

Clinical Research Coordinator- Manage Study Record Guide

Introduction

Clinical studies profiles are entered into Epic to ensure research charges are billed appropriately.

All clinical studies at UTHHealth meeting the below two (2) criteria are entered into Epic by a central team.

Criteria for study to be entered into Epic:

1. Study protocol dictates patient care that is performed for research purposes only and should be billed to the research account (not to patient/ patient's insurance.)

and/or



2. Study protocol dictates routine care as part of the clinical study AND the study is a Qualifying Trial per CMS determination guidelines [CMS LINK](#)
 - The study teams are required to associate/link all patients enrolled into the studies entered into Epic.
 - The study teams are required to associate/link all research visit encounters for the studies entered into Epic

Getting started

Log into Epic Production environment using your UTHHealth user name and password.

Identify / Review your study profile administrative record

Study administrative records are created by a central team. You will review your study record in Epic to verify the accuracy of all information. If changes are needed, contact Kristin Parks <Kristin.Parks@uth.tmc.edu>.

1. Click / select  **Study Maintenance** on the main toolbar.
2. In the Research Study Select window, enter the study's name or IRB ID number, and click  **Accept**.
3. Review the following details on each form of the study record for accuracy:

General study information

1. In the **Study code** field, confirm that the organizational reference number appears for this study. (This is the UTHealth IRB ID number.)
2. In the **Billing status** field, confirm that the status is active.
3. Ensure title of study is entered correctly.



The study's billing status should be set to Active so you can associate the study with patients, orders, and encounters.

Verify which users are involved with the study

Verify the list coordinators on the **Users and Providers** form in order to assign them as the research coordinator for a patient. Staff members listed here have additional study-specific access for tasks such as running reports and linking encounters to the study. Users who will be involved with this study, can be such as the following:

- Principal investigator
- Study coordinators
- Providers and nurses
- Research contacts

Review Billing Set up

1. Ensure the Peoplesoft /FMS Chartfield string is correctly entered.
2. Ensure the correct pricing contract is entered (Industry/Non Industry)

Review the study status of a research study

1. From the General Information form, review/ update the study status in the **Study status** field.

- *If you are unable to locate an applicable study, contact Kristin Parks <Kristin.Parks@uth.tmc.edu>.*
- *If you feel a study entered into Epic does not meet the criteria described in the introduction section, contact Kristin Parks <Kristin.Parks@uth.tmc.edu>.*

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