

Research Study Team Handbook

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Locate the Research Coordinator – My Studies dashboard

This home dashboard is the launch point for various reports and tools to help you manage your studies. For some study team members, this is their home workspace. If you need to locate the dashboard:

1. Select the **My Dashboards** workspace tab.
2. Click the dashboard name. In the search window, search for “research coordinator”
3. Locate the *Research Coordinator – My Studies* dashboard and click ☆ in the upper right to mark it as a favorite.
4. Click the dashboard name at any time to toggle between your default and favorited dashboards.

Use the Research Study Team Member Learning Home Dashboard

Learning Home dashboards are useful in-Epic resources that provide quick access to documentation that will help you perform basic functions pertinent to your role. These will be kept up to date with the latest documentation and tip sheets that end users find most useful at go-live.

1. Select the **My Dashboards** workspace tab.
2. Press **F1** on your keyboard to open the Help window.
3. For research coordinators and some other study team members, the *Research study Team Member Learning Home* will be your default Help dashboard. If this is not the case, click the dashboard name to open the dropdown list, locate the dashboard under *Other Dashboards*, and click ☆ next to the dashboard name to save it as a favorite.
4. Review new posts or use the hyperlinks to access tip sheets as needed.

Look up a patient

The Patient Lookup window appears when you click to open a patient-specific activity from the user toolbar (such as Patient Research Studies, or Appts) or another menu, and are prompted to identify the patient whose information you'd like to view.

1. In the Patient Lookup window, enter as much information as possible about the patient.



When looking up a patient, enter the first few letters of their last name, a comma, and the first few letters of their first name. To narrow your results, enter a unique identifier such as their Social Security number, date of birth, or sex. For the most targeted search, enter the patient's medical record number (MRN).

2. Press **Enter**. A list of matching patients appears.
3. Double-click your patient's name.



Select the **Recent Patients** tab to view the names of patients whose charts you recently accessed.

Quickly re-open a patient's record

You can use keyboard shortcuts to quickly re-open the last patient record you opened.

Enter “=” in the **Name/MRN** field of the Patient Lookup window and press **Enter** to pull in the name of the last chart accessed.

Review a patient's chart

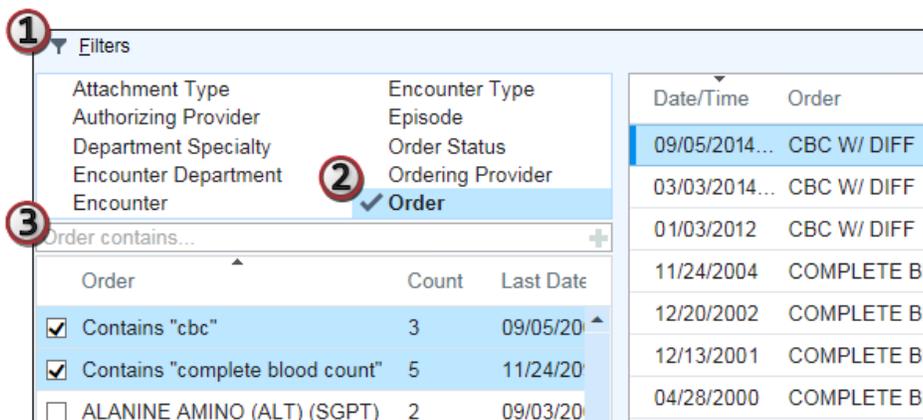
To browse information about past visits, progress notes, imaging, letters, and more, open the *Chart Review* activity.

1. From your schedule, select the patient whose chart you want to review and click  **Review** on the Schedule toolbar.
 - If you're already in a patient chart or encounter, select the *Chart Review* activity tab.
2. To view past visits and other encounters like telephone calls, select the *Encounters* tab. All the patient's visits appear in a list, organized by date.
3. Select a row to see a summary of the encounter in the preview pane.
 - If the report doesn't appear, click **Preview** at the top of the *Encounters* tab.
 - Use the links in the report to get to more detailed information. Hover over certain links, like those in the Orders Placed section, to see more info.
 - To add or update information in an encounter, click  **Encounter**. If the encounter has already been closed, you'll be prompted to create an addendum.
4. Select another tab, such as *Meds*, depending on the type of information you want to review.

