

## Guidance on Deviations, Violations, Adverse Events, Closure Requests and Other for Reviewers

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### Notify IRB: Deviations/Violations/Adverse Events and Other

#### Definition and Reporting:

**Deviations.** A protocol deviation is defined as a departure from the approved protocol that is unanticipated and happens without any prior agreement (i.e., 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.

Major protocol deviations (departure of 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.

**Minor protocol deviations.** The deviation has no substantive effect on the risks or benefits to the individual research subject, AND

The deviation has no substantive effect on the value of the data collected, AND

The deviation did not result from willful or knowing misconduct on the part of the investigator(s) or study staff.

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 five (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.

To report a deviation, violation or adverse event:

- Go to the Protocol Actions page and then to Request an Action.
  - In the Available Actions list, show Notify IRB
  - Select the action you wish to submit from the Submission Type Qualifier drop down menu. And choose from the Submission Type Qualifier field.
- Go to the [oric.research.wvu.edu](http://oric.research.wvu.edu) website and download the appropriate form.
- The form must be completed then uploaded in the Attachment field by using the browse button. Provide a description and click Add.
- Attach any other documents if relevant to the review.

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**Other.** Other notifications are usually those that are submitted by the sponsor for acknowledgement by the Board. (i.e., such as safety reports or warnings of a future amendment) )

These are usually administrative in nature and do not require an amendment or revision to the sponsored protocol, investigator brochure, consent form or other documents.

To request an Other action take the following steps:

- Go to the Protocol Actions page and then to Request an Action.
  - In the Available Actions list, show Notify IRB
  - Select Other from the Submission Type Qualifier drop down menu. And choose from the Submission Type Qualifier field.
  - Then attach the document from the sponsor and uploaded in the Attachment field by using the browse button. Provide a description and click Add.
  - Once the attachments are complete click the submit button.

Upon submission, the KC system will send a notification to you that the Notify IRB action was submitted. The action will display in the History section of your protocol with the date it was submitted and the ability to view the form(s) attached and associated comments entered.

The IRB will receive an automatic email from the KC system that a Notify IRB action was submitted. 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. If any additional activity needs to be processed for the event reported, such as, should be submitted as an amendment, instructions will be conveyed in the comments section from the IRB.

- 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 and the History notification for your regulatory binders, as the system provides no further documentation for this event.

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**Request to Close Enrollment.** It is important that all protocols where enrollment has been completed, change the status of the protocol by submitting a Request to Close Enrollment action. Submitting an amendment or continuing review stating the protocol is closed to enrollment does NOT change the status of the study. That is why it is necessary to submit the Close to Enrollment request. Upon approval by the IRB the KC system will change any pdf documents in the *Notes and Attachments* section to Close to Accrual and take out the previous watermarking.

To request a close enrollment on an active, approved protocol take the following steps:

- Navigate to the Protocol Actions page of the protocol.
  - In the Available Actions list of the Request an Action section, select the Request to Close Enrollment action.
  - In the Reason field, enter the following information: A) How many subjects have been enrolled? B) Reason for the closure of enrollment.
  - Attach any relevant information (such as a sponsor-issued memo) in the Attachment subsection and click the add button. Click the submit button to submit the request to close enrollment.

Upon submission, the KC system will send a notification to you that the Request to Close Enrollment action was submitted. The action will display in the History section of your protocol with the date it was submitted and the ability to view the form(s) attached and associated comments entered.

The IRB will receive an email from the KC system that a *Request to Close Enrollment* action was submitted. 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. If any additional activity needs to be processed for the event reported, such as it should be submitted as an amendment, instructions will be conveyed in the comments section from the IRB.

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 and the History notification for your regulatory binders, as the KC system provides no further documentation for this event.

**Re-Open Enrollment.** To re-open enrollment on a protocol that has been closed to enrollment, navigate to the Protocol Actions page and select Request to Re-open Enrollment in the Available Actions list of the Request an Action section. Enter the reasons for re-opening enrollment in the *Reason* field and attach any relevant information in the *Attachments* subsection.

**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 committee and administrative office to close its files, as well as providing information that may be used by the IRB in the evaluation and approval of related studies.

To request to close an active, approved protocol:

- Navigate to the Protocol Actions page of the protocol.
  - In the Available Actions list of the Request an Action section, select the Request to Close action.
  - Enter "see attached closure form": in the Reason field.
  - Browse for and attach a completed Closure Form (<http://oric.research.wvu.edu/r/download/148647>) in the Attachments subsection of the Request to Close section and click the add button to add the form to the action. Attach any relevant information (such as a sponsor-issued memo) in the Attachment subsection and click the add button.
  - Click the submit button to submit the request to close.

Upon submission, the KC system will send a notification to you that the Request to Close Enrollment action was submitted. The action will display in the History section of your protocol with the date it was submitted and the ability to view the form(s) attached and associated comments entered.

The IRB will receive an email from the KC system that a Request to Close Enrollment action was submitted. 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. If any additional activity needs to be processed for the event reported, such as it needing to be submitted as an amendment, instructions will be conveyed in the comments section from the IRB.

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 and the History

notification for your regulatory binders, as the KC system provides no further documentation for this event.

Once a protocol has been closed, its status will be changed to “Closed by Investigator” and it will no longer automatically appear in your active protocol lists or protocol searches. If you need to find a closed protocol to review information within it or view/print the closure letter from the IRB:

- Select the *Search Protocols* link located in the Protocols area of the main Researcher page after logging into WVU+kc. This action will populate the Protocol lookup page.
- Select *Closed by Investigator* from the drop-down options located in the Protocol Status field located on the Protocol Lookup page and click the search button at the bottom of the page. All protocols that have been closed will populate in the search results.
- Click the view link to open the protocol.

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**To access the Closure Letters:**

- Navigate to the Protocol Actions page of the protocol.
- Show the History subsection of the Summary and History section.
- Show the Correspondences associated with the Closed (administratively closed) action.
- Click the view button to view/print/save the closure letter.