

Chapter 5

APPEAL PROCEDURES

If an investigator disagrees with any Board decision or action, he or she may request reconsideration by either appearing before the Board or by requesting an advisory review panel. This request must be made to the IRB executive secretary, in writing, within seven calendar days of the investigator's receipt of the Board's hand-delivered notification.

The entire appeal process must be completed within 120 calendar days of receipt of the Board's notification to suspend or terminate a study.

The decision of the Board becomes final under any of the following circumstances:

- The investigator chooses not to appeal;
- The investigator fails to notify the executive secretary, within seven calendar days of receipt of the Board's notification, or a decision to appeal;
- The investigator or a representative fails to appear before the Board at its next regularly scheduled meeting;
- The investigator fails to request formation of an advisory review panel within seven calendar days of appearing before the Board;
- The investigator fails to make documents concerning the study available to the advisory review panel within seven calendar days of being requested to do so.

The Board will notify all appropriate parties.

A. Investigator Appears Before the Board

An investigator may ask to appear before the Board to request that the Board reconsider a decision; this appearance **must** be at the next regularly scheduled IRB meeting. The Board may affirm, modify or reverse its original decision. Within seven calendar days, the Board will notify the investigator of its decision. If the investigator is still dissatisfied, he or she may now have seven calendar days to request (in writing to executive secretary) formation of an advisory review panel.

B. Advisory Review Panel

An investigator may request reconsideration based on the report of an advisory review panel (see Appendix B). The advisory review panel must be formed within 15 calendar days of the investigator's request for its formation.

1. Composition

An advisory review panel shall consist of three persons:

- One member chosen by the IRB chair; this person may not be a current member of the Board or the IRB staff.

- One member chosen by the principal investigator; this person may not be a member of the investigator's department and may not have had any direct involvement in the activities in question.
- One member chosen by the office of the provost or Institutional Officer; this person will serve as chair, may not be a current member of the Board or the IRB staff, may not be a member of the investigator's department, and may not have had any direct involvement in the activities in question.

2. Meeting and Report

Within 30 calendar days of its formation, the panel will complete its investigation and transmit to the IRB chair a written report of its findings and recommendations. During its investigation, the panel may involve the office of the university's general counsel. The Board will consider this report at a regular or special meeting held within 30 calendar days of the chair's receipt of the report.

The Board will provide written notice (within seven calendar days) of its decision to the appropriate investigator(s) and to their department chair(s), dean(s), and vice president(s), the office of the provost, the Institutional Representative and members of the advisory review panel.

In accordance with WVU's and CAMC's agreement of assurance with HHS, the Board will submit a final report concerning noncompliance with IRB requirements to the Office for Protection from Research Risks (OPRR), the Food and Drug Administration (FDA) and other agencies (as appropriate), department chair(s), dean(s), Vice President for Health Sciences (as appropriate), the office of the provost or the Institutional Officer and the university and the health system's General Counsel. This report will include a statement of the reasons for the Board's decision and a description of any action taken by the Board.