1 PURPOSE

1.1 This procedure establishes the process to maintain Office of IRB Administration (OIA) 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 REQUIREMENTS

3.1 OIA 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 OIA and 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.
- 3.1.7 External IRB records, as applicable.
- 3.1.8 Federalwide assurances and IRB registrations.
- 3.1.9 Documentation of complaints.

3.2 Protocol files are to include, as applicable:

- 3.2.1 All approved 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 Department of Health and Human Services (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/unanticipated problem report.
- 3.2.14 Documentation of non-compliance.
- 3.2.15 Correspondence between the IRB and investigator related to the protocol.
- 3.2.16 Other correspondence, including external reports to regulatory agencies.
- 3.2.17 Significant new findings and statements about them provided to subjects.
- 3.2.18 For initial and continuing review of research by the expedited procedure:
  - 3.2.18.1 The specific permissible category(ies).
  - 3.2.18.2 Description of action taken by the reviewer.
  - 3.2.18.3 Any findings required by the regulations.
- 3.2.19 For exemption determinations, the specific category(ies) of exemption.
- 3.2.20 Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
  - 3.2.20.1 Waiver or alteration of the consent process.
  - 3.2.20.2 Research involving pregnant subjects, fetuses, and neonates.
  - 3.2.20.3 Research involving prisoners.
  - 3.2.20.4 Research involving children.
  - 3.2.20.5 Research involving adults unable to consent.
  - 3.2.20.6 Significant/non-significant risk device determinations.

3.2.20.7 Investigational new drug (IND) exemptions granted by the IRB.

3.2.20.8 HIPAA waivers of authorization.

3.2.21 For each protocol's initial and continuing review, the frequency for the next continuing review.

3.3 Policies and procedures include:

3.3.1 Checklists.

3.3.2 Forms.

3.3.3 Standard operating procedures.

3.3.4 Template letters.

3.3.5 Template minutes.

3.3.6 Worksheets.

3.4 IRB member records include:

3.4.1 Resumes or curriculum vitae (CV) for each IRB member.

3.4.2 *OIA-202 FORM: IRB Member Information*, or equivalent.

3.4.3 *OIA-344 WORKSHEET: IRB Member Addition*, or equivalent.

3.5 OIA records maintained by OIA will be stored within a UCSD-provided storage system.

3.5.1 Records documenting reliance agreements may be stored in appropriate external systems.

3.6 Unless hard copy document retention is required by policy, regulation, or law, paper records may be converted to an electronic format and stored in an electronic file.

3.7 Records documenting compliance or non-compliance with Department of Defense (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.

3.8 OIA records are made available to those outside OIA in accordance with applicable law, regulation, policy, or contract terms.

3.8.1 Generally, OIA records will not be made available to other researchers not associated with the study without permission of the principal investigator whose records would be shared.

4 RESPONSIBILITIES

4.1 OIA staff members are responsible for carrying out these procedures.

5 PROCEDURE

5.1 OIA staff will file records as follows:

5.1.1 IRB meeting minutes will be filed in the designated electronic file storage area.

5.1.2 Correspondence related to a specific protocol will be filed in the designated electronic protocol file.

5.1.3 Correspondence NOT related to a specific protocol will be filed in the designated electronic or paper file related to that individual or topic.

5.1.4 IRB member rosters will be filed electronically and/or in paper form in the designated electronic or paper file.

5.1.5 IRB membership records will be filed electronically and/or in paper form in the designated electronic or paper file.

5.1.6 Policies and procedures will be filed electronically in the designated electronic file.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-202 FORM: IRB Member Information*

6.3 *OIA-344 WORKSHEET: IRB Member Addition*

7 REFERENCES

7.1 21 CFR 56.115

7.2 45 CFR 46.115

7.3 HIPAA regulations: 45 CFR 160, 45 CFR 164 Subpart A and 45 CFR 164 Subpart E