

Date: October 12, 2021

Subject: Recent & upcoming changes in clinical research at RWJMS: OnCore and Epic

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Dear RWJMS clinical researchers,

We are writing to let you know of a number of very important changes with regard to clinical research at RWJMS.

Some of these changes are a result of the roll-out of EPIC at RWJMS, while others pertain to the recent launch of the [OnCore Enterprise Clinical Trial Management System](#). As you likely know, OnCore has been in use at CINJ for more than 15 years, but now, under the direction of Chancellor Strom, is being implemented across the RBHS enterprise for any research which includes billable clinical procedures (i.e. tests/procedures associated with a CPT code.)

We have asked Nancy Reilly and her staff to serve as your resource for the OnCore implementation and to serve as a liaison to the EPIC team for matters related to clinical research. If you have any questions or concerns, please contact the RBHS Clinical Trials Office (CTO) at [clinicaltrials@rbhs.rutgers.edu](mailto:clinicaltrials@rbhs.rutgers.edu).

Please be advised of the following:

**1. Impact of EPIC Go-live on clinical research at RWJMS:**

- If you are ordering any procedure in EPIC for a research patient, it will be billed to the patient's insurance (regardless of whether that is the intention) unless the study has been submitted through OnCore to EPIC. Note that the CTO has been working with department study teams to enter studies into OnCore. Study staff are responsible for completing training (see below) and for providing all necessary documents and information to the CTO.
- RWJUH 499 Accounts:
  - The RWJUH 499 account process (as a process for charging research procedures) will be completely phased out when the RWJ University Hospital goes live on EPIC in early April, 2022. It will be replaced by ordering and billing processes within Epic.
  - If your study is conducted in locations which are not yet live on Epic (such as RWJUH) or if you are ordering procedures in those locations, you can continue to use the 499 account process and manually order research procedures through the current processes until RWJUH goes live on EPIC.

- Investigators who use the RWJUH 499 account process for other types of research studies (i.e. non-clinical trials, or studies which otherwise do not meet the above definition to be built in OnCore) should contact the Epic Research Support Team to build their study in Epic by generating a “Service-now” ticket: <https://rwjbh.service-now.com/sp>. This needs to be done prior to ordering any procedures through EPIC for research participants, or otherwise, by **March 1, 2022.**
- New studies using RWJUH facilities, laboratories, etc. will continue to go through the RUG process and will receive 499 accounts to use temporarily until RWJUH EPIC go-live.

## 2. OnCore Implementation at RWJMS

- While EPIC is being implemented in waves, OnCore is being implemented on a rolling basis, and can be used independently of EPIC, prior to the relevant EPIC go-live. As such, we are requiring, moving forward, that ALL new clinical trials as well as prospective non-interventional studies which entail the provision of billable clinical procedures (i.e. tests/procedures associated with a CPT code, which could be billed to a patient’s insurance) be built in OnCore.
- **Effective immediately, all new studies meeting the definition above are to be submitted through OnCore FIRST** (i.e. before initiating an eIRB or RUG application and before submitting the contract through RAPSS.) The CTO will conduct a brief feasibility review and, when appropriate, refer the study to the Scientific Review Board prior to other study start-up activities commencing. For more information on this new workflow, please visit the [OnCore page on the CTO website](#).
- The timeline for entering existing active studies into OnCore depends on whether the study entails billable clinical procedures that are performed and billed through the medical school vs. through RWJUH. If a study entails medical school procedures ordered in EPIC, the study must be submitted through OnCore **immediately** so that it is built prior to ordering any procedures for study participants. If the study entails hospital procedures only (such as laboratory testing done at the hospital lab,) the deadline for submission is **March 1, 2022.**
- If your study is managed by either the Adult or Pediatric Clinical Research Center, be advised that a plan is in place for the study to be built in OnCore and EPIC within the required timelines.

## 3. How OnCore and EPIC work together:

- Once a study is built in OnCore, the study profile (i.e. title, PI, study team, NCT number, etc.) is transmitted to EPIC if/once EPIC is live in the study location. All active RWJMS clinical trials will have a profile in EPIC.
- Upon screening, a patient is entered into OnCore (using demographic data pulled from EPIC.) All subsequent study visits will be entered into OnCore, and visits will also be documented in EPIC. The patient will be flagged in EPIC as a participant in the trial, and research procedures will be ordered through EPIC in accordance with the study schedule.

- We anticipate that these new procedures will provide important safety benefits to study patients, and will greatly facilitate ordering of study procedures and compliant billing processes.

#### 4. Training

- RWJMS study coordinators who have not already received training in Epic are expected to do so as soon as feasible. Training may be requested through a “service-now” ticket: <https://rwjbh.service-now.com/sp> or by contacting the EPIC help desk at 855-453-1950. Any study coordinator or clinician who has not completed EPIC training, **will not** have access to EPIC.
- RWJMS study coordinators who have not already received training in OnCore are expected to do so as soon as feasible by e-mailing a request to [clinicaltrials@rbhs.rutgers.edu](mailto:clinicaltrials@rbhs.rutgers.edu).

We are very excited about these developments and are fully confident that these changes will enable us to grow our clinical research enterprise with our RWJBH partners in line with our shared mission to become a premier integrated academic research institution, all the while assuring patient safety and compliance with the highest standards of conducting clinical research.

Please contact the RBHS Clinical Trials Office [clinicaltrials@rbhs.rutgers.edu](mailto:clinicaltrials@rbhs.rutgers.edu) if you have any questions or concerns. Please also visit the RBHS CTO website for more information on these changes as well as other important developments in clinical research at RBHS: <https://njacts.rbhs.rutgers.edu/clinical-trials-office/>

Sincerely,



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