

SOP: IRB Records

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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 11/1/2020.

3 POLICY

- 3.1 IRB records 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 related to the protocol.
 - 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 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 Consent document(s) and protocol when they exist.
 - 3.2.8 Reliance agreements.
 - 3.2.9 Reports of injuries to subjects.
 - 3.2.10 Reports of unanticipated problems involving risks to subjects or others.
 - 3.2.11 Documentation of non-compliance.
 - 3.2.12 Significant new findings and statements about them provided to subjects.
 - 3.2.13 Data and safety monitoring board reports.
 - 3.2.14 Continuing Review reports, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
 - 3.2.15 Progress Reports submitted by investigators, when required.
 - 3.2.16 Modifications.
 - 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 Waiver or alteration of HIPAA authorization.
 - 3.2.19.3 Research involving pregnant women, fetuses, and neonates.
 - 3.2.19.4 Research involving Prisoners.

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- 3.2.19.5 Research involving children.
- 3.2.19.6 Research involving adults unable to consent.
- 3.2.19.7 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.
- 3.2.21 The institution will maintain records of all research conducted by the organization reviewed by an external IRB. Records will include all materials identified in section 3.2.
- 3.3 Electronic Protocol files are maintained in eIRB+. Paper protocol files are securely stored in IRB Offices. Files are stored chronologically oldest to most current dates.
- 3.4 Policies and procedures include:
 - 3.4.1 Checklists.
 - 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 Curriculum Vitae or Resume for each IRB member.

4 RESPONSIBILITIES

- 4.1 HRPP staff members are responsible for carrying out these procedures.

5 PROCEDURE

- 5.1 Minutes of IRB meetings filed in eIRB+.
- 5.2 File correspondence related to a specific protocol in the protocol file in eIRB+.
- 5.3 Store all protocol-specific information (communications, documents, determinations) in eIRB+.
- 5.4 File correspondence NOT related to a specific protocol in a file related to that person or topic.
- 5.5 IRB member rosters: File in eIRB+.
- 5.6 IRB membership records (e.g., curricula vita and resumes) file in eIRB+.
- 5.7 Policies and procedures:
 - 5.7.1 File current policies and procedures in the IRB Library in eIRB+.
 - 5.7.2 File replaced policies and procedures in the policies and procedures history file.

6 MATERIALS

- 6.1 None.

7 REFERENCES

- 7.1 None.