

THE BASICS

Before a study starts in Johns Hopkins Medicine an analysis is done to determine if the study meets Medicare criteria to be able to bill certain services to the participant's insurance. This information is contained in a document called the Prospective Reimbursement Analysis (PRA) which is approved by the study's principal investigator.

Services related to a research study can be paid for by:

1. Study - This could be an industry sponsor, grant, or the department.

2. Insurance - Study-related clinical services are considered standard of care if they are provided to the research subject even if not on a clinical research study. For example, if a participant has a diagnosis of cancer, he/she would likely get chemotherapy, in or outside of a study. These services are usually billed to the research participant or his/her insurer; however, they can be billed to the research study if it is agreed upon. Please note that the sponsor must agree to pay for all participants the same way. Sponsors are prohibited from paying for some patients and not others.

3. Both, the Study and the Insurance – In many cases, the study will pay for services that are strictly research and the insurance will pay for what is considered “standard of care”.

Note: The group that develops the PRA does the determination of who pays for what and it is based on Medicare rules, the protocol, the contract, the budget, and other documents.

RESEARCH IN EPIC


Epic allows the user to link encounters and orders to the research study, document research visits, and keep track of upcoming participant appointments. Note that encounter and order linking is mandatory.

When patients are correctly registered in the Clinical Trial Management System (CRMS or OnCore) you should see the following indicator on the storyboard of  Research Participant any of the Epic applications:

Research Billing

The Clinical Research Billing Compliance Office (CRBC) is tasked with assuring that charges for research participants are reviewed for appropriate routing to participant insurance or to the research study.

For CRBC to review charges for a research participant these elements must be true:

- The study must have a PRA.
- The participant must have been entered into the CTMS in a Pre Enrollment or “Active” category before the close of the encounter in Epic. *Pre-enrollment* = Candidate and *Active Status* = Enrolled, Eligible, Consented and Follow up.
- The participant must still be Active at the time that charges are held for review. If you add the participant to CRMS and then change the status to “Off Study” before charge review, charges will be billed to the participant or his/her insurance. Please give us 30 days before taking the patient off study.
- The encounter or the order was linked to your research study. You will see this icon in Epic when the linking is done correctly: 

>Important - Please update the participant's status in the CTMS promptly to avoid billing delays. However, give us at least 30 days after the last intervention before changing the participant's status to “off study”.

>Important – The use of “Do Not Bill Insurance” at registration means “bill to the patient”; this will cause the process to break down and the participant will get a bill 100% of the time. More information [here](#).

CRBC will review all charges and if related to the study they will determine if they are billable to the research study, to the participant, or his/her insurance. To perform the adjudication they review the PRA, the charges, and clinical documentation. If the matter is not clear, CRBC will contact the research staff. To bill Medicare, certain diagnoses and other modifiers need to be added to the claims, CRBC does this as well.

RESEARCH DRUGS

For some insurance plans to pay for the administration of a “free” research drug, the drug must be billed with its administration. These drugs are “orderables” built by Willow, they are specific for each study and carry a nominal fee.

WHAT CAN YOU DO?

- Make sure that you are familiar with the protocol and the PRA. Carefully review the PRA before you approve it. Become familiar with who pays for services related to your study.
- Make sure that the subject receives and understands the *Insurance and Research Participant Financial Responsibility Information Sheet* that is part of the consent process. This form can be found in the eIRB, right below the consent form. The fact that a subject is a participant in a research study DOES NOT mean that all services are free. If the participant does not understand his/her financial responsibilities, have them meet with a financial counselor in your department.
- Make sure that you entered the participant in the CTMS before the encounter is closed in Epic and do not take them “off study” on the same date that services were provided.
- Make sure that you link your encounters and orders to the study in Epic; this is the only way to ensure that CRBC will review the charges and avoid billing mistakes.

Important clinical research billing information and helpful contacts are available at this web link: [JHM Research Revenue Cycle Website](#)

Questions? CLINIRESBILLING@exchange.johnshopkins.edu