BWH Clinical Research Patient Care Billing Toolkit

A guide for ensuring appropriate and compliant direction of research-related patient care charges

Patients who've agreed to participate in clinical research at Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital are provided with detailed information during the informed consent process about what will occur during their participation, including information about any research-related clinical services that will be performed and whether they will be expected to pay for those services. It is imperative to the trust between researchers and study subjects that accurate, compliant, and timely adherence to research-related patient care charge direction procedures be followed by research staff. Additionally, this adherence is crucial to ensuring patient privacy and to protecting the reputation of our institution and our researchers.

This tool kit is designed to provide research staff with all the information necessary to adhere to these procedures.

[Resource](#): **Clinical Trials Billing Fundamentals**

WHERE TO START: EPIC REQUIREMENTS

All functionalities required to correctly direct research-related patient care charges to a study fund, or to patient/insurance, as appropriate, reside in Epic. So, to start, two things must occur in Epic before a single subject may receive research-related patient care services:

1) The study must be in Epic
2) The study team must have access to the study in Epic

This document, "[Before Subject Study Enrollment May Begin](#)", provides instructions on how to ensure that both these necessary criteria are met.

PROCESSES/WORKFLOW

Now that your study is in Epic, and the study team has access to it, there are three primary steps to ensuring that appropriate patient care charge direction will occur: you enroll (or "associate") your subjects to the study in Epic; you link all research-related encounters to it; and you perform the Epic Research Billing Review (RBR).

1) **Enrolling ("Associating") Subjects to the Study in Epic:** As soon as a potential research subject has signed Informed Consent to participate in the research, the first step is to enroll them to the study in Epic. This informs Epic that the patient is participating in the study.
   [Tip Sheet](#): Associating (Enrolling) Patients to Research Studies

2) **Linking Research-Related Encounters to the Study in Epic:** Once the patient is enrolled to the study in Epic, all patient care encounters related to the research (including orders, appointments, admissions, and any other interventional patient care activity) must be linked to the study. Additionally, if any previously created usual care encounters will be utilized for research, those encounters must be linked to the study as well. This informs Epic that those specific encounters are related to the research, and so the resulting charges should not be released to patient/insurance until the study staff have reviewed them.

   Of note, it is common for clinical research and usual care services to be performed in conjunction with one another. If even a single research-related service is to occur during an otherwise usual care encounter, the entire encounter must be linked.

   [Tip Sheet](#): Research Linking – Encounters and Orders
   [Tip Sheet](#): Research Linking – Orders to Studies (Update)

Tip Sheet: Research Linking – Inpatient and HOV Encounters
Tip Sheet: Research Linking – Investigational Drug Orders
Tip Sheet: Research Linking – Ordering and Linking Radiology Encounters
Tip Sheet: Research Linking – Scheduler Linking Encounters
Tip Sheet: Research Linking – Linking from Appointment Desk

3) **Directing Research-Related Patient Care Charges Via the Epic Research Billing Review (RBR):** Once an encounter is linked to a study in Epic, the system will hold all the patient's charges for that date of service (or for the duration of the admission, if the subject is inpatient at the time) in the study's "Research Billing Review" (RBR). From the RBR, a member of the study team reviews the charges and directs each line item to bill the study fund or to patient/insurance, as appropriate.

Tip Sheet: Epic Research Billing Review (RBR)
Additional Info: Epic Research Billing Review (RBR) FAQ
Additional Info: Epic Research Billing Review (RBR) "Buckets"

CHARGE DIRECTION ERRORS

Charge direction errors sometimes occur. If you discover, or even suspect, that a research-related charge has been directed incorrectly, contact Margaret Lyons in BWH Research Billing Compliance at 857-307-1577 or mlyons@bwh.harvard.edu. Margaret will investigate and assist the study team with submitting any necessary Patient Care Correction (PCC) requests to Insight to have the misdirected charges corrected.

PCC requests may be submitted by anyone who has access to the fund in question's "Patient Care Charges" page in Insight's "Agreements" module. Tip sheets on how to verify whether you have the necessary access, what the options are if you do not, and how to submit the PCC request itself are below.

Tip Sheet: Checking Insight PCC Submission Access
Tip Sheet: Requesting Insight PCC Submission Access
Tip Sheet: Insight PCC Tip Sheet 1 (Ins-to-Fund)
Tip Sheet: Insight PCC Tip Sheet 2 (Fund-to-Ins)
Tip Sheet: Insight PCC Tip Sheet 3 (Fund-to-Fund)

If you have concerns about current or previous research patient care charge directions, you can request an audit of your study's billing history any time by contacting Margaret Lyons in BWH Research Billing Compliance at 857-307-1577 or mlyons@bwh.harvard.edu.

ADDITIONAL RESOURCES

Clinical Trials Billing Fundamentals
Epic Research Consent to Contact
Setting Epic Home Workspace (Dashboard)
Epic Research Tasks
Creating Epic Orders Preference Lists
Cancelling Epic Orders for Research
Epic Patient Timeline (Medicare Qualifying Trials)
Epic Media Manager (Importing Research Documents)
Epic Media Manager (Scanning Research Documents)
Epic Release of Information (ROI) to Study Sponsors
Epic Reporting Training Curriculum (HealthStream)