

MANAGING PATIENT RESEARCH VISITS TIP SHEET

This Tip Sheet provides an overview of the processes that have been approved for managing research participant visits on the Grady campus. If your study has study-specific visit requirements that differ from the processes outlined below please inform OGA to allow them to assist you in operationalizing your study.

1. Patient Enrollment.

Patient enrollment is defined as associating the patient's medical record with a research study. In general, patient enrollment must occur after consent is obtained and prior to scheduling a study visit. Refer to the *"Maintaining Patient Enrollment Information"* Epic Tip Sheet (attached) for detailed instructions.

2. Placing Research Orders.

Orders placed for research procedures/services should be identified with the ICD10 diagnosis code Z00.6, that denotes participation in a research study. Please note that other clinical diagnosis codes can/should also be indicated.

3. 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 *"OGA 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 *"OGA Research Pre-Registration-Radiology"* form to the CT Scheduling team. Refer to the *"Scheduling Radiology Services for Research Participants"* Tip Sheet for detailed instructions.
- Specialty department (e.g., Hematology/Medical Oncology) appointments are requested using (normal) departmental processes.
- CRN-ACTSI appointments are requested according to processes in that unit.

4. Appointment / Visit Day.

- The Research Team is responsible for making sure that the patient knows the location/date/time of their appointment. Accompanying the patient to the visit is recommended.
- The patient should check-in according to the departmental/unit requirements. As necessary, the patient should identify their visit as a "research" visit. This step further facilitates the visit's association with the study in Epic.
- Upon completion of the visit, the PI/Clinician should be certain to close the encounter in Epic (follow check-out procedures).

5. Visit Notification.

Visit notification is the process by which the PI/designee let's OGA know that a research visit has occurred. Notification is accomplished by submitting a *"Clinical Research Patient Tracker Form"* (PTF) within 24 hours of the visit.

Please refer to the study's Financial Clearance approval document for procedure/service details (e.g., item descriptor, payable by a third-party, etc.) that are necessary for completing the PTF as well as study-specific visit notification instructions outlined in the OGA Comments Section.

MAINTAINING PATIENT ENROLLMENT INFORMATION EPIC TIP SHEET

I. Patient Enrollment

Step One

1. Locate the patient's medical record in Epic
 - a. If a potential participant does not have a Grady medical record or medical record number (MRN) the Research Coordinator should facilitate his/her registration through Grady's Patient Financial Counseling department.
2. Go to the "Research Studies" tab in the patient chart. (See figure 1 - Research Study Summary View)
3. Locate the study by entering the unique Plan Code. The study's Plan Code is located on the ROC approval letter. Choose "Add" or enter, which will take you to the Research Studies Detail View (See figure 2).

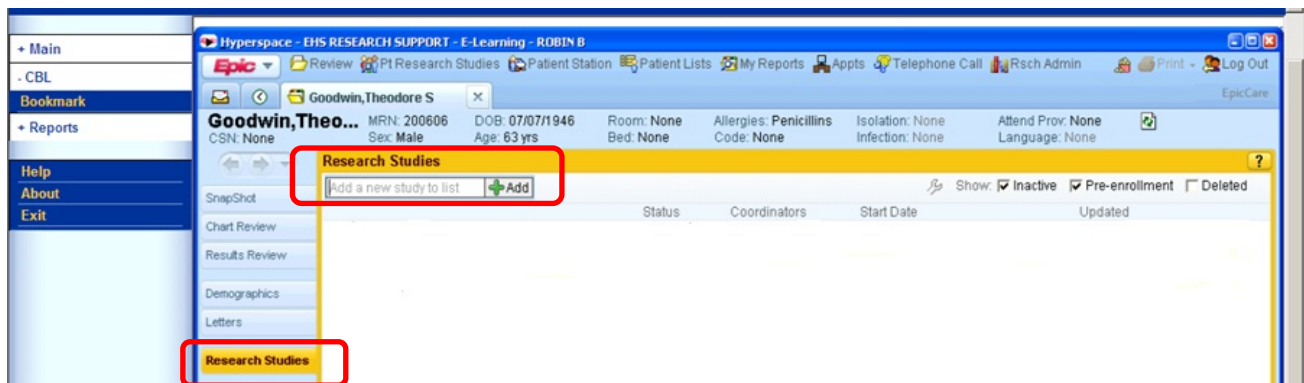


figure 1. Research Study Summary View

Step Two

Enter/Verify the required information in each field. *** Denotes required information**

1. ***Study** – Verify the patient is being enrolled in the correct study.
2. ***Status** – Indicate the patient status as enrolled. Other status options do not facilitate appointments being scheduled for research.
3. ***Active Start date** – Indicate the date that the patient was enrolled (consented) into the study.
4. **Comments** – This section should not be utilized to facilitate Research Team communication, patient notes or visit scheduling. You may enter limited comments related to the patient enrollment process.
5. Choose "Accept" to complete patient enrollment.

