

THE BASICS

Prior to a study starting 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) that is approved by the research staff.

Services related to a research study can be paid by:

- 1. The Study** - This could be an industry sponsor, grant, or the department.
- 2. The Insurance** - Study related clinical services are standard of care and would be 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.

FINANCIAL CLEARANCE

If it is determined that the study needs a PRA, the research staff has to request *Financial Clearance*. The purpose of the research financial clearance (RFC) is to protect both, the study participant and the institution, of financial responsibility. RFC is requested using the Clinical Research Management System (CRMS). Once the participant is entered into CRMS, the research staff will initiate the request. This action will trigger an automatic email to Revenue Cycle Management (RCM) that will then triage the incoming request and work with the insurances to obtain financial clearance.

>Important: Patients must have research financial clearance approval prior to enrollment on study. This green icon next to their record in CRMS indicates approval. Clicking the icon will reveal more information.



>Important: Do not proceed with enrollment with the icons below next to their enrollment record. All represent denied or unapproved clearance status. Doing so makes the PI Home Department responsible for standard of care charges denied authorization:



>Important: If financial clearance is denied (red icon) by the participant's insurance the RCM staff will provide information on how to appeal the decision if allowed by the insurance company. Enrollment is still prohibited pending the appeal outcome.

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's appointments. Note that encounter and order linking is mandatory.

When patients are correctly registered in CRMS you should see the following icon in 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 CRMS in a Pre Enrollment or "Active" category prior to 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" prior to charge review, charges will bill 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 was done correctly:



>Important - Please update the CRMS status 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 "Do Not Bill Insurance" at registration really means "bill to 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 study to 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 diagnosis and other modifiers need to be added to the claims, CRBC does this as well.

RESEARCH DRUGS

In order for some insurances 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 participant on 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 CRMS 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; this is the only way to assure 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