

7.10 Failure to Respond

Failure to submit a response to IRB requirements for an unapproved protocol within 6 months of the IRB date of determination may result in administrative withdrawal of the IRB file (for new study submissions). When research has IRB approval, and an investigator fails to respond to requirements related to a subsequent submission (e.g., a request for modification), the IRB Chair or IRB Staff member will review the circumstances, including any potential impact on human subjects, and will contact the investigator to try to secure a response. If the investigator continues to be unresponsive, the failure of the investigator may be considered non-compliance and will be reviewed in accordance with the procedures in Section 16. The investigator will receive notification, including an explanation. An extension beyond 6 months may be granted by the IRB if sufficient cause is provided by the investigator.

7.11 Appeal of IRB Decisions

When an IRB research study is disapproved or deferred, the IRB will notify the investigator in writing about the specific deficiencies and the modifications that are necessary for appropriate IRB approval. The IRB shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Similarly, when research is suspended in part or in full, or terminated, the IRB will notify the investigator in writing of the suspension or termination and the reasons for its decision. The investigator may ask that the decision be reconsidered by submitting a request in writing to the IRB Chair. The request must contain the basis for the appeal, including any substantive new information that the Board did not have the opportunity to consider previously. The request is scheduled for review at a convened IRB meeting and the Investigator invited to attend the meeting.

In cases where there is disagreement between the IRB and the investigator regarding the nature and extent of the requested changes or the necessity of or basis for a suspension or termination, and these disagreements cannot be resolved, the investigator and/or the IRB may make an appeal to the IO for a resolution of the matter. The IO may organize a meeting to help facilitate discussion between the IRB and the investigator. While the IO may provide input and make recommendations to the investigator and IRB for expeditious resolution of the matter, final determinations for approval/disapproval remain under the purview of the IRB.

Because the IO is responsible for policies and procedures followed by the IRB, the IO may review IRB decisions to ensure that the decision-making process is appropriate. If the IO has concerns regarding the process that the IRB has followed in making a decision, he/she may request that the IRB reconsider the decision. However, the IO cannot overrule an IRB decision.

7.12 Research Previously Approved By Another IRB

When an investigator transfers research to the University of Virginia that was previously approved by another IRB, the investigator must submit the research for review under the procedures covered by this section. No research activity may take place under the University of Virginia auspices without the appropriate review and approval.

Research approved as exempt at the previous institution will be reviewed according to the procedures in Section 6. All other research must be submitted as if it were undergoing initial review and will be reviewed under expedited review or by the convened IRB. Research that solely involves the analysis of existing identifiable data may be considered under Expedited Review Category 5.

For research transfers where stopping research interventions might harm subjects, the investigator can request permission from the IRB to continue research interventions under the oversight of the prior organization's IRB until final University of Virginia approval is obtained.