

Nova Southeastern University – Institutional Review Board Standard Operating Procedures		
SOP #2-5 Version #1	TITLE: Appeals of IRB Actions or Determinations	
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OBJECTIVE

To describe policies and procedures related to the appeal of IRB actions and/or determinations.

GENERAL DESCRIPTION

The university allows investigators to appeal decisions of the convened IRB. In keeping with federal regulations and university policy, research may only be disapproved by the convened IRB. No university official or committee may approve research that has not received approval or has been disapproved by the convened IRB.

For revisions requested or an action/determination by the IRB, the investigator may appeal for re-consideration by the convened IRB.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs, Institutional Official

PROCEDURES

1. If an investigator wishes to appeal a decision made by the College Representative, the IRB Chair, or the convened IRB, following a request for revisions or a determination regarding their protocol submission, they must submit a written appeal to the IRB Office.
2. The investigator must outline the reasons for the appeal, including the decision being appealed, documentation/further information regarding the issue, and the reason why the investigator is requesting an appeal. Appeals to the IRB must be made within 30 days of the date the investigator received notification of the decision from the IRB.
3. The IRB Office, Institutional Official, and/or IRB Chair/Vice Chairs will review the appeal and all relevant information. The investigator may be requested to provide additional information, if necessary.
4. If it is determined by IRB Office, Institutional Official, and/or IRB Chair/Vice Chairs that the protocol submission should be reconsidered, it will be added to the agenda for the next convened IRB. The convened IRB may invite the investigator to attend the meeting to

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provide additional information, if necessary. The investigator may not be present for any discussion or voting conducted by the convened IRB.

5. The IRB Office will notify the investigator of the decision of the convened IRB regarding their protocol submission by emailing an official memorandum.

REFERENCES

45 CFR 46
21 CFR 56.112