SOP: IRB Records

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1 PURPOSE

1.1 This procedure establishes the documents delineated as IRB records.
1.2 The process begins when records are received or created.
1.3 The process ends when records have been filed.

2 PREVIOUS VERSION

2.1 Revised from previous version 11/01/2023.

3 POLICY

3.1 In accordance with Health and Human Services regulations 45 CFR §46.115, 21 CFR §56.115, and institutional policy, the Northwestern IRB Office shall prepare and maintain adequate documentation of IRB activities, IRB records are to include:
- 3.1.1 Electronic study files in eIRB+.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all relevant correspondence between the IRB and the investigators.
- 3.1.4 Current and previous IRB member rosters and member files.
- 3.1.5 Current and previous policies and procedures.

3.2 Electronic study 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 Common 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 Relevant 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 Instrument(s) to be used for data collection, if applicable.
- 3.2.18 Reliance Agreements.
- 3.2.19 Local Context Forms.
- 3.2.20 Any existing contractual agreements for off-site research that may be pertinent to the review of the proposal.
- 3.2.21 Applications for funding, if applicable.
- 3.2.22 Compliance and education/training records.
- 3.2.23 For the initial and continuing review of research by the expedited procedure:
  - 3.2.23.1 The specific permissible category.
  - 3.2.23.2 Description of action taken by the reviewer.
  - 3.2.23.3 Any findings required under the regulations.
  - 3.2.23.4 Justification that criteria for approval are met.

3.2.23.5 The rationale for a determination that research, that otherwise meets a category for expedited review, is greater than minimal risk.

3.2.24 For exemption determinations, the specific category of exemption and HIPAA determinations, if any.

3.2.25 Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for, but not limited to:

3.2.25.1 Waiver or alteration of the consent process.
3.2.25.2 Waiver of documentation of consent
3.2.25.3 Waiver or alteration of HIPAA authorization
3.2.25.4 Research involving pregnant women, fetuses, and neonates.
3.2.25.5 Research involving Prisoners.
3.2.25.6 Research involving children.
3.2.25.7 Research involving adults with impaired decision-making capacity.
3.2.25.8 Significant/non-significant device determinations.

3.2.26 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.

3.3 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 and IRB Member Information Form HRP-202 for each member.

4 RESPONSIBILITIES

4.1 IRB Office staff are responsible for carrying out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: Save in the IRB meeting workspace in eIRB+.

5.2 File non-system correspondence related to a specific protocol in the eIRB+ protocol record or applicable compliance file.

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 within OnBase.

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 policies and procedures in the OnBase electronic document repository.

5.7 The procedures for retaining IRB Records are outlined in Document Management and Record Retention of Institutional Review Board Records SOP (HRP-072).

6 MATERIALS

6.1 None.

7 REFERENCES

7.1 45 CFR 46.115

7.2 21 CFR 56.115

7.3 Checklist: Waiver or Alteration of Consent Process (HRP-410)
7.4 Checklist: Waiver of Written Documentation of Consent (HRP-411)
7.5 Checklist: Pregnant Women (HRP-412)
7.6 Checklist: Non-Viable Neonates (HRP-413)
7.7 Checklist: Neonates of Uncertain Viability (HRP-414)
7.8 Checklist: Prisoners (HRP-415)
7.9 Checklist: Children (HRP-416)
7.10 Checklist: Cognitively Impaired Adults (HRP-417)
7.11 Checklist: Non-Significant Risk Device (HRP-418)
7.12 General Document: Investigator Manual (HRP-103)
7.13 SOP: IRB Records Retention (HRP-072)
7.14 NU Policy: Retention of University Records
7.15 NU Policy: Research Data: Ownership, Retention, and Access