



When to Submit What & Reportable Events

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OHSU Research Integrity Office
Analyst Brown Bag Session

Topics for today

- Options for submitting changes to studies
- Modification and Continuing Review submission tips
- Basics of Unanticipated Problems (UP) and Protocol Deviations (PD) Reporting

- Please ask questions *as you have them*

Modification (MR) v. Continuing (CR)

- Staff changes
- Administrative changes
- Substantive changes, requiring full board review
- Timeline: how quickly do you need the revisions approved?
- Is your study full board or minimal risk?
- Are the changes full board or minimal risk?

MR Submission Tips

Q5 and Q5.1 are the most important questions in the form.

- Q5: Briefly describe the change(s) included in the modification.
- Q5.1: Explain the rationale for these changes, including if any changes are due to an UP, PD, DSMB recommendations, Investigator Brochure update, etc.

MR Tips, Continued

- You must clarify whether the risk profile of the drug has changed if you are submitting
 - a new or revised protocol or investigators brochure **and**
 - the AE table or drug information has been updated
- If the sponsor does not provide this information, you must create a memo for the IRB reviewers.
- **Not providing this information will delay your review.**

MR Tips, Continued

- Make sure all forms affected by the change(s) are updated appropriately.
- Double check that you have uploaded all revised forms and your changes are tracked.
- When uploading revised documents, **please** use the same title as the currently approved document.
- It is helpful to include in the title if the document is “New” or “Revised.”

Continuing Review Tips

- The expiration date of the study is **not** the due date of the Continuing Review (CR).
- The CR is due to the IRB 6–10 weeks prior to the study's expiration date
- Closure information and total numbers enrolled must match numbers in treatment/follow-up
- CR is the **best time** to archive documents
- Q13 is like Q5 and Q5.1 on the MR form

UP Policy – Reportable Events

- An adverse event (AE) is considered reportable if it falls into any of the four reportable categories in the decision tree.
- Use the checkbox to indicate the category that applies to the event.
- UP Case Studies of each category are available on our website.
- If an event does not fit into a category, it does not need to be reported to the IRB.

UP Category #1

Must fit all 4:

- On protocol
- Serious Adverse Event
- Unanticipated
- Related or possibly related

UP Category #2

Must fit all 4:

- On protocol
- Anticipated
- Related or possibly related
- Occurring at a significantly higher frequency or severity than expected

UP Category #3

Must fit all 3:

- Unanticipated
- Related or possibly related
- May alter the risks and warrants changes to the protocol and/or consent process

Notes:

- May be on or off protocol

UP Category #4

Must fit all 3:

- Unanticipated
- “Other” event(s)
- May place subjects or others at a greater risk of harm or discomfort.

Notes:

- This can be on or off protocol
- Harm to a subject need not have occurred

Notes about Reporting UPs

- It is up to the investigator or monitor to determine the UP category.
- Supporting documentation must be uploaded. This could be a MedWatch report, a note from the medical file, etc.
- De-identify all documents prior to uploading.
- If it is not a UP but the sponsor wants you to report it to the IRB, let us know.

Protocol Deviations (PD)

- It is the responsibility of the PI to avoid deviations from the IRB approved protocol.
- Planned changes, must be submitted prior to initiation or implementation.
- 3 levels of protocol deviations
 - Minor
 - Moderate
 - Major

Minor PDs - No Need to Report

- No substantive direct harm or risk of harm to subject(s) or does not result in or require action to be taken or result in change to the subject's status or condition
- No substantive effect on the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator
- The deviation is easily corrected

Moderate PDs – Must be Reported

- The deviation resulted in a direct harm or risk of harm that is not greater than minimal risk and/or minimal risk interventions
- Resulted in the loss or improper collection or recording of data for one or more subjects, but did not invalidate the entire data set
- Can be acceptably resolved
- Repeated minor protocol deviations from same group
- Failure to follow action ordered to correct minor or moderate PDs

Major PDs – must be reported

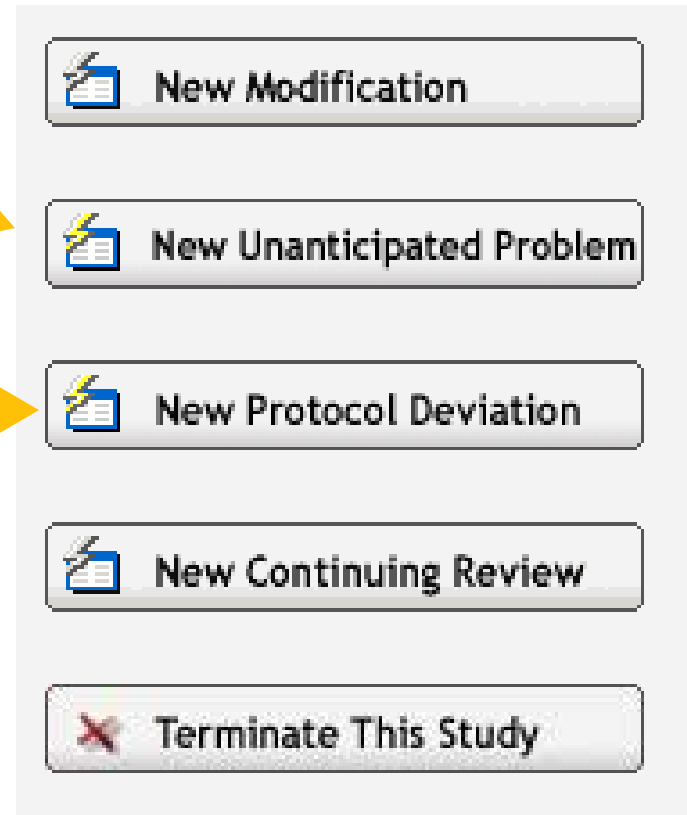
- Resulted in or required substantive action to be taken or resulted in a change to subject's condition or status
- Has harmed or posed a significant risk of substantive harm to research participants
- Has substantially damaged the scientific integrity of the data
- Is evidence of willful or knowing misconduct on the part of the investigator(s)
- There have been repeated minor and/or moderate PD from same site or failure to follow action to correct them

How to submit a UP or PD

- Click on **New Unanticipated Problem**

- Click on the **New Protocol Deviation**

- Answer all questions





Mark your calendars!

Next Brown Bag Session is
December 13th
Recruitment & Consent

11:00 to 12:00
UHS 8B60

Visit our website for more
information:
www.ohsu.edu/researchintegrity

