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GUIDELINES FOR SITE MONITORING

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1.0 SITE MONITOR RESPONSIBILITIES

1.1 Before a visit, monitors:

- Identify the site's Visit Coordinator.
- Obtain the address, telephone number, map, directions and Contact Person for all locations they will visit.
- Tell the site, in as much detail as possible, what they want to accomplish during their visit, what resources they will need, what records they want to review, and how much time they expect each activity to take.
- With the site, establish a schedule for their visit, accommodating, as much as possible, the site's other priorities. They should allow enough time to stay on schedule.
- Make sure the contact people at all locations know and accept their visit schedule.
- Confirm the above information in a timely letter to the site.
- Know all aspects of the Study and any other instructions or clarifications that have been communicated to the site.

1.2 Monitor visit objectives may include:

- Confirming that subject enrollment and visits are on schedule.
- Confirming that study personnel are complying with the protocol.
- Reviewing signed informed consent forms.
- Verifying that most current informed consent form is being used.
- Reviewing 100% or a sampling of CRF pages, and collect all completed CRF pages.
- Reviewing source documents for CRF support, unscheduled visits and adverse events.
- Reviewing the regulatory binder.
- Reviewing protocol deviation and SAE reporting.
- Reviewing study logs and Temperature Logs.
- Inspecting investigational articles and clinical supplies; assess storage facilities.
- Reconcile drug accountability records.
- Inspect randomization code materials.
- Reviewing blinding and dispensing procedures.
- Assessing the adequacy of the facilities.
- Assessing whether equipment is properly maintenance maintained and calibrated.
- Verifying that laboratory certifications and other documentation is current.
- Checking inventory levels of study drugs, clinical supplies and blank documents such as CRFs.
- Verifying that drug expiration dates have not been exceeded.
- Assessing investigator's involvement in the study.
- Assessing study personnel's knowledge of GCP and the protocol.
- Sharing the experience of other sites, e.g., in recruiting.
- Training site personnel on who to contact with specific questions
- Reviewing status of study and site with central and/or local IRB

1.3 During a visit, monitors:

- Keep their Contact Person informed of their activities.
- Review and collect all completed CRF pages. Flag pages with questions or problems and review them with the Study Coordinator.
- If they handle medications or other supplies, replace them exactly as they found them.
- Do not interrupt site personnel when they are with a patient, on the telephone or in a conversation; instead, ask their Contact Person or someone at the front desk to help them.
- Bring an organized set of the study forms and documents.
- If they identify a potential issue, discuss it as soon as possible with the site during their visit, providing details and referencing the pertinent passages in the study documents.
- Ensure, to the extent practical, that issues flagged in CRFs are resolved during the visit.
- Mark the place in the Regulatory Binder where he/she stopped his/her review.
- When raising an issue about the contents of the study documents, specifically identify the pertinent passages.
- If his/her schedule changes, notify everyone who may be affected.
- At the end of their visit, meet with the Principal Investigator to discuss findings and next steps.

1.4 Monitors review CRFs for:

- Missing entries
- Incomplete entries
- Illegible entries
- Data recorded in the wrong field
- Illogical data
- Inconsistent data
- Ambiguous data
- Entries that demonstrate protocol violations or deviations
- Missing signatures
- Missing dates

1.5 When visiting a subinvestigator or other satellite site, monitors:

- Notify the site well in advance when they plan to visit them, how long they expect to take, what resources they will need, and what they intend to accomplish during the visit.
- Communicate privately with the Visit Coordinator about any issues.
- Use discretion so as to not create issues or extra work for the Principal Investigator.
- Do not interview site personnel without previously notifying the Visit Coordinator and their Contact Person at that site.

1.6 After a visit, monitors:

- Communicate significant problems to the site immediately, before small problems become big ones.
- Transmit their report to the site as soon as possible.

1.7 Any significant deviations from these expectations should be documented and discussed with the Site Monitor, or their supervisor if necessary.

1.8 Site Monitors generally may not write on original CRF pages. Exceptions may be made only if all of the below apply:

- The Sponsor or CRO provides a written request for the Site Monitor to make changes to CRFs

- The CRO or sponsor provides an SOP detailing who, how and when it may be done
- The Director of Regulatory Affairs approves it for a specific study
- The Site Monitor signs the Signature Log and initials and dates all changes.
- Changes are made on unseparated NCR copies
- Changes are self-evident, e.g., to correctly enter data that was entered below rather than above a line.
- Changes do not require review of medical records at the site
- Changes do not require the concurrence or signature of study personnel
- Changes are not important enough to justify investment of time by study personnel

1.9 Sponsor personnel (who are not involved in site monitoring or other quality control activities for the site) may assist study personnel in completing CRFs to meet a deadline.

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