Procedure

Research at UT Health often takes place in conjunction with routine clinical care of patients, and it is necessary to ensure that billing for both routine and research services/items is handled appropriately. This procedure outlines the registration and scheduling process for clinical research patients. This procedure is applicable to all clinical research studies that involve billable services and procedures such as clinic visits, scans, and laboratory tests.

Procedure Outline
1. Identifying Applicable Clinical Research Studies
2. Registering and Scheduling Research Visits
3. Registering New Patients
4. Scheduling Research Visit
5. Registration Policies and Guidelines
6. Applicable Regulations
7. Key Terms

Identifying Applicable Clinical Research Studies

Departments must perform a coverage analysis on all studies that involve billable services not paid for by the sponsor. The Clinical Research Finance (CRF) team will review the coverage analysis to identify research studies containing billable clinical service charges, and will notify the Principal Investigator and study team members to comply with the policy.

All applicable clinical research study visits that meet the criteria outlined in HOOP XXX will be scheduled in GE Centricity.

Registering and Scheduling Research Visits

Charges paid by the research sponsor will require an EG account to submit all study charges instead of the patient’s medical insurance. Bills for routine items and clinical services provided during the study for participants under NCD guidelines will require the NCT identifier to meet CMS and requirements of third-party payors. All appointments scheduled for Research should include the NCT information.

The CRF team will submit a HEAT ticket to create the EG account and add the NCT identifier to the dictionary prior to the enrollment of study patients. EG accounts (Employer Group) will itemize charges unique to the research study. These charges are not attached to the patient’s insurance information. Reference the CRF coverage analysis procedure for additional details.

It is the responsibility of each department to ensure that all clinical research patients are registered and scheduled using the appropriate appointment type and in the appropriate schedule.
I. Options for registering and scheduling participants: There are several resources to register a participant and schedule a visit, including, but not limited to:

1. Research staff, if they have access to GE Centricity. Coordinators interested in training can go through GE Centricity Class Track for registration and scheduling. To view provider schedules, attend the Allscripts training program.
2. Practice Manager or designee at the clinic where the research is being conducted
3. UTP Call Center
4. Departmental representative responsible for research participant registration
5. Clinical Research Unit (CRU)

II. Registering New Patients: All research participants enrolled in an applicable clinical research study must have a medical record number (MRN) in GE Centricity/AllScripts. If the participant does not have an MRN in GE Centricity, the research participant should be registered and an MRN obtained.

III. Scheduling Research Visit: All research visits to UTHealth facilities will be scheduled within GE Centricity using the scheduling module. If diagnostic tests or procedures are performed at Memorial Hermann Hospital and have associated UTP professional fees, these tests or procedures should also be scheduled in GE Centricity using the designated ancillary schedule. There are three scenarios to review when adding the participant to the schedule:

1. Research-specific services paid for by the sponsor: All research-specific visits should be scheduled in the Research schedule using the RES (Research) appointment type. Any ancillary services performed by our UT providers should be scheduled in the ancillary schedule. These services will require a Case account to link all appointments to the specific EG account. Listed is a snapshot of the Case linking within the appointment.

   ![Case creation in GE Centricity](image)

   Case are created in the Case List under Patient Services
To create a Case, type G and identify the EG account to attach

In the appointment, link the new case to the appointment

The generic providers such as Research Coordinator and Research Nurse can be used in the Research Department schedule. This option allows appointments that do not involve the physician to be scheduled without impacting the clinic schedule. In order to associate the claim with the appropriate billing provider a department administrator will need to complete the following form to request the setup of the generic provider. (Insert hyperlink) There can be only one generic provider per division and provider type.

When the generic provider is used there are two options for correctly associating the claim with the billing provider.

1. The schedule heading should be changed to reflect the billing provider associated with the clinical study patient.
2. The coordinator or responsible party will need to notify the coder that the claim should be associated with a specific billing provider.
2. **Routine services part of a qualifying clinical trial:** For qualifying clinical trials, when the clinical trial schedule of events includes routine care services, the routine visit should be scheduled with the appointment type SOC (Standard of Care). The SOC appointment types can be scheduled in the research department schedule or the normal department schedule, but the appointment type must be SOC and the NCT number must be included.

3. **Visit including routine and research services:** If a single visit includes both routine services and research specific services, then the visit should be scheduled twice – one appointment with the designated research appointment type (RES) and one for the routine care services(SOC). The visit for the research services will follow the same instructions in #1 above “Research-specific services paid for by the sponsor” and the routine care services will follow the instructions in #2 “Routine services part of a qualifying clinical trial.”