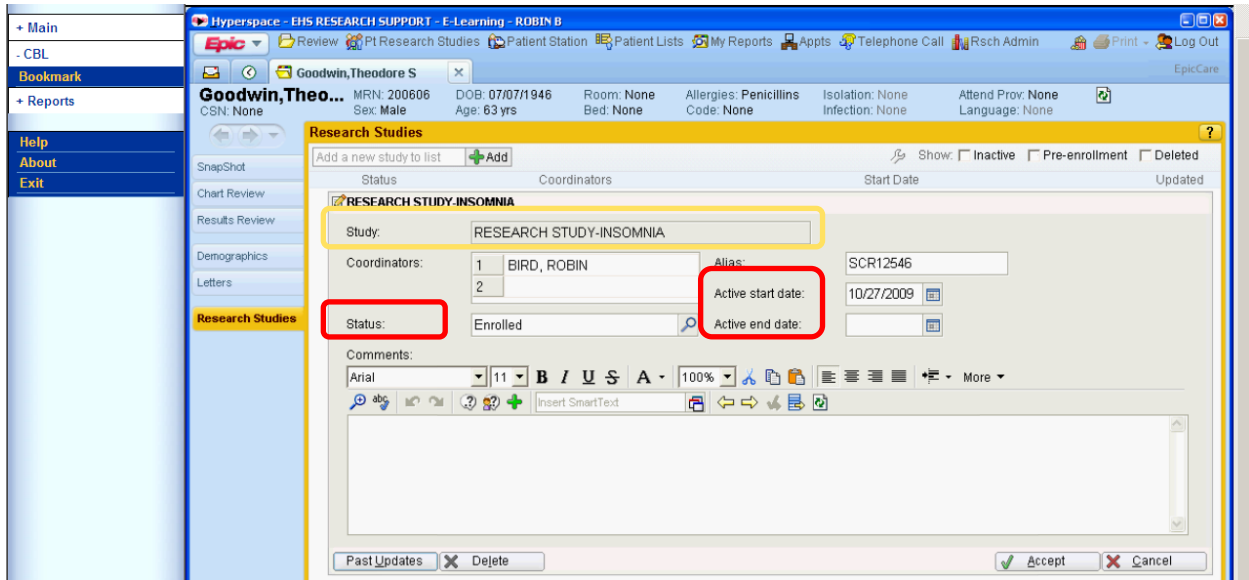
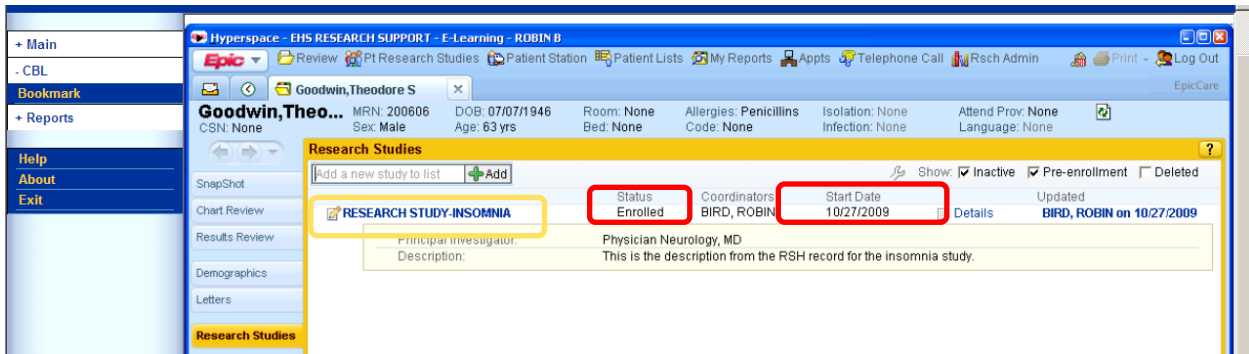


figure 2. Research Studies Detail View

Step Three

1. Verify patient enrollment information in *Research Study Summary View* (See figure 3)



II. Patient Disenrollment

When the patient ends participation in the research study go to the *Research Study Detail View* in the patient chart and do the following:

1. * Status – update the patient’s status (i.e. withdrawn, completed). * **Denotes required information**
2. * Active end date – indicate the date that participation ended
3. Verify status change in *Research Study Summary View*

Note: Patient enrollment and disenrollment in Epic facilitates accurate billing for research participants.