North Florida Foundation for Research and Education (NFFRE)

Standard Operating Procedure

Protocol for Hospitalized Research Patients

PURPOSE: To establish a standard procedure for communicating with appropriate hospital personnel when a research patient is admitted to the hospital. To assure safety of human subjects, and quality integrity of clinical trials result. To ensure that a decision is made as to whether the study drug could be responsible for the hospital admission and whether the Principal Investigator intends to continue, hold, or permanently discontinue study medication treatment

POLICY: Once a team member has been made aware that a research patient has been admitted to the hospital, the PI and research pharmacist should be notified. It should be determined by the PI as soon as possible whether the patient will continue, hold, or discontinue study medication. PI will contact the admitting physician.

RESPONSIBILITY

Principal Investigator

- The Principal Investigator will determine whether the study drug could be responsible for the hospitalization.
- PI will decide whether the medication needs to be continued, held, or discontinued.
- PI will write an order in CPRS to continue medication or place a hold on it.
- PI will contact the admitting physician

Clinical Research Site Coordinator

- The clinical research coordinator can be the liaison between PI, Research Pharmacist, nursing personnel, admitting team, patient and family members.
- If study medication is to be continued find out if patient brought medication to hospital or whether a family member can bring it in. If medication cannot be retrieved for the hospitalization, the research pharmacist will need to issue a new kit number.
- If patient does return study medication the coordinator will return to the pharmacy. Pharmacist will then dispense medications as directed to the hospital nurse to administer to patient.
- Frequent communication with the admitting team in order to ensure the protocol is being followed.
- CPRS progress notes used also to communicate between research and admitting team.

Clinical Research Pharmacist:

- The clinical research pharmacist will be available to facilitate drug accountability and re-dispensing if necessary.

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.