**Registration Policies & Guides**

1. UTP Policy: 2.9 Established Patient Registration
2. UTP Policy: 2.10 New Patient Registration
3. UTP Policy: 2.11 AppointmentSched from General Protocol
4. UTP Policy: 2.12 AppointmentScheduling Patient Appointment
5. Centricity Business Web Registration User Guide

**Charge Entry Process for Research Visits**

I. **Charge Documents**

Clinic visits and professional fees submitted for charge entry and coding will be submitted by the Principal Investigator or designee of the clinical trial. The charges can be submitted in three forms of entry:

1. **Charge Document from the clinic for Routine Cost and Services**
   a. The Appointment type SOC will provide indication for the routine services to be coded for research.

2. **Charges entered from Allscripts through MD Charge**
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a. Providers will enter the charges electronically in Allscripts. These charges will transfer into TES with the appropriate appointment indicators.

3. Charge Document provided from the PI or designee
   a. The charge document provided by the PI or designee will identify if the procedures require the NCT for third party billing or Case billing based on the form below. Clinical Research Billing Process

   ![Clinical Research Billing Process form]

   Research charges coded in pink for third party billing costs
   Research charges coded in yellow for the EG account costs

II. Charge Requirements

1. NCT Identifier
   In order to meet the required actions for third party billing, the NCT number is required for electronic submission. The eight digit code can be located in the Appointment Data Form with the numeric and short title of the study.
   a. The NCT number can be added to the encounter during charge entry in TES.

2. Diagnosis
   a. V70.7 Examination of participant in clinical trial;
      i. In the secondary position (or in the primary position if the patient is a healthy, control group volunteer);

3. Modifiers
   a. Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
      i. Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.
   b. Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.
i. Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

4. Case Billing to EG account
   a. Charges for Medicare Advantage Plan will require a case to send the charges to Medicare for the routine services identified as (SOC) appointment type with the research modifiers and diagnosis.

III. Compliance and Chart Auditing
   a. To ensure all of the Medicare and Managed Care regulations are met, a TES edit will identify routine services with the NCT indicator that does not have the appropriate modifier and diagnosis billed prior to submission.
   b. Charges billed to Medicare Advantage Plans for research studies will require a TES edit to stop the charge. A Case will be required to submit the charges to Medicare before submitting to the Medicare Advantage Plan.

Applicable Regulations

Refer to the following billing guidelines for additional information:
1. Medicare Policies and Guidelines
   a. National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
   b. Decision Memo for Clinical Trial Policy
   c. Billing Routine Costs of Clinical Trials - Dec 2012
   d. Use of an 8-Digit Registry Number on Clinical Trial Claims
   e. HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies
   f. Coverage of FDA Approved IDEs
   g. Billing Requirements for Special Services (Chapter 32. Medicare Claims Processing Manual)
   h. Mandatory Reporting of Clinical Trial Identifier Numbers on Medicare Claims
2. Clinicaltrials.gov
3. United Healthcare Policies and Guidelines
   a. Clinical Trials
4. Aetna Policies and Guidelines
   a. Clinical Trials, Coverage of Routine Patient Care Costs

Key Terms
1. **Case** is a means of grouping data (for example, invoices, and visits) that are related to an episode of care. Patient visits charged to the study are grouped together for billing purposes.

2. **Coverage Analysis** is a systematic review of the study to determine if the “patient billable” services are eligible and/or approved to be billed out to third party payers. Coverage analysis also delineates all procedures listed in the study protocol’s schedule of events to determine where these services should be billed.

3. **Clinicaltrials.gov** is a registry and results database of publicly and privately supported clinical research studies conducted around the world.

4. **Employer Group Account (EG account)** is an account created within GE Centricity to bill for research services paid for by the sponsor.

5. **National Clinical Trial Number (NCT#)** is a unique identification code given to each clinical study registered on ClinicalTrials.gov. The format is the letters "NCT" followed by an 8-digit number (for example, NCT00000999).

6. **National Coverage Determination (NCD)** is a nationwide determination by Centers for Medicare and Medicaid Services (CMS) of whether Medicare will pay for an item or service. Medicare coverage is limited to items and services that are considered "reasonable and necessary" for the diagnosis or treatment of an illness or injury and within the scope of a Medicare benefit category.

7. **NCD 310.1** is an NCD that outlines the Medicare policy for coverage of routine costs of qualifying clinical trials as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

8. **Qualifying Clinical Trial (QCT)** is a clinical trial that meets mandatory requirements set forth by Medicare to be eligible for reimbursement.

9. **Research Services** are services provided to a participant in a clinical trial that are performed for research purposes and are billed to and paid for by the study sponsor.

10. **Routine Care Services** (AKA *standard of care or conventional care*) are services that are provided to an individual for a diagnosed disease whether or not they are participating in a clinical trial.

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<td>1 Sep 2014</td>
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