

VIRGINIA TECH INSTITUTIONAL REVIEW BOARD

Failure to Submit an Acceptable Protocol or Implement Required Revisions

PURPOSE

The purpose of this policy is to reduce Institutional Review Board (IRB) and University resources spent on the review of inadequate protocols, thereby increasing review efficiency. This policy covers the following subparts:

- Subpart A: Submissions of protocol applications written in an incomprehensible or significantly contradictory manner, including protocol applications with incomplete responses to application questions or requirements.
- Subpart B: Failure of research investigators to adequately implement revisions or corrections required by the IRB to human subject protocols, or to adequately respond to the questions or concerns posed by the IRB.

SUBPART A: INCOMPREHENSIBLE OR CONTRADICTIONARY PROTOCOL APPLICATION

Human subject protocol applications received by the IRB which are written in an incomprehensible or significantly contradictory manner, including protocol applications with incomplete responses to application questions or requirements, may be returned to the research investigators by the Board or IRB personnel for correction without receiving a complete review by the IRB. This may result in the protocol application being postponed until a future IRB meeting.

If researcher investigators fail to submit an adequately corrected protocol application after two attempts, the IRB holds the authority to impose sanctions, to include one or more of the sanctions described below.

Similarly, if the principal investigator continues to submit inadequate protocol applications to the IRB, the IRB holds the authority to impose sanctions, to include one or more of the sanctions described below.

Note: IRB staff is available during regular business hours to assist researchers with completing the IRB application, and should be used as a resource when questions or issues arise during the development or revision of a research protocol. In addition, it is recommended that researchers request the review of a colleague who has experience with the IRB process before submittal or re-submittal to the IRB.

SUBPART B: INADEQUATE IMPLEMENTATION OF REQUIRED REVISIONS OR CORRECTIONS

Per 45 CFR 46.109(a), the IRB has the authority to require modifications in (to secure approval), or disapprove any and all research activities proposed in a human subject research protocol. The IRB informs investigators of required modifications or reasons for disapproval (or tabled action) in writing.

If, following such written notification, research investigators fail, after two attempts, to adequately implement revisions or corrections required by the IRB to the protocol application in question or any

subsequent protocol application of the principal investigator, the IRB holds the authority to impose sanctions, to include one or more of the sanctions described below.

Note: if research investigators provide adequate justification for not implementing the Board's required revisions, the IRB will not count this as a failure to implement the revisions.

During the third review of the protocol, the IRB may discontinue review or discussion of the protocol (e.g., protocol application is removed from the IRB agenda) immediately upon observance by an IRB member or IRB personnel of unimplemented required changes. In such a case, the protocol application will be sent back to the research investigators for completion, and will result in the protocol application being postponed until a future IRB meeting.

Note: IRB staff is available during regular business hours to assist researchers with implementing the revisions or corrections required by the IRB, and should be contacted if the revisions or corrections are unclear or not understood.

EXAMPLES OF SANCTIONS (including but not limited to):

- 3-month suspension of the IRB's review of the protocol in question to allow researchers time to properly implement requirements
- Formal or informal human subjects protection training
- For-cause audit(s) of protocol in question (after approval), or of the listed principal investigator's active or recently inactivated protocols
- Suspension or termination of the listed principal investigator's active protocol(s)
- Disapproval of the protocol in question
- Formal letter from the IRB to the investigator(s) department head, or equivalent