

REGISTRATION, SCHEDULING, AND CHARGE ENTRY IN GE CENTRICITY
OF
RESEARCH PARTICIPANTS AT UTHealth FACILITIES

I. 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

- I. **Key Terms**
- II. **Identifying Applicable Clinical Research Studies**
- III. **Research Patient Registration and Case Set up**
- IV. **Scheduling Research Visits**
- V. **Alternative Options for Registering and Scheduling Participants**
- VI. **EMR Documentation/On Study Note**
- VII. **Clinical Research Visit Billing**

II. 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
- c. analysis also delineates all procedures listed in the study protocol’s schedule of events to determine where these services should be billed.
- d. **Clinicaltrials.gov** is a registry and results database of publicly and privately supported clinical research studies conducted around the world.
- e. **Employer Group Account (EG account)** is an account created within GE Centricity to bill for research services paid for by the sponsor.
- f. **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).

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- g. **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.
- h. **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.
- i. **Qualifying Clinical Trial (QCT)** is a clinical trial that meets mandatory requirements set forth by Medicare to be eligible for reimbursement.
- j. **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.
- k. **Standard of Care Services** (AKA *routine 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.

l. Identifying Applicable Clinical Research Studies

To conduct a coverage analysis, a thorough review of all study documents, clinic procedures, and national guidelines must be performed. At UTHealth, this starts with the billing risk review by the Clinical Research Finance and Administration (CRFA) team. Each week, the CRFA team reviews all protocols submitted to the Institutional Review Board from the prior week. While reviewing the protocol, CRFA analyzes the schedule of activities to determine if any activity could generate a charge in the clinical billing system. If a study has an activity that could generate a bill, it is designated as a billing risk.

After identifying a billing risk, the CRFA team then builds out the schedule of events in the Coverage Analysis and Budget tool. The CRFA team will identify which visit each activity occurs during this build out. The CRFA team will then email the Coverage Analysis skeleton to the department administrator who will work with the Principal Investigator to determine the location where each procedure will be done and whether that procedure is standard of care or research for that visit. For all items that are determined to be standard of care, the department must provide a justification referencing a national guideline or peer reviewed publication which indicates that the activity is adequate and necessary in the treatment of the patient's condition.

Once this information has been completed by the department, they will submit the Coverage Analysis along with the signed answers to the Qualifying Questions and Billing Certification Form to the CRFA team for final review and approval. If the CRFA team has any questions or comments, they will work with the department to get to a final Coverage Analysis that is acceptable to both parties. CRFA team will then send the final Coverage Analysis to the Committee for Protection of Human Subjects for upload into iRIS, create the necessary EG billing accounts in GE Centricity, and notify Memorial Hermann of the completed Coverage Analysis (when necessary).

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- In the terms of the UTHealth Coverage Analysis, standard of care activities are those which the patient would receive regardless of their participation in the study, while research costs are those that being performed outside of this. Another way to think about the difference, is whether or not your normal clinic practice is changing to accommodate the service or procedure. In addition, any activities which are promised as free of charge in the Informed Consent Form automatically become research costs.

II. Registering and Case Set up

Study- specific EG (Employer Group) accounts and patient- specific research billing cases are set up to ensure charges that are supposed to be paid by the research sponsor are billed to the study 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.

- EG account-The CRF team will submit a HEAT ticket to create the EG account upon Coverage analysis approval and will add the NCT identifier to the dictionary prior to the enrollment of study patients.
- Case set up: "Case" set up will be required for all patients enrolled onto a study in which the conduct of the study will generate charges in the UTHealth billing system (GE Centricity) that are to be paid for by the research payor.
 - An easy way to know if Case set up is needed is to look at the coverage analysis.
 - If any items are marked as "RES" a Case set up is needed for each patient enrolled onto the study.

It is the responsibility of each department to ensure that all clinical research patients are registered, flagged as research billing cases are set up as appropriate.

A. **Registering New Patients:** All research participants enrolled into a clinical study designated as a billing risk must have a medical record number (MRN) in GE Centricity/Allscripts. (All studies in which a coverage analysis was required.)

B. **Research Flag:** All patients enrolled into a clinical study designated as a billing risk must be notated as a "Research Participant" in GE Centricity/Allscripts. The research participant flag data is entered in GE Centricity and interfaces automatically to Allscripts.

C. **Case set up:** "Case" set up will be required for all patients enrolled onto a study in which the conduct of the study will generate charges in the UTHealth billing system (GE Centricity) that are to be paid for by the research payor.

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a. An easy way to know if Case set up is needed is to look at the coverage analysis. If any items are marked as “RES” a Case set up is needed for each patient enrolled onto the study. (This information will be identified during the coverage analysis process. [click here for coverage analysis details.](#))

b. Charges generated in GE Centricity that should be billed to the research payor are:

- Services or procedures performed for research purposes only (These services or procedures would not have been performed as part of normal routine medical care.)
- Services or procedures performed as part of routine medical care but offered to be paid for by the sponsor.
- Services or procedures performed as part of routine medical care but offered for free in the informed consent document.

c. To request a “Case” to be set up on the patient’s account, complete the Case Set up request form and email it to Crf@uth.tmc.edu .

