GUIDANCE FOR REPORTING MULTIPLE RNI SUBMISSIONS TO THE IRB

EMORY UNIVERSITY

Institutional Review Board

Research Administration

Guidance for Reporting Multiple RNIs to the IRB

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 RNI submission; do not submit several RNI submissions 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 RNI submissions. Within that form, you will upload a summary document that will include details about each event (see below for an outline of what should be included). 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 the RNI Submission:

For Protocol Deviations and Noncompliance:

- The 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
  - The 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, the safety of subjects, the 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:

- The date of the event
- The 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.)
- 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 summited multiple RNI submissions already, what should I do?
If you have already submitted multiple RNI forms, please merge all the information into one RNI submission as outlined above and then withdraw the other submissions from eIRB.

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

What should I do with the other RNI submissions that I submitted?
Please withdraw the RNI submissions 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.