EPIC TRAINING

Epic Research Quick Start Guide

Manage Research Study Records

Contents

How to use this tip sheet

Keep an eye out for the following icons:

	*Look for this icon to call out information that is critical to system workflow and functionality!*
	*Look for this icon to call out additional information to support your learning.*
	*Look for this icon to identify a supporting document you can refer to for more information.*
	*Quick hints to improve your efficiency!*

Study Initiation Overview

Study Record Importation

The study record represents your study in Epic. Without it, you cannot perform research workflows related to the study.

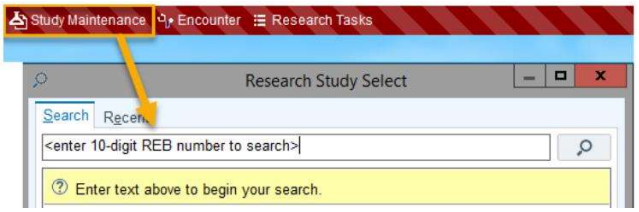
Only prospective observational and interventional studies approved by REB will be imported in Epic.

Retrospective studies, or studies that are not recruiting participants at Women's College Hospital, will not be managed in Epic.

Search using REB Number

Once the study record is in Epic, research staff can search for it using the REB number.

- The correct way to search for studies in the Study Maintenance activity is using the REB number, since there may be many studies with similar names.
    - Search by your study REB number, as searching by study 'keywords' may pull-up similar studies from other researchers.



Update and Activate the Study

Once the study record has been accessed, research staff can verify imported data and fill in additional study information.

- Automatically imported study data cannot be altered in Epic – any required changes must be approved by the REB first.
- In addition to the automatically imported data, each research study record in Epic has a number of forms with different fields that need to be updated by research staff.
- Once these fields have been updated, the study can be activated and made usable for research purposes in Epic.

Study Records: Information imported into Epic

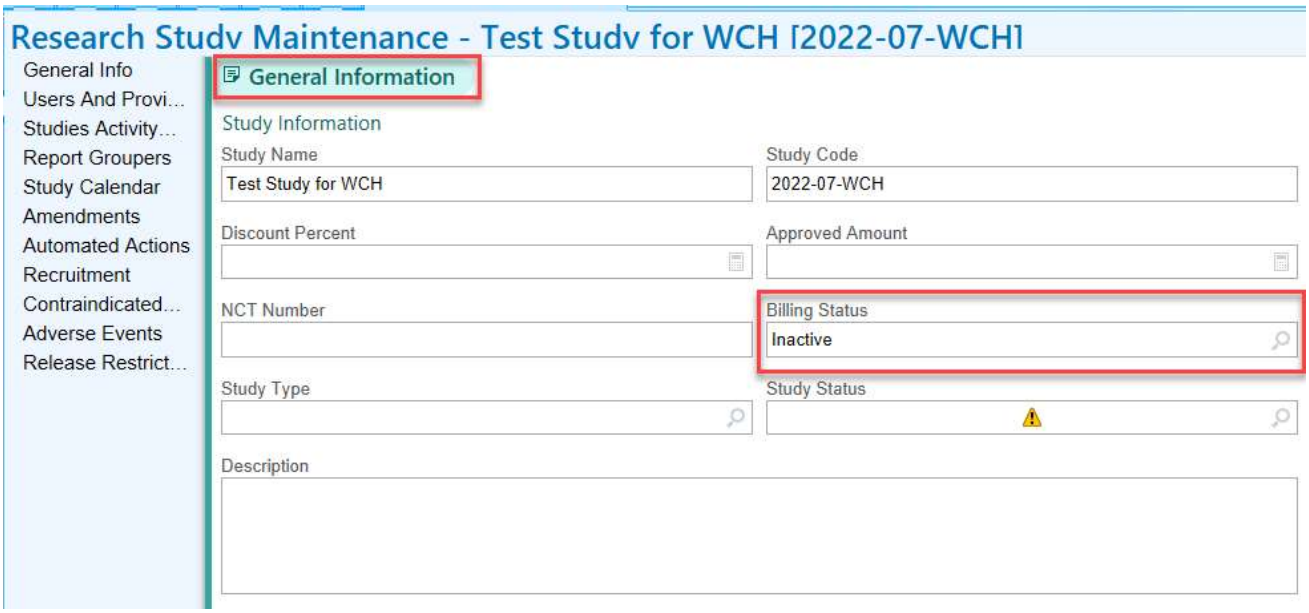
Study information imported into Epic includes:

- Study name
- REB number (also imported as 'Study Code')
- Study description
- Study type
- Study approval date and expiry date
- Information about study/sponsor funding source, research category

Study Statuses in Epic

Studies are initially imported into Epic in an Inactive status, and study teams will need to update and Activate the study record to allow for research activities in the system.

