1 PURPOSE

This SOP describes the steps for fulfilling the regulatory and clinical requirements of initiating a research study in the CRU.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Version 1.0, 19Sept2024: Initiation of new SOP

3 POLICY

N/A

4 RESPONSIBILITIES

4.1 Principal Investigator (in collaboration with study funding agency/sponsor, as applicable)

- 4.1.1 Responsible for ensuring that all participating investigators understand and accept the roles and obligations incurred in undertaking the research study.
- 4.1.2 Provide a copy of the IRB approved protocol and participant consent forms at the time of access request to the CRU unit.
- 4.1.3 Responsible for the selection, training, and oversight of research staff.

4.2 CRU Research Coordinator

- 4.2.1 Prior to the start of assigned project, the coordinator will review the study start-up checklist before, during, and after the study start-up.

5 PROCEDURE

5.1 The Principal Investigator is ultimately responsible for all procedures but may delegate study start-up procedures. These include the following:

- 5.1.1 Ensure that all duties of the study have been delegated appropriately according to education, training, and licensure, and that all team members are knowledgeable about their responsibilities (Delegation of Authority form must be filled out).
- 5.1.2 Verify that all personnel have completed required training.
- 5.1.3 Ensure that all pre-study activities required by other ancillary service providers have been completed.
- 5.1.4 Order any supplies needed for the study that have not been provided by the sponsor.
- 5.1.5 Confirm that reserved space for conducting research visits, storage of study related materials, and equipment have been prepared.
- 5.1.6 Develop or utilize sponsor-generated worksheets, checklists, flow sheets, and SOPs to assist study personnel with study conduct.

5.1.7 Confirm that the contracts have been fully executed (check with Sponsored Programs).

5.1.8 Review study procedures with assigned study staff.

5.1.9 Ensure that all regulatory documents are complete, up-to-date, and filed in the regulatory binder.

5.2 The Research Coordinator will ensure the following is executed and completed:

5.2.1 Request a start-up checklist from the study PI/sponsor or create a checklist for the study start-up if needed.

5.2.2 Establish a suitable date and time for site start up review and make sure key personnel are available.

5.2.3 Assure study personnel are familiar with all study materials (e.g. protocol, investigator brochure, CRFs etc.) in advance of study start.

5.2.4 If there is a study Monitor assigned to the study:

5.2.4.1 Request an agenda from the Monitor or create one for the start-up visit.

5.2.4.2 If needed, provide the Monitor with directions and assistance identifying nearby accommodations.

5.2.5 Ensure IRB Approval has been obtained or review is in process. IRB approval must be received before the study can start.

5.2.6 During Site Visit or Study Review:

5.2.6.1 Ensure that the PI is present.

5.2.6.2 Review details of the protocol, including study operations, with the Monitor (if applicable) or study personnel.

5.2.6.3 Discuss with PI or Monitor which key personnel are authorized to perform what study-related functions or procedures.

5.2.6.4 Document operational questions not covered in the protocol and the answers provided by the PI/Monitor or Sponsor.

5.2.6.5 Discuss test article administration and accountability (if applicable).

5.2.6.6 Review instructions on study-specific activities, such as diagnostic tests, lab kits, or study-required software and any related recordkeeping requirements (e.g. temperature logs, calibration logs etc.).

5.2.6.7 Review directions for source documentation and/or CRF completion.

5.2.6.8 If applicable, review required source documentation and the documentations that is to be provided at future monitoring visits.

5.2.6.9 Discuss applicable study-related specific training involving protocol execution (e.g. in-service for research nurse, physician investigator).

5.2.6.10 Provide the PI or Monitor with an update on any study-related issues.

5.2.6.11 Identify important PI, Sponsor or Monitor contacts and corresponding time frames (e.g. enrollment logs, safety reporting).

5.2.7 Following the site visit or study review:

5.2.7.1 File all training certificates or logs in the regulatory binder and credentials binder, if applicable.

5.2.7.2 Document the Site Visit or Study Review in the dedicated Site Visit/Study Review Log and file in regulatory binder.

5.2.7.3 Ensure receipt of written documentation summarizing important agreements made during the visit/review (such as sponsor follow-up letter, if applicable).

5.2.7.4 Assemble screening and enrollment materials.

5.2.7.5 Activate enrollment plan once IRB and sponsor approvals are obtained.

6 MATERIALS

Study Start-up Checklist
Group Training Documentation

7 REFERENCES

N/A

8 SIGNATURES

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