Filter information in Chart Review

To find specific information in Chart Review more quickly, you can filter the data that appears on a tab. For example, you can choose to see only encounters in a certain specialty. Or, you can exclude phone calls and other encounter types to quickly create a narrative of when the patient was actually seen in the office.

1. While you're reviewing data on a Chart Review tab, such as *Labs*, click  **Filters**.
2. Select the type of data on which you want to filter, such as *Order*.
3. Select the items you want to see from the list or enter keywords in the free-text search field.
 - For example, you could type "cbc, complete blood count", and then press **Enter** to make sure your filter catches labs that use both the acronym and the full name of the lab.



Attachment Type	Encounter Type	Date/Time	Order	
Authorizing Provider	Episode	09/05/2014...	CBC W/ DIFF	
Department Specialty	Order Status	03/03/2014...	CBC W/ DIFF	
Encounter Department	Ordering Provider	01/03/2012	CBC W/ DIFF	
Encounter	<input checked="" type="checkbox"/> Order	11/24/2004	COMPLETE BL	
Order contains...		12/20/2002	COMPLETE BL	
Order	Count	Last Date	12/13/2001	COMPLETE BL
<input checked="" type="checkbox"/> Contains "cbc"	3	09/05/20	04/28/2000	COMPLETE BL
<input checked="" type="checkbox"/> Contains "complete blood count"	5	11/24/20		
<input type="checkbox"/> ALANINE AMINO (ALT) (SGPT)	2	09/03/20		



The filter options you see are based on the information in the patient's chart, so they vary by patient.



Examples of helpful filters:

- On the *Encounters* tab, filter by diagnoses, encounter type, and department specialty
- On the *Labs* tab, filter by specific orders
- On the *Media* tab, filter by document type

Search the chart

If you're looking for something specific, or just want to see information that's relevant to a certain condition, save clicks and search the chart. For example, search "hypertension" to see problems, clinical notes, medications, and other orders related to that condition.

1. Within a patient's chart, enter a keyword in the **Search** field at the top of the patient's Storyboard and press **Enter**.
 - Results appear organized by date, so you can get an idea of the history.
 - If you prefer to keep your results in view as you chart, click at the top right of the Search activity and select **Move to Sidebar**.
2. Hover over a search result to see more info. For example, hover over a medication to see its history, hover over a problem to see relevant meds and labs, and hover over a note to see relevant snippets.
 - If necessary, click a search result to open a full report.
3. If you get too many results, narrow them down using the filter buttons at the top. For example, click **Meds** to see only the patient's medications related to hypertension.
 - You can also filter the search results to quickly find relevant notes, labs, imaging, and more.
 - Click **All** to clear your filter.

Review patient information from the schedule

Before you open a patient's chart, you can use reports available from the schedule to view a variety of patient information. For example, use the default patient report to review a patient's active problems, vitals, allergies, scheduled appointments, and more.

1. Single-click a patient on the schedule.
2. In the report pane, click a report's name to view it.
3. To choose from a list of all available reports, click in the **Report** field and make a new selection. To configure which reports appear as buttons on the toolbar by default, click .

Review a study record

Study information originates in OnCore and is sent to Epic upon IRB approval (some fields are manually updated by the Epic Research team). When updates to a study are made in OnCore, those updates will also be sent to Epic.

1. Click **Study Maintenance – View Only** on your user toolbar.
2. In the Study Select window, search for your study by title or IRB number. When you locate it, click **Accept**.
3. Review key study information on the various forms:

- General information: The study name, study code, NCT #, Study Type, Study Status, and Description fields are pulled automatically from OnCore.
- Users and Providers: The study roster from OnCore is pulled automatically.
- Report Groupers: Contains data such as study department, funding source, IDE # and study team contact information.

