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 responsible areas involved with research, registration and scheduling processes for clinical research patients. This procedure is applicable to all clinical research studies that involve billable services to an insurance payor or research payor and procedures such as clinic visits, scans, and laboratory tests.

Procedure Outline

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1. **Key Terms**
   a. **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.
   b. **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.
   c. **ClinicalTrials.gov** is a registry and results database of publicly and privately supported clinical research studies conducted around the world.
   d. **Employer Group Account (EG account)** is an account created within GE Centricity to bill for research services paid for by the sponsor.
   e. **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).
   f. **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.
2. Research Staff

Identifying Applicable Clinical Research Studies
Departments must perform a coverage analysis on all studies. The coverage analysis will outline the services billable to the research payor or to the insurance payors. All applicable clinical research study visits that meet the criteria outlined in HOOP XXX will be scheduled in GE Centricity and/or applicable billing systems.

Registering and Scheduling Research Visits
It is the responsibility of each department to ensure clinical research patients are registered and scheduled using the appropriate appointment type and in the appropriate schedule.

   I. Registering New Patients: All research participants enrolled in an applicable clinical research study must have a medical record number (MRN) in GE Centricity/Allscripts.

   II. Appointment Types: Patients scheduled in the GE Centricity system for research will use the following appointment types.
   a. RES-Research appointment type identifies billable services payable by the research payor. The charges will require a Case number to be added to the patient’s account to link charges to the Research EG account.
   b. SOC-Standard of Care appointment type identifies billable services payable by the insurance payor. The charges will require the NCT number to be added to the patient’s account to acknowledge the participation in a clinical study.

   III. Scheduling Research Visit: All research visits to a UT Health facility or interpreted by a UT physician (i.e. Radiology, Anesthesia, and Cardiology) will be scheduled within GE Centricity. There are multiple combinations for scheduling research appointments; here are the top three recommendations.
   a. Research-specific services paid for by the sponsor (research payor): All billable research-specific visits will be scheduled in GECB Research Schedule with RES as the appointment type.
      i. These charges will require a unique Case number for the EG account prior to scheduling an appointment. Complete the EG account setup form within the Clinical Trial Budget Tool and submit the document to the CRF team crf@uth.tmc.edu.
ii. The Research schedule will include the option for Research Coordinator(s) to schedule appointments for the research portion of a patient’s visit.

iii. The Research Coordinator template will require a dictionary setup request to GECB IT support to identify the naming convention for the schedule and the associated PI (principal investigator) for billing purposes.

iv. The Research Coordinator schedule can be based on the billing divisions for each department should there be multiple coordinators schedules required.

b. **Routine services part of a qualifying clinical trial:** For qualifying clinical trials, when the clinical trial schedule of events includes routine care services.
   
i. The SOC appointment types can be scheduled in the research department schedule or the normal provider’s schedule and the NCT number must be included.

c. **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 standard of care (SOC).

IV. **Options for registering and scheduling participants:** There are several resources to register a participant and schedule a visit, including, but not limited to:

a. 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.

b. Practice Manager or designee at the clinic where the research is being conducted

c. UTP Call Center

d. Departmental representative responsible for research participant registration

e. Clinical Research Unit (CRU)
3. Call Center & Registration Staff

Scheduling Requirements

I. Patient Registration:
   a. Research Coordinators or appropriate designees will provide registration information to schedule research related services in GE system. Complete the registration process for these patients using the current GECB policies and procedures.
   b. The Research Coordinators will create appointments or request modification to an appointment using the two appointment types listed below.

II. Appointment Types & Scheduling: Patients scheduled in the GE Centricity system for research will use the following appointment types.
   a. RES-Research appointment type will identify services charged to the research payors.
      i. Case-EG Account: The charges will require a Case number to be added to the patient’s account to link charges to the Research EG account.
         1. The Research Coordinators are responsible for requesting the case number prior to the appointment.
         2. Link the case number to the appointment.
      ii. Scheduling Providers: Appointments will be scheduled in the Research Department using the billing provider (Principal Investigator), the research coordinator or research procedure (Anesthesia, Cardiology, and Radiology).
      iii. Research procedures: Procedures including, but not limited to x-rays. Cat scans, ultrasounds, EKG’s, stress tests are scheduled in the Research Department using the closest scheduling availability to the Memorial Hermann appointment.
   b. SOC-Standard of Care: appointment type will identify services charged to the insurance payors.
      i. The charges will require the NCT number to be added to the patient’s account to acknowledge the participation in a clinical study.
      ii. The NCT table is located on the Appointment Data Form field. The Research Coordinator will provide the appropriate NCT related to the research account.
   c. Locations: All billing locations will be available on the Research Department schedule to identify where the services are being held.
   d. Patient Check-In: Patients that are scheduled for multiple appointments in the same location, that includes Research and Standard of Care appointments should be simultaneously arrived in the schedule. Review the patients’ appointment list as reference; if the Research schedule is not a part of the Appointment Manager setup.
4. Clinical Billing Staff

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:
   a. **Charge Document from the clinic for Routine Cost and Services**
      i. The Appointment type SOC will provide indication for the routine services to be coded for research.
   b. **Charges entered from Allscripts through MD Charge**
      ii. Providers will enter the charges electronically in Allscripts. These charges will transfer into TES with the appropriate appointment indicators.
   c. **Charge Document provided from the PI or designee**
      iii. The charge document provided by the PI or designee will identify if the procedures require the NCT for third party billing or Case billing. The charges are divided into color coded sections for third party billing versus Case billing.

II. Charge Requirements
   Medicare with the addition of some of the top insurance payors (Blue Cross Blue Shield, United Healthcare and Aetna) are requesting the following information to be included in the charge(s) submitted.
   a. **NCT Identifier**
      i. In order to meet the required actions to bill the insurance payors, 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.
      ii. The NCT number can be added to the encounter during charge entry in TES.
   b. **Diagnosis**
      i. **V70.7** Examination of participant in clinical trial;
         1. In the secondary position (or in the primary position if the patient is a healthy, control group volunteer);
   c. **Modifiers**
      i. **Q0** - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
         1. 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.
      ii. **Q1** - Routine clinical service provided in a clinical research study that is in an approved clinical research study.
         1. 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.

2. 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).

d. **Research Coordinator & Research Procedures**
   a. The Research coordinator or designee will need to notify the coder that the claim should be associated with a specific billing provider (i.e. Principal Investigator) using the Research charge document.
   b. The research procedures are changed based on the interpreting provider identified in the clinical notes.

### III. TES Edits

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.

### 5. Applicable Regulations

Refer to the following billing guidelines for additional information:

a. Medicare Policies and Guidelines
   i. National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
   ii. Decision Memo for Clinical Trial Policy
   iii. Billing Routine Costs of Clinical Trials - Dec 2012
   iv. Use of an 8-Digit Registry Number on Clinical Trial Claims
   v. HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies
   vi. Coverage of FDA Approved IDEs
   vii. Billing Requirements for Special Services (Chapter 32, Medicare Claims Processing Manual)

b. Mandatory Reporting of Clinical Trial Identifier Numbers on Medicare Claims
   i. [Clinicaltrials.gov](https://clinicaltrials.gov)

c. United Healthcare Policies and Guidelines
   i. Clinical Trials

d. Aetna Policies and Guidelines
   i. Clinical Trials, Coverage of Routine Patient Care Cost

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