North Florida Foundation for Research and Education (NFFRE)

Standard Operating Procedure

Monitoring Visits for NFFRE Clinical Trials

PURPOSE: To establish a standard procedure for monitoring visits which are conducted to assure protection of rights and safety of human subjects, and quality integrity of clinical trials result. To ensure that necessary data for such monitoring is available, including designated space and responsible staff.

POLICY: The Principal Investigator (or designee) will collaborate with the Sponsor (or designee) in scheduling the monitoring visit. The Principal Investigator will assure that all staff involved with the clinical trial(s), including the clinical research site coordinator, research nurses, research pharmacist, and regulatory specialist are available to the monitor and present for the findings and de-briefing at the end of the visit. The Principal Investigator will assure that all data necessary to conduct a thorough clinical trials audit are available and centrally located for the monitor.

RESPONSIBILITY

Principal Investigator: The Principal Investigator will assure that all necessary source documentation is available to demonstrate that the site and designated personnel have adequate qualifications and resources, including number of qualified staff and facilities, to safely and properly conduct (the) clinical trial(s). The Principal Investigator will demonstrate via source documentation and regulatory files that the conduct of the trial is accordance with protocol, Code of Federal Regulations, and Good Clinical Practice.

Clinical Research Site Coordinator: The clinical research coordinator will prepare an itinerary for all upcoming monitoring visits. The clinical research site coordinator will reserve adequate space, defined as a quiet space with table and electrical outlet, for the monitor. The clinical research site coordinator will notify all involved study personnel of dates when the monitoring visit will be conducted. The clinical research site coordinator assure that subject study binders and original source documents are centrally available for data verification. The clinical research site coordinator will assure that subject logs and all signed informed consent forms are also available for verification.

Clinical Research Pharmacist: The clinical research pharmacist will be available and facilitate drug storage inspection and drug accountability via signed and dated hard copy shipment verification to inventory status, dispensation logs, and running temperature logs. The clinical research pharmacist will supply necessary documentation to demonstrate adequate instruction to study participants on dosing, handling, storing and return of investigational products.

Regulatory Specialist (or designee): The clinical regulatory specialist will pull and have centrally available all essential documents pertaining to the study(ies) being monitored, including site personnel CVs and training history, study site personnel responsibility log, FDA 1572, IRB membership list, disclosure/confidentiality agreement letter, IRB assurance letter or compliance

statement, IRB and Sponsor correspondence, SAE, Investigator Brochure(s), protocol and amendments, copy of approved informed consent, IRB approvals and renewal, laboratory certification(s) and ranges, clinical supplies accountability and shipping forms, equipment calibration logs, monitoring logs and product information. The clinical regulatory specialist will assure that all forms are current, complete and organized.

PROCEDURE

Upon notification from the Sponsor of scheduling of an upcoming monitoring visit, the Clinical Research Site Coordinator will notify all involved study personnel, including Principal Investigator(s), Clinical Research Regulatory Specialist, Clinical Research Pharmacist, and Research Nurses of the planned dates for the visit. Visit dates and availability of key personnel will be confirmed with site personnel and Sponsor (designee). A space for the monitoring visit will be reserved.

The site will receive notice from the Sponsor (or designee) prior to arrival which will confirm the dates and the focus for the monitor visit.

Prior to the Monitor's arrival, research binders and source documentation, including progress notes, flow sheets, laboratory or diagnostic reports, consent forms, diary cards or questionnaires, and drug/product accountability logs will be pulled and be placed or ready to go into the reserved space once the monitor arrives. Essential documents for the study(ies) being monitored will be pulled for review either in this centrally reserved room for the monitor or in the office of the Clinical Regulatory Specialist. Drug product will be assessed in the research pharmacy.

At the end of the monitoring period, site personnel will meet for debriefing with the monitor. The Monitor will review findings of the monitoring visit. The site will use findings from the monitoring visit as part of the site-specific QM plan.