



Policy/Procedure Title	Appeal of Decision of the Institutional Review Board
Version	2
	November 29, 2010
Effective Date	January 1, 2011

PURPOSE

To define the appeal process to be taken by an investigator in the event a decision is made by the Board with which the investigator is in disagreement.

POLICY

To ensure appropriate and adequate steps are taken by the IRB for each Investigator and study to receive an impartial and comprehensive review.

SCOPE

This policy covers all human subject research that is conducted under any CAMC Health Systems, Inc. facility, involving any CAMC Health Systems, Inc. patient, or under any agreement in place for review by the CAMC/WVU-Charleston Division IRB.

SUBMISSION PROCESS AND TIMING OF APPEAL

The Principal Investigator, upon receipt of the letter with the Board’s determinations, may begin an appeal process of the Board’s decision by notifying the Director of Research and Grants Administration, in writing, within 10 business days of the date of the IRB review letter.

RESPONSIBILITY

Upon receipt of this notification the *Director of Research and Grants Administration* will notify the IRB Chairperson. The *IRB Chairperson* and the *Director of Research and Grants Administration* will call a committee of a minimum of three persons to review the decision of the Board. *Research and Grants Administration staff* are responsible for ensuring committee members receive paperwork in a timely fashion to allow adequate time for review. *Research and Grants Administration staff* are responsible to ensure all committee reports are forwarded to the Board per this policy for review.

APPEALS COMMITTEE

The committee must consist of at least one Board member or Alternate member who was in attendance during the convened meeting where the determination being appealed was made, one Board member or Alternate member who was not in attendance during the convened meeting where the determination being appealed was made and a third person who may be a Board member or Alternate member or may be a non-member with expertise in the field of knowledge being reviewed.

REVIEW PROCESS

The committee will be provided information from the convened meeting where the determination being appealed was made, including but not limited to: 1) meeting minutes; 2) all information supplied for initial continuing renewal by the Principal Investigator; 3) additional information gathered by the Research and Grants Administration staff as directed by the Chairperson, Board and/or committee; 4) additional information provided by the Principal Investigator (this additional information must be received by the Office of Research and Grants Administration no more than 5 days after receipt of the written appeal request).

The committee will review and discuss all information provided. The committee will prepare a report for presentation to the Board at the next convened meeting.

DECISION OF THE BOARD ON APPEAL

The Board will make a determination to: 1) affirm the initial decision; 2) request additional information of the Principal Investigator; 3) change the determination of the initial decision; 4) request the committee to gather additional information.

The Board, after review of the committee's report, will notify the Principal Investigator of their decision in writing.

Decisions of the Board after an appeal process are final and may not be overturned by anyone or any body.