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

Protocol Deviations	• Promptly: 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. • Never: if they do not affect any of the above.
SAEs or Deaths	• Promptly: 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. • Never: SAEs if not related to study participation.
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.
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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