vitae for each IRB member
- Current and previous versions of IRB member rosters
- Current and previous versions of controlled document
- Correspondence to and from the IRB related to human research
- <Reliance Agreements>

2.3. Study files are to include the following information when it exists:

- Correspondence and submissions to and from the IRB related to the study
- Protocols or research plans
  - HHS-approved sample protocol
- Investigator brochure
- Scientific evaluations, when provided by an entity other than the IRB
- Recruitment materials
- Consent documents
  - HHS-approved sample consent document and protocol
- Progress reports submitted by investigators
- Reports of injuries to subjects
- Records of continuing review activities
- Data and safety monitoring reports
- Modifications
- <Unanticipated Problems Involving Risks to Subjects or Others>
- Documentation of <Noncompliance>
- Significant new findings and statements about them provided to subjects
- For initial and continuing review by the expedited procedure:
  - The specific permissible category
  - Description of action taken by the <Designated Reviewer>
  - Any findings required by law
  - For the research subject to <Revised Requirements>:
    - 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.
    - 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 [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