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

#### Protocol Deviations
- **Promptly**: if substantive deviations from protocol and affect rights and welfare of subjects, safety 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.

#### 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.

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

#### Non-Compliance
- **Promptly**: The CoRe team will make a determination if it is possibly serious and/or continuing; if so, 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 learn about the event

(***): Periodically: at continuing review

This guidance does not apply to VA studies.