## Timing of Report of Internal Protocol Deviations, Serious Adverse Events (SAEs), Deaths, Confidentiality Breaches, Non-Compliance, and External Events for Emory IRB Approved Studies (*)

<table>
<thead>
<tr>
<th>Category</th>
<th>Promptly:</th>
<th>Periodically:</th>
<th>Never:</th>
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| **Protocol Deviations** | - if substantive deviation from protocol and affects rights, safety or welfare of subjects, their willingness to continue in study or the integrity of the research data.  
                          - if they do not affect any of the above.                                                                                                   |                                                                                                  |                                                                                                  |
| **SAEs or Deaths**   | - SAEs that represent an unanticipated problem or related deaths  
                          - Periodically: if the SAE is anticipated and related to study participation; deaths that are not related.  
                          - if they do not affect any of the above.                                                                                             |                                                                                                  |                                                                                                  |
| **Confidentiality Breach** | - Always promptly reportable to the IRB.                                                                                                                                                           |                                                                                                  |                                                                                                  |
| **Non-Compliance**   | - Promptly: The IRB compliance review (CoRe) team will assess if event is possibly serious and/or continuing; if so, Full Board (Committee Q) will review.  
                          - if not, only events that meet the unanticipated problem criteria are reportable to the Emory IRB.                                               |                                                                                                  |                                                                                                  |
| **External Events**   | - If the study is under a sponsor-investigator, the above criteria will apply for events taking place at an external site  
                          - If not, only events that meet the unanticipated problem criteria are reportable to the Emory IRB.                                                                                     |                                                                                                  |                                                                                                  |

**Promptly:** 10 business days from the date the PI first learned about the event  
**Periodically:** at continuing review  
**Unanticipated Problem:** event that is unanticipated, related and involving risk to participant or serious.

(*)Studies approved by an External IRB: Send the RNI to the external IRB. Egregious events should be reported to both the reviewing and the Emory IRBs.

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