III. **Scheduling Research Visits**

It is the responsibility of each department to ensure that all clinical research visits are scheduled using the appropriate appointment type and in the appropriate schedule.

A. **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.
- 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 routine care services (SOC).

B. **Scheduling Research Visits**: 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.

1. **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.

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- i. These charges will require a unique Case number for each patient prior to scheduling an appointment. Complete the Case Setup Request form on CRF website and submit the document to the CRF team crf@uth.tmc.edu.
 - a. Note you must have the EG account number for the study you have enrolled the patient on prior to making the request for case set up. If you are not sure, contact CRF crf@uth.tmc.edu
 - ii. Schedule visit as visit type RES.
 - a. Each department may set up a Research Coordinator schedule for an increased separation between the research schedule and the clinic schedule.
 - i. 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.
 - 1. The Research Coordinator schedule can be based on the billing divisions for each department should there be multiple coordinators schedules required.
- 2. 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.
- 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 standard of care (SOC).

C. **Additional Guidance:**

- A. Detailed patient registration and scheduling information can be found [here](#)

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IV. Alternative Options for Registering and Scheduling Participants: Requirements for Utilizing Call Center & Registration Staff.

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 should contact Revenue Cycle GE Centricity Training Team. To view provider schedules, attend the Allscripts training program. (Your department's Operations Manager will have the contact information.)
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)

If a researcher/study coordinator chooses to utilize options 2 through 5 above for research patient registration and/or scheduling the below processes should be followed:

- 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. The research coordinator will be responsible for identifying appointment type RES or SOC.
 - 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.

 - b. **SOC-Standard of Care:** appointment type will identify services charged to the insurance payors.

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- 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. **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.

V. **EMR Documentation/On Study Note-CMS requirements**

A. All research participants enrolled in an applicable clinical research study must have documentation of research study participation in medical records (Allscripts). Utilize the administrative note template labeled, "CMS Research Note" in Allscripts.

- **Research documentation note requirements:**
 - **Study name**
 - **Sponsor's study protocol number**
 - **PI Name**
 - **Research contact name/phone**
 - **After hours contact name/phone**
 - **Date Consent signed**
 - **Expected completion date**
 - **Optional--Comments (include any possible drug reactions, etc.)**

VI. **Clinical Research Visit Billing**

The PI is responsible for ensuring charges for the research visits are properly billed.

A. Charge Entry Process:

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. **Clinical Research Charge Document Log**: The most efficient way to communicate clinical charges that are part of a clinical research study to the billing staff is to utilize the "Clinical Research Charge Document Log" (CRCDL). The CRCDL document is located on SPA website.

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- a. **Email or deliver completed CRCDL to billing manager/billing staff prior to or immediately after each study visit.**
 - i. Study Visit Templates- Best practice is to create a CRCDL template for each study visit as soon as the coverage analysis is approved.
 1. The CRCDL should match the Coverage analysis information exactly.
 2. The CRCDL must contain the following information:
 - a. Patient name, and MRN
 - b. Date of service
 - c. Description of services provided
 - d. Research rates/charges
 - e. RES (indicates to bill to Research account
 - f. SOC (indicates to be billed to patient/patient's FSC)
 - i. If SOC also provides:
 - ii. Diagnosis codes
 - iii. Research modifiers
 - g. If you have any questions on how to complete the CRCDL, contact CRF at crf@uth.tmc.edu for assistance.

2. Charges entered from Allscripts through MD Charge

- a. Providers will enter the charges electronically in Allscripts. These charges will transfer into TES with the appropriate appointment indicators.
- b. The appointment types RES and /or SOC must be utilized to ensure proper disposition of charges.
 - i. *Case number must be provided within the appointment if RES*
 - ii. *NCT number must be provided within the appointment if SOC.*

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3. Charge Document from the clinic for Routine Cost and Services.

- c. The Appointment type must be SOC to provide indication for the routine services to be coded for research. If routine clinic visit appointment types are used, the charges will be billed to patient/patient's insurance.

B. 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.

VII. 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.

VIII. 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);

IX. 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

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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).

- X. **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.

C. 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.

VI. Applicable Regulations

Refer to the following billing guidelines for additional information:

- [CR 8401: Mandatory Reporting of and 8-Digit Clinical Trial Number on Claims](#): This document outline the regulations requiring the NCT number on CMS claims
- [Mandatory Reporting of National Clinical Trial \(NCT\) Identifier Numbers on Medicare Claims – Q&A](#): This document provides guidance for CMS billing related to the NCT number requirement
- [ClinicalTrials.gov Frequently Asked Questions \(FAQ\)](#): This website provides additional information regarding NCT numbers.
- <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA> This website provides information National Coverage Determination (NCD) for Routine Costs in Clinical Trials
- <https://www.aapc.com/blog/5539-billing-for-routine-clinical-research-services/> This website provides AAPC guidance for billing for routine clinical research services
- <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf> This is a link to the Medicare Claims Processing Manual Chapter 32- Billing requirements for special services.
- <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/signaturevalue-mmj/clinical-trials-sv.pdf> United Healthcare guidance for billing for clinical research services

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- http://www.aetna.com/cpb/medical/data/400_499/0466.html Aetna guidance for billing for clinical research services

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