Marshfield Clinic

Record Keeping and Retention

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. None

3. PROCEDURE BODY

This document outlines the recordkeeping and retention requirements for IRB-related records, including requirements for written procedures as dictated by federal regulations. This includes IRB-approved consent forms signed by subjects.

3.1. Background

a. Department of Health and Human Services (DHHS) regulations at 45 CFR 46.115 and Food and Drug Administration (FDA) regulations at 21 CFR 56.115 state that an institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
- Minutes of IRB meetings which shall be sufficient in detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
- Recruitment materials ;
- Data Safety Monitoring Reports;
- Unanticipated Problem Reports;
- Amendment/Revision/Update Forms;
- Reports of Non-Compliance;
- Records of continuing review activities;
- Copies of all correspondence between the IRB and the investigators'
- A list of IRB members(See the procedure, "IRB Membership");
- Written procedures for the IRB in the same detail as described in 45 CFR 46.103(b)(4) and (5) and 21 CFR 56.108(a) and (b). (Marshfield Clinic's Federal-Wide Assurance term A.6. also requires specific written procedures.); and

- Statements of significant new findings provided to subjects as required by 45 CFR 46.116(b)(5) and 21 CFR 50.25.

b. This section of these regulations go on to state that records must be retained for at least six years after completion of the research, and that all records must be accessible for inspection and copying by authorized representatives of the DHHS and the FDA at reasonable times and in a reasonable manner.

c. Regulations other than the human subject protection regulations referenced above dictate recordkeeping and retention requirements for investigators conducting research. In terms of a researcher's records, this procedure dictates only the requirements for maintaining copies of signed consent forms for purposes of IRB-related audits, and may be less restrictive than other record retention requirements that researchers must follow.

3.2. Procedures

a. IRB Records

- IRB staff will be responsible for maintaining copies of all documents reviewed by the IRB, documentation used to support decisions of the IRB, completed IRB member reviewer guides, and correspondence with investigators, sponsors, regulatory agencies and others regarding the review of studies.

b. Signed Consent Forms

- The Principal Investigator (PI) shall be responsible for maintaining signed Consent Forms and all records relating to the research conducted. These must be available to the IRB upon request. Note that there are other recordkeeping requirements related to investigational drugs and devices which are not addressed by this policy. See Clinical Research Department policies for additional record retention requirements.

c. Meeting Minutes

- Minutes of IRB meetings which shall be sufficient in detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

d. IRB Procedures

- The Office of Research Integrity and Protections (ORIP) will be responsible for ensuring that, at a minimum, the following written procedures are maintained and accessible to IRB members and investigators:
  - Procedures the IRB will follow for: (a) conducting initial and continuing review and approving research; (b) reporting its findings and actions to the investigator and institution; (c) determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (d) ensuring prompt reporting to the IRB of proposed changes in approved research, and for

ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

- Procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and when applicable, appropriate DHHS and FDA funding and regulatory agencies: (a) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR 46 or 21 CFR 50 and 56, or the requirements or determinations of the IRB or institution; and (b) any suspension or termination of IRB approval.
- Procedures for verifying whether proposed activities qualify for exemption from, or waiver of, IRB review

e. Retention Period and Access

- Records identified in this procedure shall be retained for a period of six years past the date the project is officially terminated with the IRB. This includes studies that were closed with the IRB without ever having enrolled participants. Records of the IRB are considered confidential and, unless otherwise expressly permitted above, are released only to IRB members, the Executive Director of MCRF, members of research administration as dictated by the Executive Director of MCRF, and to authorized individuals for inspection purposes.

4. ADDITIONAL RESOURCES

4.1. References:
- None

4.2. Supporting documents available:
- None

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #863.3 (no changes made)
2.0	

3.0	

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
Co-Author(s):
Approver(s): This document has been electronically signed and approved by: Ziemba, Steven J PHD on: 10/5/2015 2:22:49 PM