If updates to study information are needed, these changes must be made in OnCore or by the Epic Research team.

Review a patient's study enrollment information

All patient-study association information originates in OnCore and is sent to Epic. When updates to a patient's enrollment information are made in OnCore, those updates will also be sent to Epic.

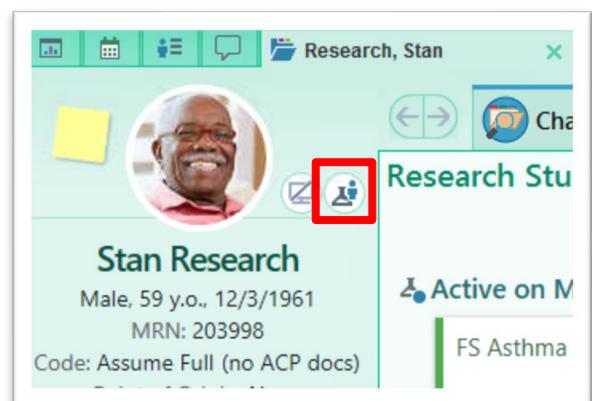
4. Click  **Research Studies** on your main toolbar.
5. Look up your patient and click **Accept**.

Patient-study association statuses are grouped into buckets, which you can filter using the checkboxes in the upper right.

- Select *Inactive* to toggle between showing and hiding these enrollment statuses:
 - Declined
 - Withdrawn
 - Not Eligible
 - Off Follow-up
 - Off Study
 - Off Study (Expired)
 - Consent Refused
- We currently do not use any Pre-Consent statuses
- Deleted statuses typically indicate information added erroneously, then removed
- Statuses that are considered active, and always appear, include:
 - Eligible
 - Eligible (O)
 - Consented
 - On Study
 - On Treatment
 - On Follow-up
 - Off Treatment
 - Consent Waived

Click the study title to open more study information. Click **Additional Info** in the upper right to open a report with additional study details, including a list of study-related visits and orders.

From anywhere in the chart, quickly identify the patient as an active study participant in a study by looking for the  badge next to the patient photo in the Storyboard.



Scan research consents

Research consent forms will continue to be signed on paper, and optionally, scanned into Epic. Research Consents will be scanned at the patient level and will be visible to all Epic users.

1. Use Chart Search to launch Media Manager.
2. Search for your patient (the document will be scanned at the patient level).
3. Click on Scan in the toolbar to launch the OnBase Integrated Scanning window.
4. Place the document in the scanner and click **Scan**.
5. Once the image preview loads, click **Index Document**.
6. Use the document type of *Research Consent*.
7. Complete any additional information as needed, then click **Upload Images** to complete scanning.
8. Verify the consent appears in Media Manager.

It is also possible to import saved images by clicking **Import** from the Media Manager toolbar. From there, locate your document and complete document details as needed, then click **Accept**.

Review research consents

Research consent forms will continue to be signed on paper, and optionally, scanned into Epic. If scanned, these are viewable on the Media tab in Chart Review.

1. Open Chart Review and click to the *Media* tab.
2. Look for a document type of *Research Consent*. The document type appears in-line with document-specific information and will not be shown if the patient has no research consents on file in Epic.

Find your research participants using reports

1. In the *Research Reports* component of the My Studies dashboard, locate the *Actively Enrolled Patients* dashboard component.
2. If it did not run automatically and display a patient total, lick the icon to run it.
3. When the report has completed running and you see a patient total, click the report name to view the results.
4. Perform any follow-up actions from the report results as needed.



Note that you must be listed on the study roster in OnCore for this report to work as expected.

Follow up on event notifications for study participants

You will receive a Research Patient ADT Event Notification (short for Admission, Discharge, Transfer) In Basket message when a study participant on your study is seen in the ED or admitted to the hospital. That way, you can follow up on any care concerns related to the patient's study participation.

