

Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.8
Policy Title: Institutional Review Board (IRB) – Appeals Process

Purpose

The purpose of this policy is to identify circumstances when a Principal Investigator (PI) may appeal decisions made by the IRB.

Definitions

See policy 2011-007.0 for definitions of:

IRB Approval | Suspension | Termination

Policy

In the event that an application is disapproved, suspended or terminated by the IRB the principal investigator may appeal the decision in writing to the convened IRB. The investigator may also appeal contingencies required by the convened IRB to secure approval or other determinations made by the board. The PI will have 90 days from the date of the convened meeting at which the IRB decision was made to file an appeal. The PI may file a subsequent appeal (within 90 days of the appeal meeting date) only if additional information is available to supplement the initial appeal.

An appeal can only be made to the panel that has oversight of the study.

Procedure

Appeal of IRB Decision to Deny Approval, Suspend or Terminate a Study

If electing to appeal the IRB's decision to deny approval or suspend or terminate a study, the PI will submit a written appeal that includes information that supports the PI's position.

Designated IRB Regulatory Specialist (RS) will place the appeal on the meeting agenda and distribute the material to IRB members. The Chair will assign primary reviewers to lead the discussion, with preference of using the same reviewers who conducted the review that resulted in the disapproval, suspension or termination.

The Chair may elect to convene a special meeting to process the appeal or to place it on the agenda for the next regularly scheduled meeting.

- at the discretion of the Chair, the PI may be invited to attend the meeting at which the appeal will be processed;
- if attending, the PI will present his/her case and may engage in discussion with the IRB to provide additional information;
- the Chair will excuse the PI prior to deliberations and voting.

The PI will be informed in writing of the final decision of the IRB. The letter will be prepared by the RS for signature by the Chair.

The PI may file a second appeal within 90 days of the initial appeal meeting if additional information is available to support the PI's position. The procedure noted above is followed.

Appeal of Contingencies or Other Determinations:

The initial appeal will be filed through a written response to the IRB Chair explaining why the contingency imposed by the IRB, or the determination made by the IRB, is not appropriate.

If the appeal is related to a contingency for approval the Chair may elect to do one of the following:

- agree with the investigator and grant approval providing the contingency does not affect the regulatory criteria for approval (i.e. minimization of risk, reasonableness of risk in relation to benefits, equitable selection of subjects, the process or required elements of consent, adequate provisions for monitoring data to ensure subject safety, adequate provisions for privacy and confidentiality of data, protection of vulnerable subjects);
- disagree with the investigator and still require that the contingency be addressed, or
- refer the matter back to a convened board meeting for review, e.g. if the Chair and investigator cannot come to agreement and/or the contingency is directly related to a regulatory criteria for approval.

Designated IRB staff will communicate the decision of the IRB Chair in writing to the PI. If referral to the convened board is made, the procedure noted in the first section will be followed.

If the appeal relates to a determination made by the IRB (e.g. that an issue represents serious non-compliance,) the appeal will be reviewed by the convened board and the procedures noted above will be followed.

Related Policies

2009-003 – Imposing and Lifting Suspensions of IRB Approval or Imposing Terminations of IRB Approval

2011-007.0 – Definitions Applied to Policies

2011-009.5 – Institutional Review Board – Review by Convened Board

2011-009.7 – Institutional Review Board – Assignment of Status Codes

2011-009.12 – Institutional Review Board – Criteria for Approval

Basis

45 CFR 46

21 CFR 56

Document Attributes

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Reviewed and Approved By:

Signed Richard H. Simon

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Richard Simon, MD

Director Human Subjects Protection Office