Timing of Report of Protocol Deviations, Serious Adverse events, Deaths and Non Compliance *

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.

Serious Adverse Events

- Promptly **: if unanticipated, related and involving risk to participant or others or if happening at increased frequency, duration or intensity that previously anticipated.
- Periodically ***: if related to study participation.
- Never: If not related to study participation.

Internal Deaths

- Promptly**: if related to study participation.
- Periodically ***: If not related to study participation.

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.

(*) This applies to internal events, and external events from sites of Emory sponsor-investigator studies.
(**) Promptly: 10 business days from the date the PI first learned about the event
(***)Periodically: at continuing review
NOTE: This guidance does not apply to VA studies.

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