

Valparaiso University
Institutional Review Board (IRB)
Office of Sponsored and Student Research

INSTITUTIONAL REVIEW BOARD (IRB)
APPEALS PROCESS

1. Purpose

Principal Investigators (PIs) may disagree with an IRB decision regarding the PI's application. The PI may appeal IRB decisions to disapprove, suspend, terminate, or require modifications to a submitted protocol and associated materials.

2. Process

The IRB Chair (or designee) will inform the PI of the IRB's initial decision in writing. If the PI wishes to appeal the IRB's decision, the PI must respond in writing, providing justification and support for the appeal request. The IRB Chair will share this information for the IRB's consideration and review at its next meeting. The PI may attend the convened meeting to explain the appeal and answer questions from the IRB members. If appropriate, the IRB Chair may invite an expert consultant to participate in the review discussion. The PI must leave the room when the IRB votes on the appeal.

The IRB Chair (or designee) will notify the PI of the IRB's decision regarding the appeal in writing. Outcomes of the appeal include:

- Accept the appeal and continue with the IRB review process;
- Require modifications to the research protocol and/or investigator and team members; or
- Deny the appeal and the original IRB determination stands.

The IRB's ruling on the appeal is final.