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 Administrative Updates

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.
- 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.
- 3.2.18 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.
  - 3.2.19.5 Research involving adults unable to consent.
  - 3.2.19.6 Significant/non-significant device determinations.
  - 3.2.19.7 HIPAA waivers of Authorization.
- 3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review.

3.3 Protocol files are maintained in chronological order with the latest information in front.

3.4 Policies and procedures include:

3.4.1 Checklists.070
3.4.2 Forms.
3.4.3 SOPs.
3.4.4 Template letters.
3.4.5 Template minutes.
3.4.6 Worksheets.

3.5 IRB member files include a resume or CV 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: Minutes of IRB meetings are stored in the IRBNet system.

5.2 File correspondence related to a specific protocol in the protocol file.

5.3 Records maintained that document compliance or non-compliance with DoD regulations must 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.

5.4 File correspondence NOT related to a specific protocol in a file related to that person or topic.

5.5 IRB member rosters: Are stored electronically and in paper.

5.6 IRB membership records (e.g., curricula vita and resumes): Are stored electronically and in paper.

5.7 Policies and procedures:

5.7.1 Policies and procedures are stored on the UC Davis SharePoint site, which is a password protected website.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None