Guidance on Deviations, Violations, Adverse Events, and Other for Reviewers

Notify IRB

The PI needs to submit all substantial deviations and adverse events within five (5) working days of occurrence or has come to the attention of the PI.

Deviations

A protocol deviation is defined as a departure from the approved protocol that is unanticipated and happens without any prior agreement (protocol visit scheduled outside protocol window, blood work drawn outside protocol window, participant unable to come in for visit on time, etc.). The IRB will review these reports for frequency and may audit any protocol reporting frequent deviations.

Only major protocol deviations need be reported within five (5) working days.

Major protocol deviations (departure from the approved protocol):
The deviation has harmed or posed a significant risk of substantive harm to the individual research subject and increased the risk/benefit ratio, OR
The deviation has compromised the scientific integrity of the data collected for the study, OR
There is evidence of willful or knowing misconduct on the part of the investigator(s) or study staff, OR
The investigator(s) or study staff demonstrated other serious or continuing noncompliance with federal, state or local research regulations.

Investigators are required to report major protocol deviations that occur only at WVU’s research site(s) to the IRB within five (5) working days of their occurrence or within five (5) days of the investigator becoming aware of their occurrence.

Any minor protocol deviations may be reported with the next continuing review.

Adverse Event (AE)

An adverse event is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article.

Only Adverse Events that meet the following criteria need to be reported within 5 working days:
1. Adverse events involving direct harm to participants which in the opinion of the principal investigator meet the criteria for an unanticipated problem involving risk to subjects or others.

2. An unanticipated event related to the research that exposes participants to potential risk but that does not involve direct harm to participants.

3. An unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk.

Any other adverse events may be reported with the next continuing review submission.

**Deviations/Violations/Adverse Events and Other:**

Once the PI or coordinator submits one of these actions, the system will send a notification to the IRB that the Notify IRB action was submitted. The action will display in the History section of the protocol with the date it was submitted and the form(s) attached with associated comments entered.

Once the IRB staff receives the email notification, the email is forwarded to the designated Board reviewer. The Board member goes into the protocol, then to Protocol Actions, then to the History section of the Protocol. In the History section will be the notification and required attachments for review. All of these notifications must be accompanied by an attachment. The deviations and adverse events should use the forms from the IRB website. Any “Other” notifications must have the attachment that needs to be acknowledged.

The reviewer should determine if the information is sufficient and can be acknowledged or if further information is needed. The reviewer should then return the email to IRB staff with review comments. Do not attempt to enter any comments in the actual protocol.

If you are requesting additional information the request will be given the PI and upon resubmission will be sent back to the reviewer for determination.

The request and responses will be tracked in the History section of the protocol.

Once the action is acknowledged by the reviewer, IRB staff will acknowledge the action in the protocol, which will be recorded in the protocol History section.
Request to Close an Approved Protocol

The completion or termination of the study, whether premature or not, is a change in activity and must be reported to the IRB. Although subjects will no longer be "at risk" under the study, a final report to the IRB allows it to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies.

Once the IRB staff receives the email notification, the email is forwarded to the designated Board reviewer. The Board member goes into the protocol, then to Protocol Actions, then to the History section of the Protocol. In the History section will be the notification and required Closure Form from the oric.research.wvu.edu.

The reviewer should determine if the information is sufficient and can be acknowledged or if further information is needed. The reviewer should then return the email to IRB staff with review comments. Do not attempt to enter any comments in the actual protocol.

If you are requesting additional information the request will be given the PI and upon resubmission will be sent back to the reviewer for determination.

The request and responses will be tracked in the History section of the protocol.

Once the action to Close is acknowledged, the PI may not conduct any actions on this study.