



# Researcher Guidance for Reportable Events & Notifying the IRB

Office of Research Integrity & Compliance

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This document to help investigators determine what event(s) need to be reported to the WVU IRB and how to report these event(s), as well as certain actions that need to be taken on every protocol as the research concludes. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at [IRB@mail.wvu.edu](mailto:IRB@mail.wvu.edu).

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## Reportable Events

Adverse events are any physical, psychological, or social harm to subjects during the course of biomedical and/or social and behavioral research. If:

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

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

Deviations, depending on the nature and risk of the deviation, are classified in two ways:

1. **Minor deviations** are an administrative departure from the IRB-approved protocol procedures and were made without prior IRB, and sponsor (if applicable), approval. It is an accidental or unintentional change, or non-compliance, with the research protocol that neither:
  - a. Increases the risk, not decreases benefit, to the participant(s)
  - b. Significantly affects the subject's rights, safety or welfare and/or the integrity of the research data

Examples of minor deviations include:

- i. A protocol visit scheduled outside the protocol window
- ii. Bloodwork drawn outside the protocol window
- iii. Participant unable to come in for a visit on time,
- iv. Consent forms are not dated, and/or the participant did not initial each page

Note: Any actions that the Primary Investigator (PI) considers to be minor deviations, according to the criteria listed above, may be reported upon the protocols next submission or renewal.

2. **Major deviations** are a departure from an approved protocol that:
  - a. Has caused harm or posed a significant risk to an individual associated with the research
  - b. Has compromised the scientific integrity of the data collected for the study
  - c. There is evidence of willful or knowing misconduct on the part of the investigator(s)
  - d. Continuing non-compliance with federal, state, and/or local research regulations

Note: Investigators are required to report major deviations to the WVU IRB, as defined above, and occur 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.

[Related events](#) arise and can be linked to one of the protocol procedures if the procedure increases the risk of the event occurring, or the procedure and event affects the rights and welfare of current participants.

[Serious events](#) are anything that results in one of the following: death, is life-threatening, requires hospitalization or prolongation of hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

[Unanticipated Adverse Device Effects \(UADE\)](#) are defined as “any serious effect on health or safety or any life-identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects” (21 CFR 812.3(s)). A violation is an accidental or unintentional change to, or non-compliance with the IRB-approved procedures without prior sponsor and IRB approval.

[Unanticipated event](#) is a broad term to include research related events that occurred unexpectedly. This can also occur when the frequency, severity, or specificity is not consistent with the current investigator brochure, protocol, consent form, package insert, or label of a drug.

[Unanticipated Problem Involving Risk To Subjects or Others \(UPIRTSO\)](#) is a term used when an unanticipated problem(s) presents risk to the subject, multiple subjects, or others:

1. Is unexpected or unanticipated at the time of its occurrence and is not already described as potential risks in the approved research protocol or consent document, not listed in the Investigator Brochure, not due to an underlying disease, and does occur at an increased frequency or increased severity than what is expected.
2. Is related or possibly related to participation in the research.
3. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

[Violations](#) generally increase risk and/or decrease the benefit; affect the subject’s rights, safety or welfare and/or the integrity of the research data. This term is not defined by The Common Rule or FDA Regulations.

## Submitting a Notify IRB

This action must be taken to report any of the above defined events. To submit a Notify IRB, please follow these directions:

1. Got to the Protocol Actions tab. In the Available Actions list of this page, there should be an option to Notify IRB. Click the ‘Show’ button. The following options are available for selection:
2. Select the type qualifier that best matches the notification you wish to submit.
  - a. Other
  - b. Significant new finding
  - c. Deviation/Violation
  - d. Complaint/Concern
  - e. Exception
  - f. Self-report for Noncompliance
  - g. Unanticipated Problems - UPIRTSO
  - h. DSMB Report
  - i. Adverse Event

3. If the notification is a deviation/violation, severe adverse event or UPIRTSO go to the [Forms page](#) of the ORIC website and complete the form title *Deviation/Exception/Violation* if the event is a deviation, UPIRTSO, or SAE. Attach the completed form with any other relevant material to the Notify IRB submission.
4. If it is not a deviation, UPRITSO, or adverse event, and needs to be reported to the IRB, use the select the type qualifier 'Other.' There is no form for this. Attach the document(s) that the Board needs to review; these documents intended to be informational items not meant to be part of the protocol attachments or procedures.
  - a. If one of the other options from the list is chosen, please attach the appropriate paperwork.
5. Click 'Submit.' Upon submission, the electronic system will send a notification to the investigator(s) to alert them of the submission of the Notify IRB.

