1 PURPOSE

1.1 This procedure establishes the process to maintain IRB records.
1.2 The process begins when records are received or created.
1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB records are to include:
- 3.1.1 Protocol files.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all correspondence between the IRB and the investigators.
- 3.1.4 Current and all previous IRB member rosters.
- 3.1.5 Current and all previous IRB member files.
- 3.1.6 Current and all previous policies and procedures.

3.2 Protocol files are to include, as applicable:
- 3.2.1 All submitted materials.
- 3.2.2 Protocols.
- 3.2.3 Investigator brochures.
- 3.2.4 Scientific evaluations.
- 3.2.5 Recruitment materials.
- 3.2.6 Consent documents.
- 3.2.7 DHHS-approved sample consent document and protocol, when they exist.
- 3.2.8 Progress reports submitted by investigators.
- 3.2.9 Reports of injuries to subjects.
- 3.2.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
- 3.2.11 Data and safety monitoring board reports.
- 3.2.12 Amendments.
- 3.2.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.2.14 Documentation of non-compliance.
- 3.2.15 Correspondence between the IRB and investigator related to the protocol.
- 3.2.16 Significant new findings and statements about them provided to subjects.
- 3.2.17 For initial and continuing review of research by the expedited procedure:
  - 3.2.17.1 The specific permissible category.
  - 3.2.17.2 Description of action taken by the reviewer.
  - 3.2.17.3 Any findings required under the regulations.
  - 3.2.17.4 The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.
- 3.2.18 For exemption determinations the specific category of exemption.
- 3.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.
  - 3.2.19.1 Waiver or alteration of the consent process.
  - 3.2.19.2 Research involving pregnant women, fetuses, and neonates.
  - 3.2.19.3 Research involving Prisoners.
  - 3.2.19.4 Research involving children.

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3.2.19.5 Research involving adults unable to consent.
3.2.19.6 Significant/non-significant device determinations.
3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review.

3.3 Policies and procedures include:
3.3.1 Checklists.
3.3.2 Forms.
3.3.3 SOPs.
3.3.4 Template letters.
3.3.5 Template minutes.
3.3.6 Worksheets.

3.4 IRB member files include a resume for each IRB member.

4 RESPONSIBILITIES

4.1 IRB staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: File in minutes binder.
5.2 Store all protocol-specific information (communications, documents, determinations) in the electronic system.
5.3 File correspondence NOT related to a specific protocol in a file related to that person or topic.
5.4 IRB member rosters: File in IRB member roster binder.
5.5 IRB membership records (e.g., curricula vita and resumes): File in IRB member files.
5.6 Policies and procedures:
5.6.1 File current policies and procedures in the IRB Library in the electronic system.
5.6.2 File replaced policies and procedures in the policies and procedures history file.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None

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