- You **cannot** return a study to an Inactive billing status once it has been Activated.



Do <u>not</u> update the Billing Status field to 'Completed' as this will close the study in Epic. If this is done, the study team will need to go through the entire REB approval process all over again to get a new study record (with a new REB number in Epic) - this is because only one of each unique REB number can exist in Epic.
<u>Studies will only be marked as Completed in the system by the Epic team when they have been closed by the REB.</u>

Study Records: Forms to update

Before activating a research study record in Epic, research staff will need to update the following forms:

Note that we are not using the following Study Record forms at this moment:

- Amendments
- Study Calendar
- Release Restrictions
- Recruitment
- Contraindicated Medications

General Information

Study Information

Study information is automatically imported into Epic, such as the REB number (Study code), Study type and Description can be viewed here.

- An NCT clinical trial number can be entered (if applicable)

After the other forms in the study record have been fully updated (per the steps detailed below), research staff will return to the General Information form and change the study Status from Inactive to Active, thereby making it usable for patient recruitment and other research workflows in Epic.

IRB Approval Information

- This section contains imported REB data ('IRB') on approval and expiration dates for your research study

- You can view historical information on REB approval & expiration date updates by clicking the 'Show IRB Date History' button to see additional information

- You can use the Upcoming IRB Expiration Dates component on your Research Dashboard to monitor which of your research studies have upcoming REB/IRB expiration dates (or have already expired!)

Users and Providers

Principal Investigator (PI) on the study

Only one PI can be noted in the study record; co-investigators, qualified investigators, and research collaborators can be listed as 'Other providers' or 'Research contacts'.

- PI's listed in this will field will be able to receive research-related InBasket notifications in Epic.

Study coordinators

These are any research staff who are part of the study team (as approved by the REB) and who will be performing research study administration and management workflows in Epic e.g. research assistants/coordinators/managers, clinical research nurse specialists, fellows, students (MSc/PhD/MD).

- This field can be updated even after activating the study record e.g. if a new research coordinator joins the study team

- Only staff listed in this field will be able to receive research-related InBasket notifications in Epic.

Other providers

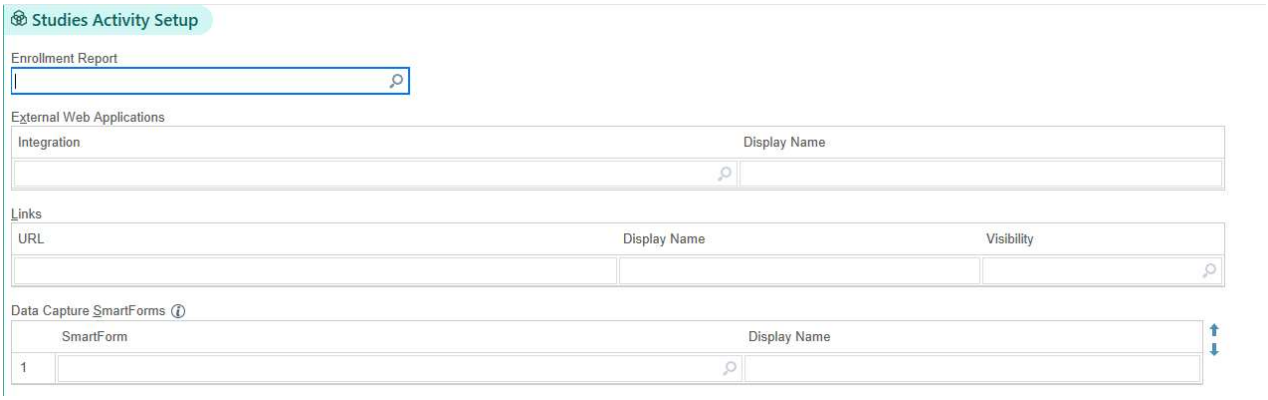
List your study co-investigators in the ‘Other providers’ field if applicable.

Research Contacts

List other research contacts such as admins in the ‘Research contacts’ field.

Study Activities Setup

- Links: A website URL can be added to link to additional study information from Epic e.g. a ClinicalTrials.gov page. Links updated here will show up in the patient's chart and MyChart if they are a participant in the study. Set visibility to ‘Hyperspace and Patient Portal’.



