



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 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.
- 2.3 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

- 3.1 The following IRB records are maintained in an electronic system compliant with 21 CFR Part 11:
 - 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, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
 - 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.
 - 3.2.17.4 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 OF ICH E-6 (R2) and protocol-specific findings supporting those determinations for.
 - 3.2.19.1 Waiver or alteration of the consent process.



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- 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, 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. Records will include all materials identified in section 3.2
- 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 Copies of current policies and procedures are maintained on the HSRO's website for transparency.
- 3.5 IRB member files include a resume or curriculum vitae for each IRB member.
- 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 to carry out these procedures.

5 PROCEDURE

- 5.1 Store records in binders or electronically as applicable.
- 5.2 Minutes of IRB meetings are retained in the electronic IRB system.
- 5.3 File correspondence related to a specific protocol in the protocol file.
- 5.4 Store all protocol-specific information (communications, documents, determinations) in the electronic system.
- 5.5 File correspondence NOT related to a specific protocol in a file related to that person or topic.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 AAHRPP elements I.1.A, I-9, II.5.A