1. From your home dashboard, open the Research Patient ADT Event Notification In Basket folder.
2. Select the patient message to review.
3. Review the report below about the patient's hospital encounter.
4. Follow up with hospital staff as needed according to the study protocol.

5. After your follow-up is complete, click **✕ Done** on the folder toolbar to remove the message.

Associate encounters with a research study

Linking an encounter to the study is important for clinical and billing purposes. It indicates that some or all the billable services in a visit are related to the study protocol (even if they will be paid for by the patient or their insurance), or that you are providing care related to the study protocol during the visit.

An encounter can only be linked to the study if the patient is actively associated with the study. This can be completed at any point after scheduling and must be done before the visit is completed.

View upcoming appointments for study participants using a personalized report

Scheduling staff can link an encounter to a study during the scheduling and registration process. Encounters should be linked before the visit begins to ensure that the patient and the study are billed appropriately. You can proactively monitor these visits and check their linking using reports.

View upcoming appointments for research study participants by creating a custom report for your study. Then, use this report to verify that upcoming visits are correctly linked to the study.

1. Click  **My Reports** in the toolbar to open the My Reports activity.
2. Select the *Library* tab and search for "research."
3. Click **+ New Report** next to the "ES Appt Search for Research Coordinators" report template.
4. On the *Criteria* tab, select your research study in the *Research Study* criterion. If you want the results for multiple studies returned in one report, you can enter multiple studies here.
5. In the *Enrollment Status Type* criterion, select **Active**.
6. Notice the date range at the top – this defaults to 2 weeks, but you can manually change the date criteria if desired.
 - Note: Use the 'T+' convention to add relative dates: for example, enter 'T+7' to indicate the report should always run over the 7 days following the day you are running the report.
7. On the *General* tab, rename the report to reflect your new criteria and save the report.
8. Click **Save** to save your settings, then **Run** to see the report's results.
9. Click the  next to the report in your search results to save it as a favorite. You will now be able to locate and run the report directly from your home dashboard under *Favorites and Subscribed Reports*.



Although patient access staff can link an encounter to a study, it is ultimately the study team's responsibility to ensure encounter linking is completed correctly.

Verify that upcoming visits are correctly linked to studies

1. Run your saved version of the ES Appt Search for Research Coordinators report.
 - If you saved your custom report as a favorite, access it directly from your home dashboard.
2. Review the appointments.
3. If an encounter needs to be linked, select the appointment and click  **Link to Research Study** on the report toolbar.
4. Select the study that this appointment should be linked to and click **Accept**.
 - You can also "unlink" an appointment by de-selecting the encounter.

Associate an encounter with a study during the visit

If you are unable to associate a patient's encounter with the study ahead of time, you can associate the visit with your research study directly within the clinical workspace. Examples of when this may happen include: creating an unplanned encounter (such as a telephone call), or if your participant completes the consent process during the visit.

1. Open your patient's encounter by double-clicking their name from either the Schedule (for an outpatient visit) or Patient Lists (for an admission).
2. From the Visit Navigator, open the *Research Studies* section.
 - You can also complete this step from the Research Studies activity. Note that you must be within a visit, not just the patient chart, to complete this step.
3. Click **Link Encounter** in the upper right.



Identify encounters associated with research studies in Chart Review. Associated encounters appear with an  icon in the Research column.

Place a procedure order with a co-signature

Per policy, non-credentialed research coordinators can place procedure orders and sign these orders with a co-signature from a provider. These orders are active immediately and can be executed before the provider completes their co-signature.

