MANAGING ONCOLOGY CLINICAL TRIAL PATIENT RESEARCH VISITS
TIP SHEET

This Tip Sheet provides an overview of the processes that have been approved to manage Oncology trials and participant research 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.

About Centers for Medicare & Medicaid Services (CMS) Reporting

In January 2014 CMS began the enforcement of the requirement to report the National Clinical Trial number (NCT) on claims for items and services provided in clinical trials that qualify for coverage as specified in the Medicare National Coverage Determination (NCD) and are determined to be billable to a 3rd Party Payor (Insurance, Medicare/Medicaid). The Research Finance process relies on the determination made by the Affiliate Institution and Principle Investigator (PI)/Designee participant visit management for Grady to meet this federal reporting requirement.

The PI/Designee is required to do the following to manage each study/trial, participant visits, and facilitate CMS reporting:

I. PRE-APPROVAL

ORA Financial Clearance Form (FCF) Completion Requirements:

1. Provide the National Clinical Trials Number (NCT#) [Section I, Study Type].
2. Specify whether the participants' visits will be inpatient or outpatient [Section III.B, Question 5]
3. As determined by the Affiliate Institution, itemize the procedures/services that will occur at a Grady site. Refer to Attachment A instructions to correctly identify procedures/services that are billable to the Sponsor and/or to a 3rd Party Payor.

II. POST-APPROVAL

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 a general out-patient appointment for a research participant. However, scheduling for Medical, Surgical, Radiation, and Hematology Oncology research participants occurs according to departmental processes. For example, if appointments are normally scheduled using a central department representative, in comparison to a Physician scheduling process, research visits should be handled in the same manner. Remember that research visits should be identified as such in Epic.

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.
   - Upon arrival, the patient should check-in according to the departmental requirements.
   - At visit completion, the PI/Clinician should be certain that the encounter in closed in Epic (follow check-out procedures). These steps are critical for appropriate billing.

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. The 'Research' code can be used with other clinical diagnosis codes. To facilitate this process, the PI/Designee can use the GHS Cancer Research Smart Set that automatically provides the diagnosis code for laboratory services.

5. **Participant Visit Notification.**

   All clinical trial activity is subject to Grady's research patient visit reporting requirement. Visit notification is the process by which the PI/Designee alerts ORA Finance that a research visit has occurred and the procedures/services that were performed. Notification is accomplished by submitting a *"Clinical Research Patient Tracker Form"* (PTF) within 24 hours of the visit for procedures/services. Procedures/services determined to be payable by a 3rd party payor are identified by checking the "insur" box on the PTF.

   If the research team requires additional information or training to comply with this requirement, contact researchfinance@gmh.edu.

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 to ResearchFinance@gmh.edu.

PLEASE NOTE:

- The instructions provided in this document are specific to Oncology clinical trials. To obtain instructions pertinent to research conducted in other areas of the Grady refer to the *"Managing Patient Research Visits"* Tip Sheet.
- The coding requirement does not initiate or alter Grady's billing to 3rd Party Payors.