

NOTE: SPRINT 1 OF THE ONCORE IMPLEMENTATION GOES LIVE ON OCTOBER 5, 2023. IT ONLY APPLIES TO ONCOLOGY AT JHH AND SMH, AND TO SELECTED STUDIES AND PRINCIPAL INVESTIGATORS. ALL OTHER STUDIES WILL USE CRMS UNTIL THE SECOND SPRINT IN APRIL, 2024

THE BASICS

The Clinical Research Management System (CRMS) is Johns Hopkins Medicine's official registry of participants in a research study at any Hopkins location. The use of CRMS is mandatory for all studies with a Prospective Reimbursement Analysis (PRA) and encouraged for all other studies. Using CRMS facilitates Epic data association and study recruitment.

The Office of Clinical Research Billing Compliance (CRBC) is tasked with assuring that charges related to study participation are billed appropriately to the participant's insurance or to the research study as outlined in the study PRA document. CRBC uses the data from CRMS to determine:

- If the participant is enrolled in the study
- If the participant's financial clearance has been approved
- If enrolled participants continue to be active in the study

CRMS PARTICIPANT STATUS

Pre-consent	Active	Inactive
Triggers Epic "Active" Flag	Triggers Epic "Active" Flag	No Epic flag
<ul style="list-style-type: none">• Candidate	<ul style="list-style-type: none">• Consented• Eligible• Enrolled• Follow up	<ul style="list-style-type: none">• Not Candidate• Not Eligible• Off Study

>Important Tips:

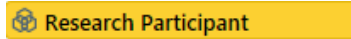
- Activate your study in CRMS. This is not an automatic function, even after IRB approval.
- Participants must be entered into CRMS in a Pre-consent or Active category **prior** to the close of the encounter in Epic. *Pre-consent* = Candidate and *Active Status* = Enrolled, Eligible, Consented and Follow up for charges to hold for CRBC review.
- A participant should not stay in a Pre-enrollment or Active status indefinitely. You are expected to update CRMS within three business days of the change in status. Be mindful that leaving a participant in a Pre-consent or Active status in CRMS will mean that CRBC will consume staff resources for unnecessary charge review activity.
- **Exception:** If you 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 after the last date of service before taking the patient off study in CRMS, unless your department has provided other guidance for off study date.

RESEARCH IN EPIC

The CRMS interface with Epic allows the user to link encounters and orders to the research study, document research visits and keep track of a participant's upcoming appointments. **Note that encounter and order linking is mandatory.**



>**Important** - You will not be able to link encounters or orders in Epic unless your participants are correctly registered in CRMS. When patients are correctly registered in CRMS you should see the following indicator on the storyboard of any of the Epic applications:



HELPFUL HINT

In CRMS, you can use the location and subject progress fields for free text to communicate with CRBC.

<input type="checkbox"/> Test, Test Sibley - Enrolled	Sibley Memorial Hospital S1400A Arm 1 v1	CRFs Docs	2nd trimester done 9/25/15				
MRN:		Consent:	09/25/2015	Scr. Failure: [Add]	Start Int: [Add]	End Int:	
Subject No:	&*(&U(*)&*hjhfk...	On Study:	[Add]	Evaluable: [Add]	Last Int:	Off Study:	[Add]

WHAT CAN YOU DO?

- Make sure you activate the study in CRMS before enrolling any participants.
- 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 your participants have insurance clearance **before** enrolling them in the study.
- Make sure that you link your encounters and orders to the study; this is the only way to assure CRBC will review the charges and prevent billing mistakes.

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

Questions? CLINIRESBILLING@exchange.johnshopkins.edu