INSTITUTIONAL REVIEW BOARD RECORDS

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

Applies to: 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(MCW) 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:
   - x 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.
   - x 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.
   - x Records of continuing review activities.
   - x Copies of all correspondence between the IRB and Investigators.
   - x 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

a. If a research project is closed without subject enrollment, IRB records are maintained for at least seven (7) years after closure.

2. IRB records include the below listed files and documents, but are not limited to:
   - x eBridge submissions
   - x IRB submission documents
   - x Research protocols
   - x Scientific evaluations
   - x Consent forms
   - x Continuing Progress Reports submitted by Investigators
   - x Reports of unanticipated problems and/or injuries to subjects
   - x Records of continuing review activities
   - x Correspondence between the IRB, the Investigator, and project team members
   - x Amendments and/or changes to IRB approved documents
   - x Statements of significant new findings provided to subjects
   - x Documentation of non-compliance
   - x Emergency Use reports
   - x Humanitarian Use Device submissions and reports
   - x For each protocol's initial and continuing review, the frequency for the next continuing review
   - x Membership rosters
   - x Minutes
   - x

- x Initial and continuing review of research and for reporting its findings and actions to the Investigator and the institution;
- x 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;
- x 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;
- x Assuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any 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 46.108
21 CFR 56.108
45 CFR 46.115
21 CFR 56.115

SUPPORTING DOCUMENTS:
N/A

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