FRANKLIN UNIVERSITY

PROTOCOL VIOLATIONS

Federal regulations require the IRB to review proposed changes in any research activity and to ensure that the investigator does not initiate such changes in approved research without IRB review and approval except when necessary to eliminate apparent immediate hazards/risks to the participant [45CFR46.108(a)(3)(iii)]. Research activity includes all aspects of the conduct of the research study (e.g., recruitment methods, consent process, procedures used to protect privacy and confidentiality, etc.) and all of the information outlined in the IRB application/protocol reviewed and approved by the IRB.

DEFINITIONS

A protocol violation is any exception or deviation involving a single or multiple participant(s) that is not approved by the IRB prior to its initiation or implementation. These protocol violations may be major or minor violations.

A major violation is one that may impact participant safety, make a substantial alteration to risks to participants, or any factor determined by the IRB Manager, IRB Chair, or IRB member as warranting review of the violation by the convened IRB. Examples of major violations may include, but are not limited to:

- Failure to obtain informed consent, i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures;
- Enrollment of a participant who did not meet all inclusion/exclusion criteria;
- Performing a study procedure not included in the IRB approved protocol;
- Failure to report serious unanticipated problems/adverse events involving risks to participants to the IRB and, if applicable, the sponsor;
- Study visit conducted outside of required time frame that, in the opinion of the PI or IRB, may affect participant safety.

A minor violation is a violation that does not impact participant safety or does not substantially alter risks to participants. Examples of minor violations may include, but are not limited to:

- Implementation of unapproved recruitment procedures;
- Missing signed and dated consent form;
- Missing pages of executed consent form;
- Inappropriate documentation of informed consent, including:
  - Missing participant signature;
  - Missing investigator signature;
  - Copy not given to the person signing the form;
  - Someone other than the participant dated the consent form; or
  - Individual obtaining informed consent not listed on IRB approved study personnel list.
- Use of invalid consent form, i.e., outdated/expired consent form;
- Failure to follow the approved study procedure that, in the opinion of the PI, does not affect participant safety or data integrity, such as:
  - Study procedure conducted out of sequence;
  - Omitting an approved portion of the protocol;
  - Enrollment of ineligible participant (e.g., participant's age was 6 years above age limit); or
  - Study visit conducted outside of required timeframe.

Effective Date: 02/13/2019
Older Versions: 02/13/2019, 03/11/2020, 03/28/2022
Last Reviewed and Modified: 11/20/2024

- Over-enrollment.

PROCEDURES

Submission of Protocol Violations

1. The PI submits any and all protocol violations that occur during the course of a study to the IRB immediately upon discovering them and within 14 calendar days of the occurrence. To submit the protocol violation, the PI completes an Incident Report in Cayuse and includes all relevant information and attachments.

2. The PI also reports all protocol violations to the sponsor, if applicable, following the sponsor's requirements.

Screening of Submissions

1. IRB staff screen the Incident Report for completeness and accuracy. If the submission is incomplete, IRB staff either return it to the PI or continue to process the submission but request additional information from the PI, which they forward to the IRB upon receipt.

2. IRB staff screen to determine whether the violations involve vulnerable populations or require documentation of specific regulatory findings. If either of the above applies, IRB staff advise the IRB of any regulatory requirements the IRB should address in conducting the review. The IRB is responsible for applying the regulatory requirements.

Determining Mechanism of Review (i.e., Expedited vs. Full, Exempt Protocols)

1. IRB staff assign the Incident submission to the IRB Chair, if available, or to a voting member of the IRB for review.

2. The IRB Chair or IRB member makes a determination regarding whether the violation is major or minor and whether to review the violation using full or expedited review procedures, respectively, unless the sponsor/PI requests full review. If the violation is minor, the IRB Chair or assigned IRB member conducts a review using expedited procedures.

3. If the sponsor or the PI specifically requests full review procedures, IRB staff place the protocol report on an agenda for full review following procedures outlined in the Initial Full Review SOP.

4. If the Incident submission comes from an exempt study, the IRB Chair or IRB member makes a determination regarding whether the violation is major or minor and whether the issue can be resolved by the IRB Chair or IRB member, or if the issue requires full board review following the procedures below.

Expedited/Full Review Procedures

1. The IRB Chair or a voting IRB member conducts expedited review using standard expedited review procedures. (See Expedited Initial Review SOP)

2. If the protocol report undergoes full review, the IRB Chair or assigned IRB member has the option to invite the PI to attend the meeting to answer any questions or concerns that the IRB may have concerning the protocol violation.

3. IRB staff notify the PI in writing if he/she must attend the IRB meeting. IRB staff schedule the submission for review and send IRB members a copy of the Incident Report in the agenda packet.

4. If the IRB determines that the violation is reportable to external agencies, IRB staff prepare a report to the applicable federal agency and maintain records.

REVIEW OUTCOME(S)

1. The IRB may, if appropriate, make a determination that the protocol violation(s) constitute "serious" or "continuing noncompliance", or an "unanticipated problem involving risks to participants or others". (See Noncompliance and Unanticipated/Anticipated Problem/Adverse Event Reporting SOPs)

2. If the PI has concerns regarding the IRB decision, he/she may submit them to the IRB in a written document that includes justification for changing the IRB decision.