UNIVERSITY OF MIAMI

SOP: IRB Records				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-070	7/9/2019	C.Gates	C.Gates	1 of 2

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
2.2 Revised for clarity and to establish document that electronic records required by a predicate rule must be maintained in an electronic system compliant with 21 CFR Part 11.

3 GUIDING PRINCIPLES

3.1 The following IRB records are maintained in an electronic system compliant with 21 CFR Part 11:
- 3.1.1 Submission 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 Submission 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 one or more regulations of ICH E-6 (R2) 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 and continuing review, the frequency for the next continuing review.

3.3 Policies and procedures are maintained in paper format in a regulatory binder and include:
3.3.1 Checklists.
3.3.2 SOPs.
3.3.3 Worksheets.

3.4 Copies of current policies and procedures are maintained on the HSRO's website for transparency.

3.5 IRB member roster files include a resume of curriculum vitae for each IRB member and are stored .

3.6 Correspondence NOT related to a specific protocol is stored in Outlook.

3.7 IRB member roster files are maintained in paper format in a regulatory binder and include:
3.7.1 Curricula vita or resume
3.7.2 Copy of appointment letter
3.7.3 Copy of designated reviewer appointment letter.

4 RESPONSIBILITIES

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

5 PROCEDURE

5.1 Store records in binders or electronically as applicable.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None