corticalmetrics

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 <Nonviable 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.

3. REFERENCES

3.1. 21 CFR §56.115

3.2. 45 CFR §46.115