Guidance on Investigator Interactions with Monitors

Monitoring of clinical research sites by Sponsors and/or Clinical Research Organizations (CROs) is a routine part of the clinical research process. The frequency, extent and quality of monitoring varies widely between Sponsors, CROs and individual monitors, depending on the size of the trial, complexity of the research and the level of risk to which subjects may be exposed. This document provides Overall Principal Investigators guidance regarding their role, responsibilities and risks associated with the monitoring process.

All communication, written and electronic correspondence, exchanged documents and records of monitoring visits are auditable and may be subject to review by regulatory authorities such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Monitoring Visits:

Overall Principal Investigators must take an active role in the monitoring process by:

- Knowing when a site-monitoring visit is scheduled. You should receive notification prior to the visit identifying the date of the visit and what areas of the facility the monitor intends to visit.
- Meeting with the monitor prior to their leaving the site. If you cannot meet in person, arrange to speak by telephone. Review with the monitor any observations or concerns the monitor may have that requires corrective action be taken by you and your research team.
- Maintaining a Monitoring Visit Log to document monitoring visits.

In addition, the monitor may ask to visit and inspect any area of the facility associated with the conduct of the protocol. The monitor may also request to interact with any responsible personnel. This includes but is not limited to the research pharmacy, clinical facilities and storage areas for maintaining research records. Any materials not associated with the protocol are confidential and should be kept out of view or made inaccessible.

Monitoring Follow-up:

- After each monitoring visit, you should receive a Monitoring Visit Report. Do not ignore this correspondence. Follow-up with the monitor if a report is not received.
- The Monitoring Visit Report is official documentation of the monitor's visit and observations about the overall conduct of the research at the site. The report may innumerate specific concerns or deficiencies the monitor noted during the visit.
- Review the Monitoring Visit Report for content and accuracy. If you feel the report contains erroneous information you must bring this to the monitor's attention and ensure its revision. Correction of a disputed Monitoring Report may require sustained follow up to resolution.

Remember, all information associated with the Sponsor Monitoring process is an auditable part of the research process. You are ultimately responsible for its accuracy.