Guidance for Reporting Multiple REs to the IRB

In order to alleviate work for both coordinators and the IRB, please follow the steps below when submitting multiple reportable events to the IRB at the same time.

Please combine multiple events into one RE submission; do not submit several RE forms simultaneously: If you have multiple events to report at the same time, regardless of whether the events are related to each other, you should use one RE form. Within that form you will upload a summary document that will include details about each event (see below for an outline what should be included). For this reason, the type of RE form you initially choose does not matter because the form will merely act as a shell and the summary document will be what the IRB reviews. If you use RE assessment forms to document PI assessment, you may upload scanned copies in lieu of a summary document, but they would be expected to address the same details.

Details to Include in an RE Submission:

- For Protocol Deviations and Noncompliance:
  - Date of the occurrence
  - When the PI learned of the potential issue
  - Whether this is a substantive deviation from the protocol as approved by the IRB
  - Whether the deviation affects:
    - Rights/welfare of subjects
    - Safety of subjects
    - Integrity of the research data
    - Subject’s willingness to continue study participation
  - Whether a third party specifically asked you to file this report
  - Description of the deviation/violation and how/why it occurred
  - Explain any adverse effects of the deviation/violation which might affect the rights/welfare of subjects, safety of subjects, integrity of the research data, or subjects’ willingness to continue study participation.
  - Explain if these events may require a revision of protocol, consent or IB change. If you have a revision, please submit it via an amendment.
  - Describe the corrective and preventive plan to avoid recurrence.
  - Please note: for multiple events we will rely on the summary document rather than the questions in the eIRB form.
  - The IRB will provide you with one letter making a brief reference regarding each event.

- For Adverse Events that may be Unanticipated Problems:
  - Date of the event
  - Date the PI learned about the event
  - Whether the event occurred at an Emory-affiliated site (which includes any site under an Emory S-I), or at a non-Emory site
  - Whether the event was unanticipated in terms of its frequency, duration, or severity in light of the research procedures described in the protocol-related documents (e.g. protocol, informed consent document)
  - What is the relationship of the event to the study? (e.g. probably related, possibly related, unknown, etc.)
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- Was the event associated with (or the cause of) a death, life-threatening event, hospitalization, prolonged hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect, or breach of confidentiality?
- Explain whether the event puts subjects or others at increased risk of harm that was not previously known.
- Explain why the event is considered unanticipated
- Explain if these events may require a revision of protocol, consent and/or IB change. If you have a revision, please submit it via an amendment
- Explain if this event involves a breach of confidentiality and if so, why.
- Please indicate if you have reported the event to other entities (e.g. Sponsor, FDA, DSMB)
- Please note: for multiple events we will rely on the summary document rather than the questions in the eIRB form.
- The IRB will provide you with one letter making a brief reference regarding each event.

Frequently Asked Questions:

**I have submitted multiple RE forms already, what should I do?**
If you have already submitted multiple RE forms, please merge all the information into one RE form as outlined above and then withdraw the other submissions from eIRB.

**How can I add all the information in one RE form?**
You may copy the information from the separate RE forms, paste it into a single Word document, and then upload it to one of the completed RE forms. Alternatively, you could also use the “print view” option and save to PDF. Then you can upload those PDFs into one RE form.

**My PI already submitted the forms, does he/she needs to submit the RE form again?**
As long as you modify one of the submitted RE forms, instead of creating a new one, the PI will not need to click “submit” again. Of course, we recommend that the PI still review the final form version to make sure all of the information from the multiple forms was appropriately covered in the modified submission.

**What should I do with the other RE forms that I submitted?**
Please withdraw the RE forms that will not be used. If you have any issues, please let us know and we can walk you through the process.

If you have additional questions about this guidance, please contact the [QA and Education Team](mailto:qa@emory.edu).

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