- Data Capture Smart Forms: Can be used to link research Smart forms to the study record with the option to send them to the study participants via MyChart

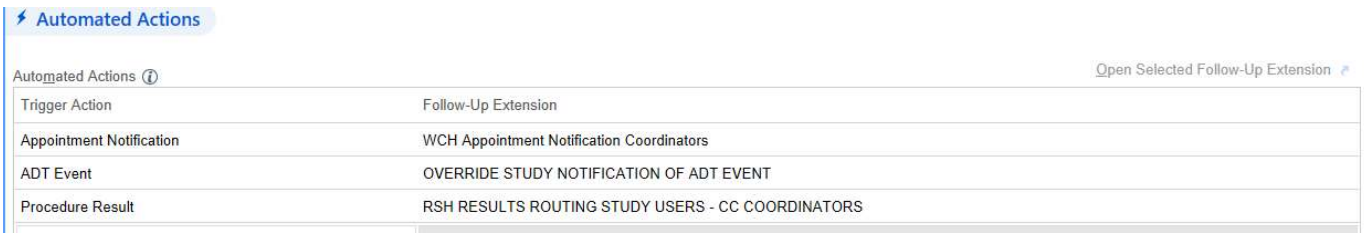
Report Groupers

- Verify the information imported from REB in the Free-text Groupers section
- Any corrections to this information must be made directly in REB system; updates will be imported weekly into Epic.

Automated Actions

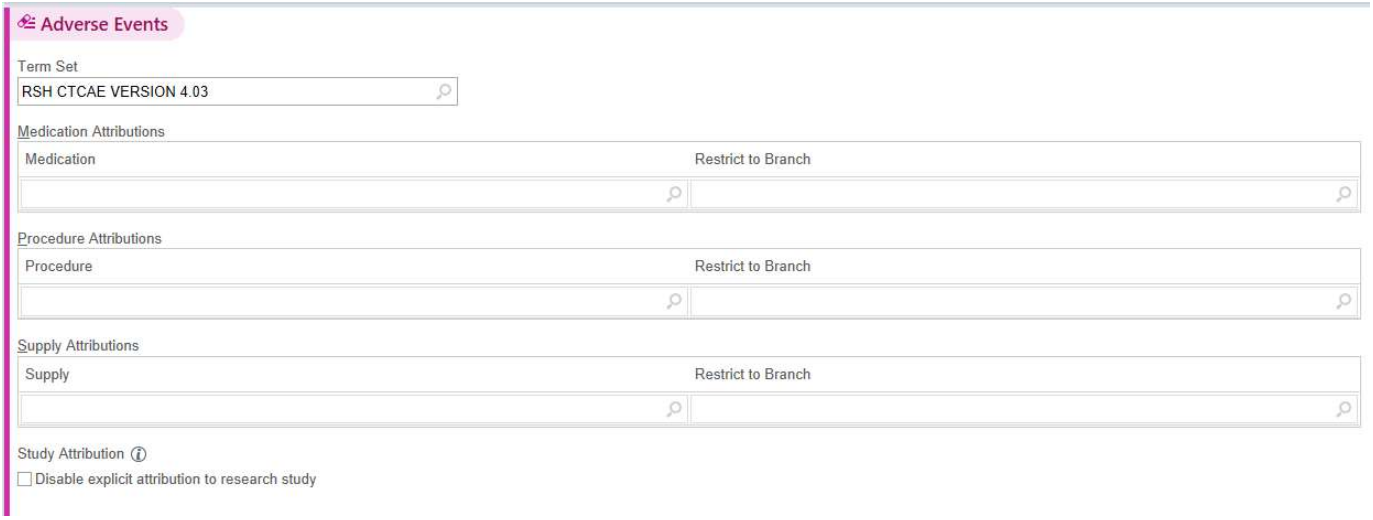
If desired (i.e. this setup is optional), InBasket notifications to the PI and/or Study Coordinators (choose the appropriate Follow-Up Extension) can be set up here:

- ADT Event notifications are sent to InBasket when study-associated patients are admitted to inpatient units (surgery)
- Appointment Notifications are sent when study-associated appointments are either cancelled, changed or rescheduled
- Procedure Result notifications can be sent when study-associated tests are resulted. These notifications are only sent to users listed as Study Coordinators in the study record.



Adverse Events

Study teams can document Adverse events for they participants. There are two versions of the CTCAE available in Epic – 4.03 and 5.0. Study teams need to use this form to setup the appropriate version for each study.



- Adverse Events Term Set: if your study will be recording and reviewing adverse events in Epic, you must select one of the available Adverse Events Term Sets in this section.
- Once a Term Set is established in the study record, you may choose to add Medication, Procedure and Supply attributions to the study. You will then be able to attribute Adverse Events (AEs) to specific medications, procedures, if relevant.
- You can also choose to disable explicit attribution to the study by checking off the box below. This can only be disabled if at least one attribution record is specified. If a branch does not have additional attributions defined, study attribution will be enabled for that branch regardless of this setting.