

- I. Purpose – This Standard Operating Procedure describes activities and identifies individuals responsible for scheduling patient visits at the Carolina Center for Clinical Trials.
- II. Scope – This Standard Operating Procedure applies to procedures for utilizing the Carolina Center for Clinical Trials (CCCT) as the site for conducting an industry-sponsored clinical trial.
- III. Applicability – Study coordinators and principal investigators schedule their study patients' visits according to the strict guidelines of each study protocol. In order to accommodate the study schedule, the patients' preferences and the CCCT's availability, they will need to understand the procedures set up by the CCCT to complete the processes in an efficient and convenient manner.
- IV. Responsible Parties
 - A. The principal investigator or study coordinator will be responsible for contacting the CCCT's Receptionist by e-mail, or telephone to schedule patient appointments and completing all paperwork required by the CCCT.
 - B. The CCCT Nurse Manager will be responsible to review and sign off on the Study Checklist to verify that all appropriate paperwork has been completed by the principal investigator.
 - C. The CCCT Receptionist will be responsible for keeping and updating the CCCT appointment calendar and make sure it is made available to the CCCT Nurse Manager.
 - D. The CCCT Receptionist will be responsible for paging the study coordinator and CCCT's Nurse Manager upon patient arrival and greeting and registering the patient.
 - E. The study coordinator will be responsible for filling out the "Laboratory Request Sheet" and portions of the "Clinical Record Sheet".
 - F. The CCCT's Nurse Manager or designee will be responsible to make sure patient is shown to a room and vital signs/phlebotomy taken, if appropriate.
- V. Procedures
 - A. The principal investigator or study coordinator must contact by telephone or e-mail the CCCT's receptionist to set up patient visits at the CCCT. Appointments should be set up in advance, but if a last minute request is made, the CCCT staff will always do their utmost to accommodate. Information given to the receptionist must include:
 1. Approximate appointment length
 2. Study protocol Institutional Review Board (IRB) number
 3. Visit number
 4. Study coordinator/principal investigator name and pager number
 5. Special requirements for the visit
 6. Visit date and time
 - B. The CCCT Receptionist will confirm the date and time of the appointment by e-mail or telephone within 24 hours and will place the visit on the

CCCT's appointment calendar after verifying that the CCCT Nurse Manager has signed the Study Checklist. The Study Checklist must indicate the following:

1. Current protocol/or pertinent sections available
2. IRB letter of approval and stamped consent(s) available
3. Date of IRB approval
4. Amendment approval letters available, if applicable
5. IRB renewal approval letters available, if applicable
6. "Request for Assistance" has been completed
7. "Memorandum of Understanding" has been completed

- C. The afternoon prior to the scheduled appointment, the CCCT Receptionist will calendar the appointment on the CCCT's posted scheduling board, assemble any needed paperwork for the CCCT Nurse Manager or CCCT Phlebotomist and clarify the following day's schedule of patient appointments for staff.
- D. Upon each patient's arrival to the clinic, he/she will be greeted and registered by the CCCT Receptionist who will also page the CCCT's Nurse Manager and designated study coordinator to alert them of the patient's arrival at the CCCT.
- E. Upon arrival to the clinic, the designated study coordinator will collect the "Laboratory Request Sheet" and the "Clinical Record Sheet", from the CCCT Receptionist and pick up needed supplies from the clinic storage areas. The study coordinator will apprise the CCCT Nurse Manager of nursing needs (other than height, weight, time heart rate and blood pressure).
- F. If the CCCT Phlebotomist is needed, the study coordinator will complete the requisite portions of the "Laboratory Request Sheet" and submit to the CCCT phlebotomist/CCCT Receptionist.
- G. After the patient leaves the clinic, all pertinent clinic paperwork will be filed by the CCCT Receptionist in the appropriate study file.
- H. If appropriate, CCCT Receptionist or study coordinator will give the patient a next visit slip and the CCCT Receptionist will schedule the patient's next appointment on the CCCT's appointment calendar.

VI. Attachments

- A. Request for Assistance
- B. Clinical Record Sheet
- C. Laboratory Request Sheet
- D. Study Checklist

VII. References

ICH Good Clinical Practice Consolidated Guideline
Title 21 Code of Federal Regulations
UNC Office of Human Research Ethics Policies