SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	IRB Records, Storage and Retention	Effective: 12/22/2017
		Approved: 12/18/2017
SOP ID		Last Revised: n/a
IRB-SOP-104		Expiration: n/a

PURPOSE

This SOP establishes the process to maintain and retain IRB records.

SCOPE

This SOP applies to records associated with research activities under the jurisdiction of any Ascension Wisconsin IRB.

DEFINITIONS

Minimal Risk The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

PROCESS

1. **IRB records are to include the following:**
   - Protocol files.
   - Copies of all correspondence between the IRB and the investigators.
   - Minutes of IRB meetings.
   - Current and all previous IRB member rosters.
   - Current and all previous IRB member files.
   - Current and all previous policies and procedures.

2. **Protocol files are to include the following, as applicable:**
   - **2.1.** All submitted materials.
   - **2.2.** Protocols.
   - **2.3.** Investigator brochures.
   - **2.4.** Scientific evaluations.
   - **2.5.** Recruitment materials.
   - **2.6.** Consent documents.
   - **2.7.** DHHS-approved sample consent document and protocol, when they exist.
   - **2.8.** Progress reports submitted by investigators.
   - **2.9.** Reports of injuries to subjects.
   - **2.10.** Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review.
   - **2.11.** Data and safety monitoring board reports.
   - **2.12.** Amendments.
   - **2.13.** Reports of unanticipated problems involving risks to subjects or others.
   - **2.14.** Documentation of non-compliance.

2.15. Correspondence between the IRB and investigator related to the protocol.

2.16. Significant new findings and statements about them provided to subjects.

2.17. For initial and continuing review of research by the expedited procedure:

- The specific permissible category.
- Description of action taken by the reviewer.
- Any findings required under the regulations.
- The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.

2.18. For exemption determinations the specific category of exemption.

2.19. Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.

- Waiver or alteration of the consent process.
- Research involving pregnant women, fetuses, and neonates.
- Research involving prisoners.
- Research involving children.
- Research involving adults unable to consent.
- Significant/non-significant device determinations.

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.

2.21. For Veterans Administration (VA) research:

- Correspondence between the IRB and the Veterans Administration (VA) Research and Development Committee.
- Internal or local serious adverse events.
- Documentation of protocol deviations.
- Reports of complaints from subjects.
- Records of expedited review activities.
- HIPAA Authorization documents.
- Audit results and documentation of compliance with remediation requirements.

3. IRB Record Storage

3.1. Minutes of IRB meetings are created in the electronic eIRB system and are stored electronically and in paper.

3.2. All protocol-specific information (communications, documents, determinations) stored in the electronic eIRB system.

3.3. IRB member rosters are stored electronically and in paper.

3.4. IRB membership records (e.g., curricula vita and resumes)are stored electronically and in paper.

3.5. Policies and procedures:

- Policies and procedures are stored electronically in a department shared drive, on an institutional server. Final versions are made available via the intranet, internet and/or electronic eIRB system.

4. IRB Record Retention

4.1. Protocol files are to be retained as long as required by law and institutional policy and then destroyed. All records not in protocol files are retained indefinitely.

4.2. Records may be maintained in printed form or electronically.

4.3. Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.

4.4. All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.

4.5. All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

4.6. Protocol files are destroyed when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law. In the case of multi-center research, three years is referenced to the organization's involvement in the research, not the entire study.

REFERNCES

45 CFR 16.115
21 CFR 56.115

RELATED MATERIAL

None

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/27/2017	New- Initial Integration Update	J. Blundon