Research Study Team Super User FAQs

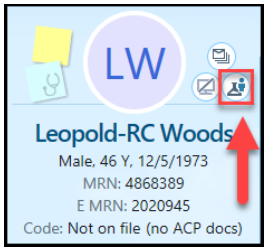
This is a list of questions that commonly come up during a Research go-live. Answers are included, as well as troubleshooting tips where applicable. Take this document with you and use it as a resource while supporting your colleagues during go-live.

Research Studies Activity

- ***Why can't I edit content in the Research Studies activity?***
  - If a user has access to the Research Studies activity, but cannot edit anything in the activity, contact the Help Desk. They might need additional security.
  - If patient study information (enrollment comments, patient timeline, etc.) is read-only, you may need to have your security adjusted in order to edit the record.
- ***Who is creating the Research (RSH) record in Epic?***
  - For non OnCore studies, OCRICC will create the new study record. Once the study is IRB approved, OCRICC will set the record to active. The study team will then update the Research record.
  - For OnCore studies, the study record is created in OnCore. OCRICC receives auto notification. Once IRB approved, the research record is created in Epic by OCRICC. The record will be made active.
- ***How will I update the patient's study status?***
  - For non-OnCore studies, the the Research Coordinators will update the patient's study statuses within Epic.
  - For studies managed in OnCore, the status association will be updated automatically (As long as the record exists in Epic and is active).
  - Refer to the Study Status Crosswalk for additional information.
- ***What triggers Epic to pull info from OnCore? Is it as soon as a patient has a consented status in OnCore?***
  - Any active or inactive status gets mapped to Epic. Pre-consent statuses are not mapped, and need to be updated manually.
- ***How do we define "Off treatment?" Does it mean from a billing perspective? Or off "active" study treatment/intervention?***
  - We are using OnCore definitions for this. OnCore defines it as "Subject has been assigned a treatment arm and a treatment start date and subject is on active treatment – date of treatment start"
  - If a patient has a status of "Off Treatment", they will qualify for research billing review.
- ***What Pre-Consent statuses are used for Recruitment?***
  - Statuses for Recruitment are populated in Epic and will not update the OnCore Screening log. OnCore will need to be updated to include these patients.
    - Identified
    - Interested
    - Declined

- ***Why can't I view all of a patient's study associations?***
  - Verify that the **Inactive** and **Pre-Consent** check boxes are selected.

- ***I can't find the Research Studies Activity.***
  - The activity can be found using Chart Search or the Hyperspace toolbar.
  - Staff can also access it from the patient's **Storyboard** by clicking the icon.
  - It will only appear in Storyboard if the patient has an active status.



- ***Are FYI Flags being eliminated?***
  - Yes and no. We will not be converting or retiring existing FYI Flags.
  - End users will find that they are not able to create new clinical research FYI Flags starting with Go-Live.
  - The MCW tissue banks will continue to use them.
- ***Does Epic keep a record of patient-study association even if the patient is deceased?***
  - Yes

Visits

- ***How can I enroll a patient in a study during a current visit and link the visit to the study?***
  - Update the patient's participation status in the research study.
  - Create a patient timeline, if applicable for the study.
  - Link the visit to the study (and timeline, if applicable) from within the Patient Research Studies activity.
  - If you have a Research Studies navigator section in your encounter, use the linking tools there.

- ***Does the upcoming appointments report for encounter linking default to two weeks?***
  - Yes, two weeks is the default but you can edit that by going in the report settings and adjusting the date range. It can be extended, shortened, or set to show appointments in the past.

- ***CITI & Non-CTI Research Coordinator-Only Visits***
  - ERS & NRS will be used moving forward. Research Visit Type will be retired.
  - The two pieces of documentation will be required for visitation:
    - Note Documentation
    - Chief Complaint – set to "Research" and documented manually for each visit
- ***Do you set the automated actions per study/trial?***
  - They are set per trial in the RSH record
- ***How should automated actions be configured if we want to cc coordinators on all results and only send the PI abnormal results?***
  - For all results, add in the coordinator. For abnormal results, add the PI.
  - Plug in the automated action set-up per configuration that you would like.
- ***Why can't a visit be scheduled with a specific study coordinator?***
  - On 10/21, all research visits will be scheduled to a generic resource and not a specific individual.
- ***Why can't users link an encounter to a study?***
  - Is the patient active on the study?
  - Are the start and end dates populated for the patient in the Research Studies activity? The appointment date must fall on or between the start and end dates for this study and patient.

Orders

- ***How do I enter orders?***
  - Research coordinators can enter both outpatient and inpatient orders with an order mode of "Per Protocol: Co-sign Required" with a Provider name that will route the orders for co-signature. This process will be consistent with the Orders – Patient Care policy and the current expectation for compliant practice.
- ***Why can't I associate orders or encounters with a research study?***
  - Check to make sure that you updated the patient's status in the research association.
  - If the patient is active on a study, but the association option doesn't appear, create a help desk ticket.
  - Note: For Beacon users, this association is done automatically.
- ***Where are my pended orders?***
  - Verify that you've opened the correct encounter (correct department, date, time and provider) – orders pended in one encounter will not be visible in a different encounter.
- ***Why can't I find an order I'm searching for?***
  - Are you logged into the correct department? Often order lists are based on specialty.
  - Did you check the Facility List tab? If an order is still not found, contact the Help Desk.

