

**Nova Southeastern University
Office of Grants and Contracts
Institutional Review Board
Policies and Procedures**

Appeal of IRB Actions/Determinations

Effective 03/08/2007; Revised 01/02/2008

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Purpose:

To establish policy and procedures related to the appeal of IRB actions/determinations.

Definitions:

None

Policy:

The university will allow the PI to appeal decisions of the convened IRB. In keeping with federal regulations and university policy, research may only be disapproved by the IRB at a convened meeting and no external body, institutional official, or other individual may approve research that has not received approval of the IRB or has been disapproved by the IRB.

For revisions requested as a part of the center level review or expedited review, the PI may request that his/her protocol be reviewed at the next highest level. For protocols reviewed by the full board, the PI may request reconsideration by the full board.

References:

45 CFR 46

21 CFR 56.112

Procedures:

1. If the PI wishes to appeal a decision of the full IRB board, the researcher may submit in writing an appeal to the vice president for research and technology transfer (VP) and to the Chair of the IRB. The investigator's statement must outline the reasons for the appeal. Appeals to the IRB must be made within 30 days of the date the investigator received notification of the IRB's decision. The VP and IRB chair will then review the appeal, the minutes of the respective IRB meeting(s), the IRB file, and other documentation. If the VP and the Chair feel that the protocol should be considered by the board again, it will be placed on the agenda for the next IRB meeting. The board may invite the investigator to attend the meeting of the IRB to provide additional information if necessary. The investigator may not be present for any discussion or voting conducted by the IRB.

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2. If the PI wishes to appeal a decision made by the Center Representative or the Chair, following expedited or center level review, he/she may submit in writing the appeal, and request that the protocol be reviewed at the expedited level (if the PI is appealing a center level decision) or full (if the PI is appealing an expedited decision).