1. In the Visit Taskbar, at the bottom of the screen, click **+ Add Order**.
 - If you are in an admission or a hospital-based visit, navigate to the Orders activity tab and click New.
2. Enter a few letters of the order name in the search field. Orders that you frequently place appear as you type.
 - If you see the order you want, select it from the list.
 - If you don't see the order you're looking for, press **Enter**. A list of matching orders appears.
3. Double-click an order to select it from the list. The order appears in a shopping cart to the lower right.
 - If you are in an admission or a hospital-based visit, the orders will appear in the Sidebar.
4. Click the order in the shopping cart to modify order details, such as the dose of a medication or the expected date for a procedure. The  icon indicates required items.
5. After updating the order details, click  **Accept**.
6. Click  **Associate** to associate your new orders with diagnoses. (See the **Associate diagnoses with orders** section for more details.)
7. Click **Sign** to sign the orders.
8. The co-signature request will be automatically sent to the visit provider. If the visit is not scheduled with an authorizing provider, the *Providers* window will open. Specify the authorizing provider and click  **Accept**.

Enter order details for a lab or procedure

Select the order status that indicates when and how the order should be released:

- Select a status of **Normal** if the test or procedure will occur once, during the current visit. For example, use this for a point-of-care test to be done during this visit.
- Select a status of **Future** if the test or procedure will occur only once, at some point after this visit. For example, use this for a lab that the patient will have drawn in a few days.
- Select a status of **Standing** if the test or procedure will occur more than once, like a recurring lab test, for example. Then choose the number of occurrences and the interval at which they will occur.

Select the order class that indicates where the test or procedure will be performed. If you need a specimen to be collected by clinic staff, select **Clinic Collect**.

Associate diagnoses with orders

Prior to signing, all procedure orders are required to be associated with a diagnosis.

1. To associate a diagnosis, click  **Dx Association** in the shopping cart. If the diagnosis you need isn't listed, search for it in the **Add Diagnosis** field or, select it from the **Common**, **Previous**, or **Problems** dropdown menus.
2. Click the cell where an order and diagnosis intersect to associate them. Click **Accept**.
3. To associate all orders with a single diagnosis, click the diagnosis name.

Associate orders with research studies

Associating an order with a study indicates the order is being executed as part of the study protocol. *It does not necessarily indicate how the charge for the service should be billed*, so all study-related orders should be associated with the study.

To associate an order with a study, the patient must have an active status for that study. Each order can only be associated with one study.

These associations appear in *Order Review*, as well as in the orders-related tabs of Chart Review, such as the *Procedures* tab. This gives a more complete picture of a patient's care so that other clinicians and staff can make better informed care decisions for study participants. It also makes billing easier for study-associated orders and helps with identifying and filtering study-related results.

1. Enter an order and open the Associate Research Studies window using one of these paths:
 - In the shopping cart (from the Visit Taskbar), click  **Research Association**
 - In the Orders activity and other ordering activities, click **Options** and select **Research Association**.
2. Select the order that should be associated with the study and click **Accept**. An  icon appears next to the order name.
3. Sign the orders as usual.



Identify orders associated with research studies in Chart Review and Order Review. Associated orders appear with an  icon in the Research column.

Add orders to your Preference List as you place them

Preference lists are shorter, customized lists that display the most pertinent options for easier selection. System preference lists are typically specialty-focused, but you can create a personalized preference list with orders and order details you use most often.

1. Search for and select an order as you normally would. Then edit the order details and click  **Accept**.

2. Before signing your order, click ☆ to add it to your preference list.
3. In the Add To Preference List window, enter any other details you want to use when you place this order in the future, such as instructions or answers to questions, and click **Accept**. Remember that these details appear only for you, and you can always update them later.
 - a. In the *Display name* field, enter an easy-to-remember name for the order. The next time you need to place this order, you can search for your saved order using this name.
 - b. In the *Section* field, enter the section of your preference list in which you want this order to appear. Or, click **New Section** to add another section to your list.

Place an order for a research-only sample collection

Sometimes, blood draws are needed as part of a study for non-diagnostic reasons, such as PKs or other samples that are being sent to a study sponsor.

Research-only sample collections will be ordered in Epic, including instructions on which tubes to draw and how many of each. Study-specific collection and processing instructions should not be documented within Epic.

1. In the visit taskbar (or Orders activity in the hospital setting) search for *Research Only Sample*.
2. Complete the order details, including the number of labels needed.
3. Click the ☆ to add it to your preference list if you will place the order with these same details often.
4. Associate the order with a diagnosis, link the order to the research study, and sign the order.

