



## Appealing IRB Decisions

### 1. SCOPE

#### 1.1. System-Wide

### 2. DEFINITIONS & EXPLANATIONS OF TERMS

#### 2.1. Suspension

- An official action by the IRB to suspend or temporarily close the conduct of a study. Suspension does not include protocol-planned suspension (e.g., for interim data analysis).

#### 2.2. Termination

- The permanent closure of a study and its IRB oversight. Termination may be initiated "for cause" by the IRB or voluntarily by the principal investigator.

### 3. PROCEDURE BODY

The Marshfield Clinic Research Foundation (MCRF) Institutional Review Board (IRB) has the authority to approve human subject research activities conducted at Marshfield Clinic, by its employees or at other institutions for which MCRF IRB serves as the IRB of record. However, at the time of initial review, continuing review, or review of proposed changes or amendments to approved research, or at any time additional information is received, the IRB may conclude that not all aspects of proposed research meet approval criteria (see the document, "[Criteria For Approval](#)"). In such circumstances, the IRB may ask for supplemental information, or require revisions to the research design, procedures, and/or related documentation, before approval (see the document, "IRB Approval With Conditions"). The IRB may also disapprove, suspend, or terminate the research, in whole or in part. When these actions are taken, the IRB will include in its written notification a statement of the reasons for its decision and give the principal investigator (PI) the opportunity to respond in person or in writing. If a PI disagrees with such IRB decisions, he or she may request an appeal.

#### 3.1. Appealing an IRB Decision

- a. If a PI disagrees with an IRB decision in whole or in part, he or she may submit a written appeal to the Office of Research Integrity & Protections (ORIP). The written appeal must be submitted within 30 days of receiving written notice of the disapproval, suspension, or termination. The PI should include information that supports his or her justification for bringing the appeal and addresses the specific concerns of the IRB and basis for the IRB's decision.
- b. Consultants, as approved by the IRB Chair, may be invited to present relevant information or background in regards to the issues being appealed. The convened IRB will consider all relevant information from the IRB's prior discussion and decision, as well as all additional information provided by the PI, and if applicable, the consultants.
- c. The appeal will be considered by the convened MCRF IRB or by expedited review as detailed in 3.2 and 3.3, below.

### 3.2. Convened MCRF IRB Review of Appeal

- a. If the MCRF IRB disapproved a study or required revisions as part of review conducted by the convened IRB, the convened IRB will review the appeal. The PI may attend the meeting to provide additional information or clarification, but cannot be present during the final discussion and vote on the appeal.

### 3.3. Expedited Review of Appeal

- If the revisions are requested as part of expedited review, the IRB Chairperson, or his or her designee, who requested the revisions will review the written appeal. The expedited reviewer may make a decision on the appeal, or choose to forward the appeal to the convened IRB. If the expedited reviewer makes a decision on the appeal, and the PI subsequently expresses disagreement with the outcome, the appeal will be referred to the convened IRB for consideration.
- If the expedited reviewer refers the appeal to the convened IRB, the PI may attend the convened IRB meeting to provide additional information or clarification, but cannot be present during the vote on the appeal.

### 3.4. Possible Actions on Appeal

- a. The expedited reviewer or convened IRB may take one of the following actions after considering the appeal:
  - Accept the appeal and continue with the IRB review and approval process.
  - Require different actions to secure approval of the item.
  - Deny the appeal.

### 3.5. Outcome of Appeal

- a. After the MCRF IRB makes a determination on an appeal, the PI will be provided with a formal letter documenting the outcome. The IRB minutes and this letter will become part of the IRB file.
- b. If an appeal is denied, the denial cannot be overturned at any higher institutional official or body, as federal regulations require IRB approval before any research activity can take place.

## 4. ADDITIONAL RESOURCES

### 4.1. References:

- [Changes/Amendments to Approved Research](#)
- [Continuing Review](#)
- [Criteria for IRB Approval](#)
- [Expedited Review](#)
- [Human Subjects in Research](#)
- [IRB Approval With Conditions](#)
- [Non-Compliance with Federal Regulations, Institutional Policies and IRB Approved Applications and Protocols](#)

### 4.2. Supporting documents available:

- None

**5. DOCUMENT HISTORY**

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library - #4424.1. Definition of termination revised.
2.0	Added hyperlinks to policies/procedures in additional resources sect.

**6. DOCUMENT PROPERTIES**

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PROCEEDURE