



## Data Integrity and Safety Committee (DISC) Reporting Requirements FAQ

### WHO should be reporting events to the DISC?

- Any study that is assigned by the Scientific Review and Monitoring Committee (SRMC) to be monitored by the DISC should send reports to the DISC. You can check your most recent SRMC decision letter to see if your study is currently monitored by the DISC.

### WHAT should be reported?

- All serious adverse events (SAEs), regardless of expectedness or relatedness. This applies to all SAEs that occur from the time any study intervention is initiated until 30 (thirty) days following the last protocol intervention, at a minimum. Extended SAE reporting intervals may be required as defined per protocol.
  - Include the following information (if applicable) for SAE reports:
    - Event Date
    - Event End Date
    - Discovery Date
    - Event Narrative
    - CTCAE Grade or Severity
    - Unexpectedness
    - Dose-limiting Toxicity
    - Attribution
    - Outcome
- Major study deviations, including regulatory and protocol noncompliance.
  - Include the following information (if applicable) for major deviation reports:
    - Deviation Date
    - Date Discovered
    - Description of Deviation
    - Effect on Patient Safety
    - Action Taken
    - Reported to the IRB?

### WHERE should these reports be sent to?

- You can use [UFHCC-DSMB@ahc.ufl.edu](mailto:UFHCC-DSMB@ahc.ufl.edu) to report serious adverse events and instances of major deviations.
- All SAEs and deviations **must** be entered into Oncore within the SAE or Deviation tabs of the Subject Console so that these events are available for cumulative DISC review and monitoring. **This reporting is in ADDITION to any study CRF/EDC entries.** Please view the OnCore Subject Registration and Reporting Process Guidance document for how to enter these events.

### WHEN should these reports be sent?

- Reports should be sent in within 5 business days of discovery.
- Any follow-up information for a reported event should be sent in a timely manner.