

MANAGING PATIENT RESEARCH VISITS TIP SHEET

This Tip Sheet provides an overview of the processes that have been approved for managing research participant visits in the Grady Health System. Contact the Office of Research Administration (ORA) Financial unit (Research Finance) for guidance implementing study-specific visit requirements that differ from the processes outlined below.

1. Patient Enrollment.

Patient enrollment is defined as associating the patient's medical record with the research study Payor Code that is assigned when ROC approval is granted. Patients' Epic enrollment must occur after consent is obtained and prior to scheduling a study visit. Refer to the "*Maintaining Patient Enrollment Information*" Tip Sheet (attached) for detailed instructions.

2. Pre-Registration.

Pre-registration is the process used to request an out-patient appointment for a research participant. These appointments are requested by submitting an "*Research Pre-Registration Form*" (*Pre-Reg form*) to the Central Scheduling team for research (CSResearch) according to the directions on the form. Appointment Confirmation is routinely provided via email.

Please note the following exceptions to this process:

- Radiology Services (e.g., CTs and MRIs) are requested by submitting an "*Research Pre-Registration-Radiology*" form to the CT Scheduling team. Refer to the "*Scheduling Radiology Services for Research Participants*" Tip Sheet for detailed instructions.
- Other Specialty Departments (e.g., Hematology/Medical Oncology, Ophthalmology, etc.) appointments are requested using typical departmental processes. Contact ORA Finance for assistance.
- GCRC-Grady (GCTSA/ACTSI) appointments are requested according to processes in that unit (5C).

3. Appointment/Research Visit.

- The Research Team is responsible for making sure that the patient knows the location/date/time of their appointment. Having research personnel accompany the patient to the appointment is recommended.
- The patient should check-in according to the departmental/unit requirements.
- Upon completion of the visit, the PI/Clinician should be certain that the encounter is closed in Epic (follow check-out procedures).

4. Placing Research Orders.

Orders placed for research participants must be correctly identified with the ICD10 diagnosis code Z00.6 which denotes participation in a clinical trial. Please note that other clinical diagnosis codes can also be indicated.

5. Participant Visit Notification.

Visit notification is the process by which the PI/Designee let's ORA Finance know that a research visit has occurred and the procedures/services that were performed on the date of service. Notification is accomplished by submitting a "*Clinical Research Patient Tracker Form*" (PTF) within 24 hours of the visit.

To accurately report approved procedure/service information on the PTF, refer to the study's approved Financial Clearance Document (Attachment A); and, the ORA Comments Section which outlines study-specific visit notification instructions.

6. Charge Validation.

The PI/Designee is responsible for reviewing and validating charges on the monthly invoice. If any charges have been omitted ORA Finance should be notified so an amended invoice can be distributed.

Invoices are distributed to persons indicated in Section I of the FCF. Additional personnel can be added by providing their contact information in writing to ResearchFinance@gmh.edu.