**How to Prepare for Monitor Visits**

**Scheduling**

* 1. Monitoring visits are pre-arranged and conducted on working days (preferably Tuesdays through Thursdays) between 8:30 am and 4:00 pm. The coordinator and the monitor are responsible for scheduling the visit. If the monitor requests additional appointments with the PI, pharmacy or other areas, the coordinator is responsible for arranging the appointment times in advance of the visit.
  2. When a date is scheduled, the coordinator emails the CRSP Director and Manager with the date. No more than two monitor visits are scheduled for the same day. If it is necessary to schedule more than two monitor visits on the same day, the CRSP Management must approve the additional visits.
  3. If on-site, a working location will be provided for the monitor with access to appropriate research staff.
  4. During the monitoring visit the Study Coordinator and all appropriate documents will be available to the monitor.

CRSP Management must review the results of the monitoring visit. Study Coordinators are responsible for seeing that the monitors allocate time towards the end of their visit for an exit interview. The exit interview will be conducted after all CRFs and regulatory documents have been reviewed by the monitor.

**Regulatory documents**

* 1. The Regulatory Coordinator is responsible for resolving any regulatory issues of the monitoring visit.
  2. The Regulatory Coordinator prepares the regulatory documents for the monitor visit. The Regulatory Coordinator will place the regulatory binders in the monitor room prior to the monitor visit if on-site. During the visit the Regulatory Coordinator will meet with the monitor to discuss any issues or concerns and address as many as possible prior to the completion of the visit. The monitor may not remove any regulatory documents or study documents from the CRSP offices.

**Participant documents**

* 1. The Study Coordinator is responsible for the resolution of the monitoring issues concerning clinical aspects of the study. The coordinator must notify and review issues with the CRSP Manager.
  2. The Study Coordinator maintains up to date participant source documents and case report forms. The coordinator prepares for the visit by making sure that all study paperwork is complete and ready for the monitor to review. If taking place on site, prior to the monitor visit the Study Coordinator places all the necessary documents requested by the monitor in the monitor room.

**Conclusion**

* 1. Upon conclusion of the monitoring visit and exit interview, the monitor will confirm that a written summary of all clinical and regulatory findings will be sent to the Study Coordinator and Principle Investigator within two weeks of the visit.
  2. When the visit is concluded, the Regulatory Coordinator returns all regulatory documents to the proper location. The Study Coordinator returns all study paperwork to the proper location.
  3. If on site, the Study Coordinator and Regulatory Coordinator make sure the room used for the monitor visit is left clean and in order.
  4. The monitor’s follow up letter must be reviewed and signed by the Principal Investigator. The letter is then given to the Regulatory Coordinator with the corrective action items for IRB submission.
  5. The Regulatory Coordinator prepares a memo response to the IRB with the monitor letter addressing all issues and corrective actions taken.