



MCW Office of Research Standard Operating Procedure

INSTITUTIONAL REVIEW BOARD RECORDS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:

This procedure outlines the necessary maintenance of IRB office records associated with research activities under the jurisdiction of the Medical College of Wisconsin and Froedtert Hospital (MCW/FH) Institutional Review Board (IRB).

DEFINITIONS:

N/A

PROCEDURE:

1. Federal Regulations require an IRB to 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 in sufficient 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.
 - Records of continuing review activities.
 - Copies of all correspondence between the IRB and the investigators.
 - A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.
 - Written procedures for the IRB as required by 56.108 (a) and (b)
 - Statements of significant new findings provided to subjects, as required by 50.25.

IRB Research Records

1. The MCW/FH IRB will retain files and documents that relate to the protection of human research subjects for at least seven years following completion of the project. This will allow a reconstruction of a complete history of IRB actions related to the review and approval of the study in accordance with laws, regulations, codes, and guidance. If a research project is closed without subject enrollment, IRB records are maintained for at least seven years after closure. Such files and documents include, but are not limited to:

- eBridge submissions
 - IRB submission documents
 - Research protocols
 - Scientific evaluations
 - Consent forms
 - Continuing Progress Reports submitted by Investigators
 - Reports of unanticipated problems and/or injuries to subjects
 - Records of continuing review activities
 - Correspondence between the IRB, the Investigator, and key study personnel
 - Amendments or changes to IRB approved documents
 - Statements of significant new findings provided to subjects
 - Documentation of non-compliance
 - Emergency Use reports
 - Humanitarian Use Device submissions and reports
 - For each protocol's initial and continuing review, the frequency for the next continuing review
 - Membership rosters
 - Minutes
 - Other correspondence not related to a specific research project.
2. For initial and continuing review of research using the expedited procedure, the files will include:
 - The specific permissible category
 - Description of action taken by the reviewer
 - Any findings required under the regulations
 3. For exemption determinations the specific category of exemption.
 4. For activities determined by the MCW/FH IRB to not be research involving human subjects, records will include copies of all documentation submitted and/or correspondence between investigators and OHRP, as well as information documenting the determinations.
 5. Paper records on site are maintained in a locked file cabinet or locked offices within the IRB Office and are available only to HRPP and IRB staff. Paper files of studies that have been officially closed via IRB approval of the Final Progress Report are maintained in storage at a secure external site. These paper files may be recalled, if needed. Electronic files through eBridge are maintained on secure servers by MCW IS.
 6. All records are accessible for inspection by authorized representatives of the OHRP, FDA, sponsors, and other authorized entities at reasonable times and in a reasonable manner. When the retention period for a paper record expires, and a decision is made by the Director of the Human Research Protection Program or designee in conjunction with the Institutional Official to no longer retain the record, the record will be shredded or otherwise destroyed. The IRB anticipates maintaining its electronic records indefinitely.

IRB Research Procedures

1. The MCW/FH IRB will keep written policies and procedures on file and available on the HRPP website as a reference for Investigators, Study teams, IRB staff, and IRB Committees, which will address the following:
 - Initial and continuing review of research and for reporting its findings and actions to the Investigator and the institution;
 - Determining which projects require review more often than annually and which projects need verifications from sources other than the Investigators that material changes have not occurred since previous IRB review;

- Assuring prompt reporting to the IRB of proposed changes in a research activity, and for assuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects;
- Assuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any serious and expected adverse events and/or unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Federal regulations and IRB policies and procedures, or the requirements or determinations of the IRB and any suspensions or terminations of IRB approval.

REFERENCES:

45 CFR 46.115


21 CFR 56.115

SUPPORTING DOCUMENTS:

N/A

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