

Expectations for Registering Research Participants in CRMS and Research Consent Form Availability.

August 31, 2020

For studies with a PRA, it is important to register research participants as “consented” and subsequently “enrolled” in as close to “real time” as possible in CRMS. We suggest that registration statuses be updated in CRMS within 48 hours. Registering these patient statuses in CRMS activates the “research flag” in the participant’s Epic medical record, thereby providing important information to the patient’s care team. In addition, this enables the Clinical Research Billing Compliance Team to accurately process research-related charges. For CRMS support please contact: crmshelp@jhmi.edu.

Signed clinical research consent documents are required to always be readily available and accessible for inspection by oversight entities. One mechanism to help ensure that the research consent is readily available for clinical trials with a Prospective Reimbursement Analysis (PRA) is to upload a scanned copy of the signed consent form in the Epic patient record. For this reason we have created processes to support this upload.

Effective September 1, 2020 the Office of Clinical Research Billing Compliance (CRBC) will no longer be uploading the faxed/scanned clinical research consent documents in the Epic patient record or placing the Certificate of Confidentiality (COC) flag in Epic. This will become the responsibility of the study team.

In order to be able to upload the signed research consent forms into Epic, study team members will need to complete the “Integrated Research Scanning 100” training provided in MyLearning if it has not been taken in the last two years. The study team member will then need to get their security role updated in Epic to permit uploading of consent documents. The relevant department’s security coordinator will need to request the new template in the ARM2 system. If you do not know who your security coordinator is, please email: JHH-Arm-Requests@jhmi.edu.

Requests for technical assistance or inquiries regarding the process for uploading of consent documents may be sent to the Epic Research team at epicresearch@jhmi.edu or submitted to the team through an Epic Help Desk ticket or by calling the Help Desk at 410-955-HELP (4357).