1 PURPOSE

1.1 This SOP 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 Revised from the version 5/30/2017.
2.2 Revised from the 6/30/2019 version.

3 SOP Statement

3.1 IRB records are to include:
- 3.1.1 Electronic study files in the protocol and management system.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all relevant correspondence between IRB and the investigators.
- 3.1.4 Current and previous IRB member rosters.
- 3.1.5 Current and previous IRB member files.
- 3.1.6 Current and previous policies and procedures.
- 3.1.7 Reliance Agreements documenting the specific responsibilities of the institution and the organization operating the IRB will undertake to ensure compliance for federally supported research subject to the 2018-Requirements.

3.2 Protocol files are to include, as applicable:
- 3.2.1 All submitted materials
- 3.2.2 Protocols or research plans
- 3.2.3 Investigator brochures
- 3.2.4 Scientific evaluations, when provided by an entity other than the IRB.
- 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 caused by the research.
- 3.2.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review.
- 3.2.11 Data and safety monitoring board reports.
- 3.2.12 Modifications or amendments to previously approved research.
- 3.2.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.2.14 Documentation of non-compliance.
- 3.2.15 Relevant correspondence between the IRB and investigator related to the protocol.
- 3.2.16 Significant new findings and statements about them provided to subjects or others.
- 3.2.17 For initial and continuing review of research by the expedited procedure:
  - 3.2.17.1 The specific permissible category or categories.
  - 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.
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 review and continuing review when required, 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 .

3.2.21 The institution will maintain record of all research conducted by the organization reviewed by an external IRB.

3.2.21.1 Records will include materials identified in section 3.2 applicable to the TAMU investigators' scope of work.

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 HRPP/IRB staff members are responsible for carrying out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: Upload a copy of the approved minutes into the electronic system, place a copy in the IRB shared file. Send a copy to the Institutional Official.

5.2 File non-system correspondence related to a specific study in the study record.

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 on the IRB shared drive.

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 on the IRB shared drive.

5.6.2 File replaced policies and procedures in the policies and procedures history file on the IRB shared drive.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 21 CFR §56.115
7.2 45 CFR §46.115
7.3 AAHRPP elements I.1.A, I-9, II.5.A.