Write a Research Note

Research notes can be used to document study-related administrative information, if you would like this information stored in the patient's chart. These notes are visible to users in Epic, and to study monitors, but are not released to third parties as part of the legal medical record.

Any information that is clinical in nature or necessary for billing purposes should be documented by the appropriate clinician elsewhere in a clinical note. Research notes can be used for documenting the informed consent process or recording details of study-related tasks completed during a study visit, or other study administrative information.

1. Open a patient encounter, either from the Schedule or the Patient Lists activity.
 - To write a note on the fly, search for Write Note in the search box, and select your patient to open a notes-only encounter.
 - Add encounter details if needed and click **Accept**.
2. In the *Research Notes* navigator section, click **+ Create Note**.
3. Begin documenting by typing or using SmartTools.
4. If you would like an investigator to sign off on your note, check the *Cosign Required* box and enter your desired note cosigner. They will receive an In Basket message requesting they review the note and provide a co-signature.
5. Once complete, click **Sign**. If you are not yet done with your note, you can click **Pend** to save your work and continue it later.

Create a SmartPhrase from text you type

1. While writing a note, type the text you want to save as a SmartPhrase. Make sure the text doesn't include any patient-specific information, so you can reuse it for other patients.

You can create a SmartPhrase anywhere you see this toolbar:



2. Select the text and click **+**.
3. In the SmartPhrase Editor, enter a short, intuitive name for your SmartPhrase in the *Name* field. This is the name you'll type to insert the SmartPhrase in a note. You can't include spaces or symbols in the name.
4. Enter a summary of your SmartPhrase in the *Description* field.
5. Click **Accept** to save and close your new SmartPhrase.
6. To use your SmartPhrase later, type a period immediately followed by the SmartPhrase name. Press the **Spacebar** to insert your SmartPhrase in the note.



Note: You can also share your SmartPhrase with other user in the SmartPhrase Editor by listing them out under the Sharing section.

Document tasks in the study checklist

Use research tasks to keep track of the things you need do for patients who are associated with research studies.

1. Open the Research Studies activity for a patient and select a study.
2. Click the **Tasks** link for a study.
 - a. Click **+ Add** to add tasks manually. Select a task from the list and click **✓ Accept**.
 - b. Click the task title to edit the task name, specify a due date or completion date, and add any comments. Click **✓ Accept** to close the task.
 - c. Select the checkbox for tasks you've done.
 - d. Click **X** to remove tasks that don't apply.
3. On your My Studies dashboard, click to run the Overdue Tasks or Tasks Due Within a Week reports in the Study Operations component to manage tasks across your study participants.

Complete research charge review

For patients actively enrolled in a study, all charges generated during their period of active study participation will be held from billing until review is completed by a study team member, followed by a research biller. Research coordinators should incorporate the research charge review process into their daily workflow to comply with institutional policy.

Find patients needing research billing review for your study

1. In the *Study Operations* section of the Research Reporting Home dashboard, click the **Total Balance Needing Research Review (Study Team)** component to run the report (it may run automatically).
2. After the results load, click the  icon to view the report.
3. Double-click a patient record in the report results to open the Research Billing Review activity.

Make a research charge correction

The following buckets of charges appear in the Research Billing Review activity (note that a bucket does not appear if it is not currently holding any charges):

- Study-Related - Bill to Study
- Study-Related - Bill to Insurance/Patient
- Non-Study Charges

During your review, you can transfer one or more charges from one bucket to another if the charge is listed incorrectly. For example, if a patient comes in for a study-related visit and also receives a flu shot, the flu shot might be incorrectly listed as a study-related charge.

1. Select the check box next to one or more charges and click **Research Correction**.
2. Indicate whether the charges are **Research-Related** and enter the correct information.
 - When you bill to the study, you do not use a modifier type. When you bill to patient/insurance, specify a modifier type of either Investigational/Device or Routine in the **Modifier Type** field.
3. Click **Accept**.
4. To see your corrections reflected, you may need to click **Refresh** in the upper left.