**Note:** The content of the Notify IRB action will be listed in the History section; here, the investigative team and IRB can view the form(s) attached and any comments. If the attachment is missing the protocol will be returned to you for further information.

Once it is reviewed, the IRB will acknowledge the event in a return comment or ask for further information with an IRB. If any additional actions are needed, such as submitting an amendment or requiring additional documentation or explanation, you will be informed in the return comment, which is in the Protocol History. You will be informed of this acknowledgement action via a system-generated email. Please keep the email documentation for this event in your records.

## Closing Participant Enrollment

It is important that the investigator change the status of their research protocol in the electronic system whenever they have completed their recruitment and enrollment. Submitting a Request to Close Enrollment is the only method that the enrollment status of the protocol can be changed.

Indicating a study is closed to enrollment in an amendment or renewal does not change the study status in the system. You will need to submit a Request to Close Enrollment as a separate action.

Once this request is submitted and approved by the IRB, the electronic system will automatically change the watermark on all study documents in the Notes & Attachments section of the protocol to say "Closed to Enrollment."

### [How to Submit a Request to Close Enrollment](#)

This action needs to be taken on any protocol, when enrollment is completed. The protocol can always be reopened to enrollment at a later date. Follow these directions to submit a Request to Close Enrollment:

1. Open the protocol, in 'edit' mode, and go to the Protocol Actions page. In the Available Actions list, select the Request to Close Enrollment action.
2. In the 'Reason' field, please enter the total number of subjects enrolled and the reason for closing enrollment.
3. Attach any relevant information, such as a memo, in the Attachment section of this action.
4. Click the submit button to send the request to the IRB. Upon submission, the KC system will send a notification to the investigator(s) whenever the Request to Close Enrollment action was submitted to the WVU IRB.

The content of the Request to Close Enrollment action will be listed in the History section; here, the investigative team and IRB can view the form(s) attached and any comments.

Once it is reviewed, the IRB will acknowledge the event or ask for further information with an IRB acknowledgement, which will also display in the History section of the protocol. The acknowledgement action, will also show in the system-generated email for the action. The KC system will send you a notification. Please keep the email notification and the History notification for your regulatory binders, as the KC system provides no further documentation for this event.

### [How to Submit a Request to Re-open Enrollment](#)

To reopen enrollment, open the protocol and go to the Protocol Actions page. Once there, select the Request to Re-open Enrollment in the Available Actions section. Describe your reason for wanting to reopen the research to enrollment, and attach any relevant information as before.

### Requesting to Close a Protocol

The completion or termination of an approved 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 the administrative office to officially close the file after member review. The final report also may provide useful information that may be used by the IRB in the evaluation and approval of related studies.

Follow these directions to request to close an active protocol:

1. Go to the WVU Office of Research Integrity and Compliance website.
2. Download and complete the form titled Closure Form from the Forms page of the Human Subjects Research section.
3. Open the protocol in 'edit' mode and navigate to the Protocol Actions page.
4. In the available actions list of the Request an Action section, select the Request to Close option.
5. In the text box provided, enter "Please see the attached Closure Form". Attach the completed Closure Form and any other relevant information that should be reviewed in the Attachment subsection.
6. Click the submit button to send the closure request to the IRB. Upon submission, the KC system will send a notification to the investigator(s) whenever the Request to Close action was sent to the WVU IRB.

The request, attachments, and acknowledgment by the IRB will be recorded in the Protocol History section. Once a protocol is closed, the status will be changed to "Closed by Investigator" and it will no longer automatically appear in your active protocol list(s) or search results.

Once it is reviewed, the IRB will acknowledge the event with an acknowledgement action, which will also show in the system-generated email for the action. The KC system will send you a notification. Please keep the email notification in your binder, it will be maintained in the History of the study.

### [Searching for a Closed Protocol](#)

If you need to find a closed protocol to review information within it or view/print the closure letter from the IRB:

1. Select the Search Protocols link located in the Dashboard under IRB. This will bring up the Simple Search option, click on Advanced Search.
2. Put in the protocol number and at the bottom of the left column, click 'Both'. Then click 'Search.'
3. Click the view link to open the protocol.
4. Navigate to the appropriate section of the protocol to access the desired materials.
  - a. Correspondence associated with the Closed (administratively closed) action can be found in the Protocol History tab, as well as on the Protocol Summary page under Correspondence.
5. Click the view button to view/print/save the closure letter.