MCW IRB Committee Procedures

INSTITUTIONAL REVIEW BOARD ACTIONS

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

Applies to: Institutional Review Board Committees

PURPOSE:
This procedure describes the authority of the Medical College of Wisconsin (MCW) Institutional Review Board (IRB) according to Federal Regulations and institutional policy to render motions/determinations, to place restrictions on a research project or suspend or terminate approval of a research project that is not being conducted in accordance with institutional procedures or applicable law, or that has been associated with unexpected harm to subjects.

DEFINITIONS:
Approved: Approval may be granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111 and no changes to the research application are recommended.

Modifications Required: A "modifications required" status is stipulated only when the requested modifications are clear and specific in nature and do not require clarification by the Investigator. Clarifications that are minor and will not change the risk to the subject regardless of the response can also be given a "modifications required" status. Modifications will be reviewed by the IRB Chair or designated IRB member. Those that are not addressed may be referred to the convened Committee, as determined by the IRB Chair or Committee. The recommended modifications must be made to the IRB submission, Sponsor's protocol, informed consent documents, and/or other required documents before final IRB approval can be granted. The date of approval is the date the conditions were determined to be met. The IRB Committee provides a letter to the Investigator stipulating the specific modifications required for approval.

1. Initial submissions receiving a "modifications required" status may be administratively withdrawn if a response to the Committee recommendations has not been received by the IRB within 60 days of the date of the "modifications required" letter.
2. Continuing review submissions receiving a "modifications required" status will expire on the date of project expiration if an adequate response has not been received and approved by the IRB prior to the project expiration date.
3. Amendments receiving a "modifications required" status may not be implemented until a satisfactory response by the Investigator has been received and final approval has been granted in writing by the IRB.

Tabled: A "tabled" status is stipulated when the project does not meet the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111 or if the IRB Committee recommends substantial revisions to the IRB submission that are relevant to the determinations required by the IRB. A project that lacks sufficient information to conduct an adequate review at the convened Committee review level is "tabled" pending receipt of the requested information. The revised project must be reviewed by the convened IRB

and is placed on the next available agenda pending receipt of the additional information.

Modifications Required

1. The IRB C2 will draft the “modifications required” letter and send it to the IRB Chair for review. The IRB Chair will review the letter and either request changes to the letter or send it to the Investigator. Investigators should respond to the Committee recommendations outlining the modifications incorporated and the rationale for any

Presenting or publishing any data or results
Submission of Amendments
Submission of Continuing Progress Reports

The following activities of the project may continue at the direction of the IRB:

Follow-up on enrolled subjects (evaluate continuation of all enrolled subjects on a case-by-case basis)
Treatment regimen for currently enrolled subjects to end participation on project safely
Development of a plan to notify subjects of termination of the project to describe how Investigators will safely withdraw subjects from the project, and to transfer into clinical care or transfer to another investigator in the local area.

The following activities may continue:

Submission of Reportable Events that require prompt reporting.

5. If an IRB Committee terminates approval of a project due to the Investigator's failure to comply with the requirements of the approved protocol or institutional policies and procedure, or due to identification of immediate harm or risk to subjects, the HRPP Director shall notify the Associate Provost for Research, who shall provide written notice to the Dean, applicable Institutional Officials, Institutions where the project is being conducted and where MCW is serving as the IRB of Record, OHRP and/or the FDA and/or the head of the supporting Federal Agency.
6. Investigators must submit a final report for the project to the IRB within 90 days from the date of the IRB “termination” of approval.

Expedited Review of Submissions

The same procedures as described will apply to projects that meet criteria for Expedited review. The actions will either be performed by a single designated expedited reviewer. If the designated expedited reviewer determines the submission should be disapproved, they must forward it to the convened Full Committee for review.

Appeal Process

1. Investigators have the right to appeal an IRB determination and/or decision.
2. The appeal be written and addressed to the IRB Chair and the HRPP Director.
3. The appeal must contain the following information:
   - Reason for the appeal including new information which was not initially provided or considered by the IRB.
   - Scope of the appeal including the activities, length of time, and limitations
4. The appeal will be evaluated by the IRB Chair and the HRPP Director and/or Institutional Officials as deemed necessary by the MCW IRB Office.
5. The IRB Chair will provide the Investigator with a response to the appeal to the appeal that includes:
   - The decision
   - The rational for the decision
   - Any additional action required

REFERENCES:

45 CFR 46.111
21 CFR 56.111

SUPPORTING DOCUMENTS:
N/A

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Approved By
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