Mark charges as reviewed

After you complete your review of the charges, mark the date of service or hospital account as reviewed. Hospital and professional charges have slightly different buttons in the system, as specified in the steps below.

1. In the Research Billing Review activity, verify that your review of the patient's charges is complete.
2. Click **Mark Account as Reviewed** (for hospital accounts) or **Mark Service Date as Reviewed** (for professional charges).
 - Note: even if the charges are from a non-study visit, you must mark them as reviewed before they can be billed.
3. Enter a comment if necessary and click **Accept** to mark the account (for hospital accounts) or encounter (for professional charges) as reviewed.

Upon re-running the Patients Needing Research Billing Review report, your patient will no longer appear in the results until they have additional charges awaiting review. This report may take up to one hour to refresh.

Release information to study monitors using EpicCare Link

After study monitors receive access to the EpicCare Link web portal, you'll use reports to release information to them. Use of EpicCare Link allows monitors to complete their work remotely.



Any documentation completed after Epic go-live will be viewable in EpicCare Link. If your monitor needs to review information from prior to go-live, you should continue to provide this access using your legacy workflow.

If your study monitor does not have an existing EpicCare Link account, they will need to complete the account request and provisioning process. There is a helpful handout you can share directly with your monitor that includes these instructions, which is linked from the Research Study Team Member F1 Help dashboard.

1. Complete the LinkBlue account request for the monitor, as you do today. Then, you can complete steps 2-4 concurrently.
2. Direct them to the UK HealthCare EpicCare Link landing page:
https://link.uky.edu/EpicCareLink/common/account_request_main.asp
3. Instruct them to click the **Request Access for a Clinical Trial Sponsor** link or **Request Access for a New Research Monitor** and complete the form. You will need to supply the study monitor with the answers to enter for these fields:
 - OnCore ID
 - IRB#
 - Principal Investigator
 - Study Contact Name (this is the UK study contact)
 - Study contact email and/or phone number (this is the UK study contact)
3. Their login credentials will be sent to you within 3 weeks. You will send them to the study monitor.

Once your monitor has an active account and has the correct studies applied, you can release individual patients to their account for review:

1. Run the *Actively Enrolled Patients* report from your My Studies Reporting Home dashboard.
2. Open the report results.
3. Select the patients whose records you want to release to the study monitor.
4. Click  **Release to Study Monitor** on the toolbar.
5. Select the study, patient group corresponding to the study, and the dates the information should be available to the study monitor. Note that the maximum duration is 5 days.
6. Click  **Release**.
 - You can view release information in the Study Monitor Release Information section of the Research Snapshot and in the *Study Monitor Releases for My Studies* component on the My Studies Home dashboard.
 - Monitor access to patient charts will automatically expire after the specified number of days.

Document a telephone encounter

You can use telephone encounters in Epic to document phone conversations with your study participants, whether you placed a call to them (such as a status check), or they called you, perhaps with a question.

1. To create a telephone encounter on the fly, search for Telephone Call in the search box, and select your patient to open a telephone encounter.
2. In the *Research Studies* navigator section, associate the encounter with your study.
3. In the *Contacts* navigator section, document details about the incoming or outgoing call.
4. In the *Reason for Call* navigator section, document a reason.
5. Write a Research Note documenting call details.
7. If you are finished with your documentation, click  **Sign Encounter** to close the visit.
6. If you would like your investigator or another study team member to act on the call, list them as a recipient in the *Routing* navigator section, leave a routing comment with instructions, and click **Close Workspace** to close the patient chart and send the In Basket message.
 - a. If someone routes the encounter back to you, you will receive a message in the *Patient Call* In Basket folder. Click the folder to navigate to the message. From the message toolbar, you can reopen the encounter, or sign the visit directly from your In Basket.

The telephone encounter should be closed when all follow-up and documentation is complete.

