

SOP 2.6.3 **Appeals of an IRB Decision**

General Description:

If an application to conduct human subjects research is disapproved by the Institutional Review Board (IRB) at a convened meeting, the Principal Investigator (PI) can appeal the IRB's decision. This document describes the procedures for appealing a decision by the IRB.

Procedures:

1. In the event that the IRB disapproves an application at a convened meeting, a written response will be provided to the PI from the IRB outlining the reasons for the disapproval.
2. The PI may appeal the IRB's decision by submitting a request in writing including information about the reason for the appeal and any materials supporting the request. Supporting materials may include revised application documents, current literature, letters of support, and/or other information relating to the proposed research.
3. Appeals must be made within 30 days of PI notification of the IRB decision not to approve the project.
4. The request to appeal will be reviewed by the convened IRB at the next possible meeting. The PI will be invited to attend the meeting in person to discuss the appeal.
5. After review and discussion of the materials submitted as part of the appeals process and any information presented by the PI, the IRB will vote on whether or not to approve the project. If the IRB upholds its previous decision to disapprove the project, the decision may not be appealed again.
6. The PI will be informed of the IRB's decision in writing (through IRBNet).
7. Other institutional officials may not approve human subjects research that has not been approved by the IRB.

Related Forms, Guidance, and SOPs:

- SOP 2.5.1 Full Board Review
- 45 CFR 46.109(d)
- 45 CFR 46.112

Responsibility:

Execution of SOP:
Institutional Review Board
Research Development, Integrity and Assurance
Principal Investigators

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	December 14, 2016
Laurie Meamber	IRB Chairperson	December 14, 2016