

Research Study Monitor Process

Purpose: The purpose of this Tip Sheet is to educate Research Coordinators on how to release a record to the Study Monitor.

Audience: ALL Research Coordinators and Research Managers both ONC and Non-ONC

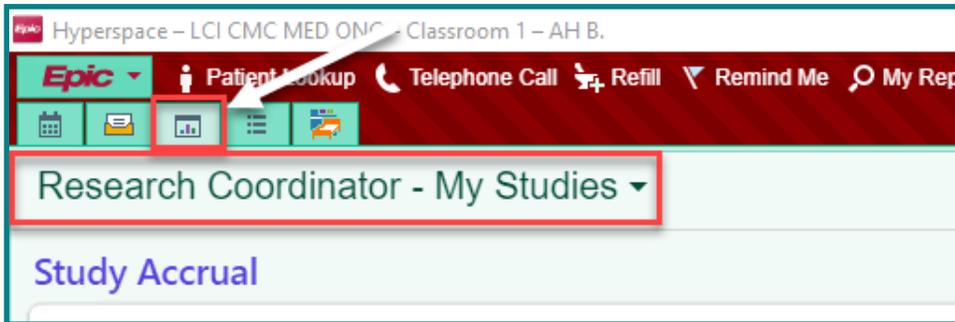
Effective Date: 12-3-23

Introduction

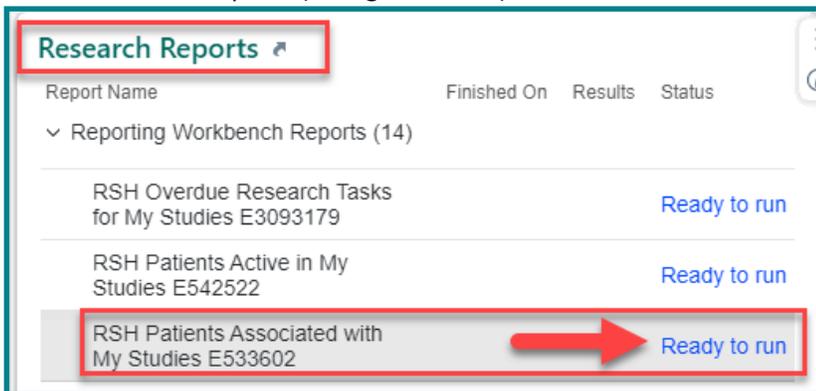
It is important that a Service Now ticket has been entered to request 1) a Patient Group be added to a study and that the Study Monitors are added to that group and 2) that the Study Monitor access is created by the EpiCare Link Team before any of the below steps are taken.

Releasing the Record to Study Monitor

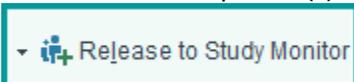
- 1) Logged into Encompass (Epic)
- 2) Go to the **Research Coordinator My Studies** Reporting Dashboard



- 3) Locate Research Reports (far right column) → Run the **RSH Patients Associated with My Studies** report.

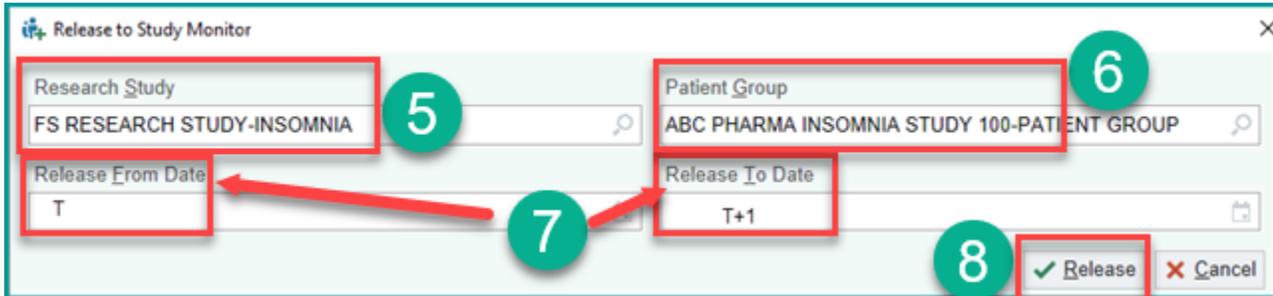


- 4) Select the desired patient(s) and click the button **Release to the study monitor**.



- 5) Select the Research Study.

- 6) Select the appropriate patient group (may only be one).
- 7) Enter the desired release time **From** and **To** date
 - NOTE: 5 days is the maximum allowable
- 8) Click **Release**.



To review past release information:

- 1) At the bottom of your screen, locate the Study Monitor Release Information section of your report.
- 2) To drill into further detail about the patients you have released to the study monitor, click **Details** within that report.
- 3) You might need to refresh this report to see the information.
- 4) Go back to and open your **Research Coordinator - My Studies** dashboard.
- 5) Refresh the Study Monitor Releases for My Studies component.
- 6) Click **View Releases** next to the study with upcoming releases.
- 7) Review the available details in the report.

General Rules of the Road

- External study monitors will request access via the EpicCare Link Access Request process.
- The Epic Research team will process requests for new accounts from external study monitors and create the necessary EMPs.
- The Epic Research team will create patient groups (PGPs) for all studies which will have external monitors needing to review patient's charts.
- The Epic Research team will email monitors once their account has been created and provide instructions for them on how to log in.
- Research coordinators will release study-patient charts to external study monitors to review via EpicCare Link.
- Patient's charts will be available to monitors in EpicCare Link for a maximum of 5 consecutive calendar days per release.
- Monitors will be restricted to logging in to EpicCare Link Monday-Friday 8am-5pm.

Tracking study amendments

- Study Amendments will be tracked in OnCore.
- New Consents for the amendments are entered into OnCore
- Study Amendments may necessitate changes in Encompass to Patient Treatment Plans, Therapy Plans, SmartSets and future One-Off Orders
- Research Coordinator will contact IAS with the list of updates to Studies that affect the treatment Plan after receiving documentation from the study sponsors whenever there are amendments' They create a list of what will need to be changed. Those things are put into a ticket to the beacon App Team while they continue processing the amendment with the IRB, etc.
- **BEACON Specific:** When changes are made to research studies after a physician has already ordered treatment plans for patients, physicians might need to update the treatment plan to reflect changes to the research study.
- **BEACON Specific:** When the updated Beacon protocol has been moved to the production environment, the Beacon project team member will update the amendment information for the study to indicate the new protocol is ready.