- ***How do I find order preference lists?***
  - Within an encounter, in the visit taskbar at the bottom of the screen, select the Preference List Browser icon to the right of **Add Order**.
- ***How do I add an order to my favorites?***
  - Look up an order you want to add to your favorites and click **Accept**. It is still an unsigned order in your cart. Click the star next to the order name to add the order to your favorites.
  - If you need to, you can edit the order's details before adding it to your favorites. The details you save here are selected by default when you select an order from your preference list.
- ***Do you link it even f it is standard of care or only for orders that are billable to research?***
  - If the order is being placed for research-related care, the linking can and should be done for transparency. Currently OCRICC audits 100% of hospital charges (non professional) and then determines the invoicing (whether the charge will be billed to insurance, invoiced to study sponsor, etc.). Charges billed or invoiced follow the calendar of events outlined in the protocol.

Reports

- ***How do I favorite a report?***
  - In the Library tab of the My Reports activity, click the star icon next to the report name. You can also do this in the Recent Results section.
- ***Where do my favorite reports appear?***
  - In the Favorites and Subscribed Reports section of your Research Coordinator - My Studies dashboard and in the My Reports activity. You might need to refresh your Favorites and Subscribed Reports section if you recently added a report as a favorite and don't see it.
- ***Do I need to create an all-inclusive report that includes all of my studies, or should I have different reports for each individual study?***
  - Either approach will work; the results will just appear slightly differently, depending on which you choose.
  - You can use filters in the report results to filter down to a particular study, if you would rather have them all in one report.
- ***How do I release information to study monitors through EpicCare Link?***
  - After a study monitor requests information through EpicCare Link (continue current process)
  - Run a report that shows the patients associated with your study, such as the Patient Associations on My Studies report and select the patients that the study monitor requested information about.
  - Click **Release to Study Monitor** on the toolbar.
  - Enter the appropriate details and click **Release**.

Adverse Events

- ***Will the AE's be required as a hard-stop?***
  - No

- ***Are there exceptions for study teams to opt-out of documenting Adverse Events in Epic?***
    - Yes. Studies that don't use CTCAE version 4.03 or 5.0 may opt out. Additionally, the study teams will need to work with the PIs to determine use of the Adverse Events activity in Epic.
- ***Could staff use a Smart(dot)phrase in the comment field?***
    - Yes, only challenge is ensuring it is filled out consistently, for standardization purpose.
- ***Will there be someone notified of an Adverse Event?***
    - Principal Investigators (Physicians 99% of the time) will receive In Basket notifications when there is an AE Review sent to them
- ***In the physician In Basket, what category will the AE messages fall under (i.e. "routed messages"), or is there a research-specific folder?***
    - AE messages are sent to their own folder called "Adverse Event Review".
- ***Are certain fields mandatory for completion in order to document it? Can some fields be skipped?***
    - Mandatory fields: whether the adverse event is serious or not, the grade, and whether the adverse event is expected.
    - Other fields are optional.
- ***Who has the ability to document attribution? Do only MD's have this ability?***
    - Coordinator will typically leave attribution blank for the PI to document, even though they have access to it.
- ***Is there a way to see when the attribution was documented?***
    - Yes. In the updated field there is a log created. You can see this in the Audit History.

Research Billing Review

- ***Why are charges not appearing in Research Billing Review?***
    - Have the charges been reviewed already? Click the Restrictions button to view previously reviewed charges.
    - Is the encounter closed (for outpatient visits), or is the patient discharged (admissions)? Charges will not appear until these events occur.
    - Was the admission within the last 5 days? If yes, the charges may not have qualified for charge review yet because of min days.

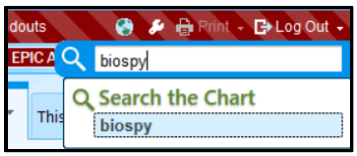
EpicCare Link

- ***Can Synopsis be added to EpicCare Link for the study monitor?***
    - Synopsis is not supported within EpicCare Link. There is access within Flowsheets from Chart Review > Encounter > click on the link for the encounter date to see what was documented. Flowsheet activity also exists.

- ***What is the maximum number of days a patient's chart can be released for at a time?***
  - 5 day timeframe. If the chart needs to be available for additional days, a new release will need to be performed.
- ***How can I see what releases have already been performed?***
  - Research coordinators will have dashboard component with current and future releases. It's also possible to see this information from within the Research Studies activity in the patient's chart using the Additional Information report link.
- ***Will everyone need to perform a release right at go-live?***
  - No. Not all studies will have study monitors. Additionally, study monitors will request chart access at different times, depending on the study. The coordinator should perform the release as appropriate for their study.
- ***Patient Group is a mandatory field. What should we enter here? How do we confirm which study monitors were given permission?***
  - When you select the looking glass, the Patient Groups available to your study will be listed. The analyst team who provisions study monitors access will build 1 Patient Group per study monitor. This Patient Group is directly linked to your study and the user's security so there are ways for us to audit if needed
- ***For a new study, will monitors still register with EpicCare Link like normal?***
  - Yes. Then once they are in system, research coordinators are able to do the study release for subsequent visits thereafter?

Efficiency Tips

- ***How do I create a SmartPhrase?***
  - From your Learning Home Dashboard → **Ambulatory Reference Material** section → **SmartTools Quick Start Guide**. SmartPhrase and other SmartTool (SmartText, SmartLink) tips are found here.
- ***How do I search quickly within a patient chart?***
  - Use the **Chart Search** tool

Press **Ctrl+Spacebar** to put your cursor in the search field in the upper right		Search a term using Storyboard
	**OR**