



Reporting IRB Actions & Findings to the Investigator and Institution

1. SCOPE

- 1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

- 2.1. Appeal

- Process through which a principal investigator (PI) may challenge the Institutional Review Board (IRB)'s decision regarding the disapproval of a research activity.

- 2.2. Expedited Review

- Review of a research activities that are no more than minimal risk and for minor changes in approved research that is conducted by an experienced member or sub-group of the IRB.

- 2.3. Convened IRB Review

- Review of research activity that is conducted at a meeting of the IRB

- 2.4. Institutional Official

- Individual who represents the Institution and is named on the Federal Wide Assurance (FWA) filed with the Office of Human Research Protections (OHRP)

3. PROTOCOL BODY

The Marshfield Clinic Institutional Review Board (IRB) will communicate results of IRB review of research activities to the Principal Investigators (PIs) who submitted IRB applications, and to Marshfield Clinic Research Foundation's Director of Medical Research and Institutional Official. 45 CFR 46.103(4)(i) and 21 CFR 56.109 (e) require the IRB to follow written procedures for reporting findings and actions to investigators and the institution. The following internal processes will follow initial and continuing review of research.

- 3.1. The determination of IRB review will be communicated in writing within approximately seven (7) days of the review taking place to each PI, with copies to his or her research staff as indicated in the IRB application. An email may also be sent as needed
- a. If a research activity is disapproved through Convened IRB Review, written notification will be sent by the IRB to the PI, which will include a statement of the reasons for the IRBs decision.

- b. If the research activity is approved with contingencies through Expedited Review or Convened IRB Review, the notification will include a description of what the investigator must do to fulfill the contingencies required for approval (see "[IRB approvals with Conditions](#)" procedure)
- 3.2. The letter communicating the determination of IRB review will provide the PI with the opportunity to appeal the IRB's decision. An appeal may be presented in writing or in person at a convened IRB meeting. (see "[Appealing IRB Decisions](#)" procedure).
- 3.3. To inform the Marshfield Clinic Institution of the actions taken by the IRB, a copy of convened IRB and expedited review minutes will be regularly provided to the Institutional Official and to the Executive Director of Medical Research

4. ADDITIONAL RESOURCES

- 4.1. References:
 - None
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- 4.2. Supporting documents available:
 - [Appealing IRB Decisions](#)
 - [IRB Approval with Conditions](#)

PROTOCOL

5. DOCUMENT HISTORY

| Version No. | Revision Description |
|-------------|--|
| 1.0 | New Document in Document Control System transferred from the Policy & Handbook Library - #955.1 Definitions revised and updated procedure titles referenced. |
| 2.0 | Added hyperlinks within document. |
| 3.0 | |

6. DOCUMENT PROPERTIES

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