

## Chapter 6

# ADVISORY REVIEW PANEL

### A. Composition of Panel

An advisory review panel shall consist of three persons, selected as follows within 15 calendar days of the investigator's request:

- 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; 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.

### B. Meeting and Report

Members of the advisory review panel will convene and use the following procedures:

- a. A member of the Board or the IRB staff will summarize the relevant facts and explain the reasons for the Board's decision. The investigator may be present during this report. The panel may involve the office of the university's general counsel.
- b. The investigator may make a statement and present additional information.
- c. The investigator and the IRB representative may call additional individuals to address the panel on the issue.
- d. Members of the panel may ask questions of the investigator, the IRB representative, or other persons addressing them.
- e. The panel will then meet in executive session to reach its decision.

Formal rules of evidence will not apply at an advisory review panel meeting.

The advisory review panel will complete its investigation and transmit, within 30 calendar days of its formation, a written report of its findings and recommendations to the IRB chair.

### C. Board Reconsideration Based on Report of the Panel

The Board will consider the report at a regular or special meeting held within 30 calendar days of the chair's receipt of the report.

The investigator and the members of the advisory panel may be present at this meeting, which will proceed essentially as follows:

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- a. The IRB chair will summarize the relevant facts, including the decision of the Board that is under review and the findings and recommendations of the advisory review panel.
- b. The chair of the advisory review panel may supplement the panel's written report with an oral presentation.
- c. The investigator may make a statement to the Board.
- d. Board members may ask questions of the members of the advisory review panel or of the investigator.
- e. The Board will meet in executive session and, by a simple majority vote of members present, may affirm, modify, or reverse its original decision. The Board is under no obligation to accept the panel's findings or recommendations.

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), vice president(s), the office of the provost, the university's general counsel and members of the advisory review panel. The Board will also notify, as appropriate, OPRR, the FDA and other agencies.