REPORTING OBLIGATIONS FOR EXTERNAL STUDIES

When and how to report to the IRB
Topics to Cover

- What events should be reported
- Who should receive the report(s)
- How to report
- Timing of reports
- Review website resources for studies under reliance agreements
- Q/A
What Requires Reporting?

Report events/information to the REVIEWING IRB according to the Reviewing IRB’s policies and process.

*If in doubt:* report anything that Emory IRB would require to be reported, and if the Reviewing IRB’s rules go beyond our requirements, you must follow their policies.

Note: You do not have to create an RNI in eIRB if you only need to report it to the external IRB.
Prompt Reports to Emory

- Report "egregious" reportable events promptly to Emory office of Compliance, Risk Management Office, and Emory IRB IN ADDITION to the Reviewing IRB.
Examples of Egregious Events

- wrong side surgery
- wrong drug, wrong patient
- fabrication or falsification of data
- HIPAA privacy matter (report any inadvertent data disclosure and we will help determine further actions)
Reporting Egregious Events

- Select "Report New Information"
- Upload a copy of the report(s) made to the reviewing IRB, and any correspondence from the reviewing IRB
- No need to wait for their determination
Periodic Reporting Requirements

Teams have an obligation to report CR data to the Emory IRB. The report should be made upon receipt of the CR approval letter provided by the reviewing IRB.
Periodic Reporting Requirements

The Emory IRB would like a summary of events reported to the External IRB during the past approval period.

The PI can select “Report Continuing Review Data” from the main study workspace.

Again, these do not need an RNI submission.
Under question #4, attach the completed “CR Workbook” as well as the renewal letter from the reviewing IRB.
**External IRB Continuing Review Report**

With this Excel sheet you will be documenting all the reports made to your external IRB in the past approval period. In addition, you will be reporting all egregious events that should have been reported promptly to both the external and the Emory IRB.

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**Periodic Reportable Event Summary**

These events should have been reported to the External (Reviewing IRB) already. The Emory IRB needs a prompt report only if the event was also considered an egregious event.

<table>
<thead>
<tr>
<th>Unanticipated problems (UPs) involving risk to participants or others</th>
<th>Non-Compliance Matters or Other Reportable Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event description</td>
<td>Event Date</td>
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(*) Past previously reported to the reviewing IRB, make sure you report these right away. In your report to the reviewing IRB, please provide a corrective and preventive action plan to avoid a late reporting instance in the future.
Alternative process for CR data reports

- If the PI is unavailable to submit the CR data, the team can log a comment along with the CR approval letter and CR workbook.
- The analyst will manage the technical process within the system.
Reportable Changes in Research

- changes to drugs or devices used in the study
- changes to local study personnel
- changes to Emory-affiliated study sites
- changes in financial interests on the part of Emory investigators
- new funding mechanisms
- No other changes need to be submitted locally to us at this time (subject to change)
How To Report Changes

- Depending on the state of your approved study, do the following:
  
  - "Active" status- submit via 'Create Site Modification' (for Emory-specific information changes) or "Update Study Details" (for study-wide changes).

  - "External IRB" status- you need to submit an "Update" to the submission.
Navigating the IRB Website
Questions?