



SPONSOR MONITORING EPIC ACCESS



OVERVIEW

- Requirements
 - EpicCare Link (ECL) Roles & Responsibilities
 - ECL Use Cases
 - Program Management
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UT HEALTH SAN ANTONIO EPIC ACCESS

- **Need:** Provide access to EPIC health records to **Sponsor Monitors** for the purpose of verifying accuracy of data submitted by the local study team.
- **EpicCare Link (ECL)** is configured so that a designated **Administrator** (CTO) can approve user account requests made by **Monitors**.
- **Monitors** will use ECL for all in-person and remote monitoring visits.
- To protect **confidentiality**, Administrators will verify the authenticity of new user account requests with a designated member of the local study team (**Coordinator**)

ECL REQUIREMENTS

- The study being monitored must have a **Velos eResearch** account
 - Subjects must be recorded in the Velos record
- The study being monitored must have an Epic **Research Account**
- A member of research team must have **Epic access**
 - This individual must be assigned to the **Coordinator Role** in Epic
 - This individual must be assigned to the **research account**
- The sponsor monitor must have access to **EpicCare Link (ECL)**
 - The monitor must be assigned to the **research account**
- The CTO Administrator must have **Epic access**
 - This individual must be assigned to the **Administrator Role** in Epic

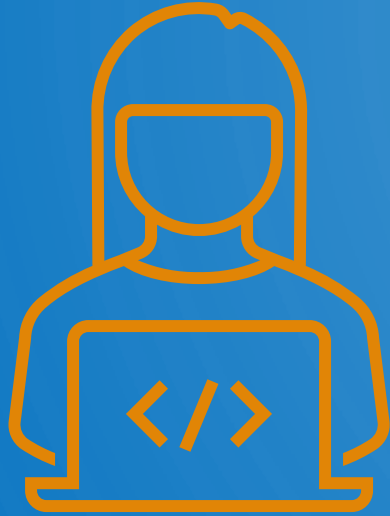
HOUSEKEEPING TASKS:

- Setup EPIC research account*
 - Assign Coordinator role*
 - Remove Coordinator role
 - Link Coordinator to study (research account)
 - Remove Coordinator from study
 - Remove Monitor from study
 - Suspend Monitor's ECL access
- *Routine CTO setup of new clinical trials/billing risk studies

The background is a solid blue color. In the four corners, there are decorative white line-art patterns that resemble circuit traces or a network diagram. These patterns consist of vertical and horizontal lines that branch out and terminate in small circles, creating a sense of connectivity and technology.

ECL: ROLES & RESPONSIBILITIES

Sponsor Monitor



CHLOE

Study Coordinator



ROSA

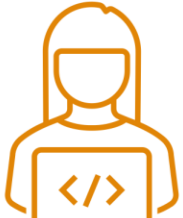
CTO Administrator



ALEXIS

MEET THE TEAM

Sponsor Monitor



CHLOE

• Sponsor Monitor

- Submits a monitoring visit request (remote or on campus)
 - Provides study ID, subjects and visit dates
- Submits new user request in ECL
- Verifies information in subject's health record using ECL
- Requests date change as needed

Study Coordinator



ROSA

• Study Coordinator

- Confirms accuracy of monitoring request
- Submits on-line request to CTO Administrator
- Selects patients and dates for visit in ECL
- Makes other arrangements for on-campus visit

CTO Administrator



ALEXI

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• Administrator

- Approves new user account request in ECL
- Approves adding an existing user to a new study in ECL
- Approves request for a repeat visit (existing user/same study) in ECL
- Changes dates for previously a approved visit in ECL

The background is a solid blue color. In the four corners, there are decorative white line-art patterns resembling circuit traces or a stylized tree structure. These patterns consist of vertical lines that branch out at various angles, ending in small circles. The patterns are symmetrical and frame the central text.

USE CASES

FOUR USE CASES

ECL Step [Role]	New Monitor	New Study	Repeat Visit	Change Dates
Submit new account request [monitor]	✓	✓		
Assign new username [administrator]	✓			
Link monitor to research study [administrator]	✓	✓		
Select subjects & set dates [coordinator]	✓	✓	✓	
First ECL log on, change password & setup dual authentication [monitor]	✓			
Select existing request, applicable subject & change dates [administrator]				✓
Review subject records [monitor]	✓	✓	✓	✓

The background is a solid blue color. In the four corners, there are decorative white line-art patterns resembling circuit traces or a network diagram. These patterns consist of straight lines of varying lengths and angles, ending in small white circles. The patterns are symmetrical and frame the central text.

MANAGING THE PROCESS

STUDY STAFF SUBMITS A REQUEST TO CTO

“*Research Monitor Visit Request*” form

Bookmark:

<https://redcap.uthscsa.edu/REDCap/surveys/?s=LCDCHMWTNK>

VPR website: Navigating the Research Lifecycle

Management » The Human Study Lifecycle

The Human Study Lifecycle

Managing Your Human Study

Click on the arrows below to expand/collapse the content.

UTHSA IRB of Record ▾

External IRB of Record ▾

Personnel Change ▾

Modifications to Funding, Budget, Contract or Agreement ▾

Financial Management ▾

Sponsor-Investigator Responsibilities ▾

Monitoring and Auditing ▲

Sponsor Monitoring - Onsite Monitoring and Remote Monitoring

Sponsor/CRO requests for onsite monitoring must be documented.

How monitors access subject records will be dependent on the institutional requirements were the study is being conducted.

Onsite Monitoring at UTHealthSA

The PI or study team are responsible for arranging space, meeting schedule, access to study records.

For visits of **more than three (3) consecutive days**, study staff must ensure the monitor obtains a POI "person of interest" designation and criminal background check.

For more information see the Handbook of Operating Procedures (HOP) policy for obtaining a POI designation and criminal background check at [Section 8.7.11 - Contractors and Vendors](#).

Access to UTHealthSA's EPIC

Submit the "Research Monitor Visit Request" form

Questions regarding sponsor monitor access to Epic?

Cancer Research - Mays-CC-Monitoring@uthscsa.edu

Non-Cancer Research - VPRCTO@uthscsa.edu

Sponsor Monitoring at University Health

Complete the UH online request form to schedule onsite monitoring

The Human Study Lifecycle

- 1 Developing your human study
- 2 Logistics for your human study
- 3 Getting approval for your human study
- 4 Starting your human study
- 5 Managing your human study
- 6 Closing out your human study

Need Help?

OIRB: IRB@uthscsa.edu; 210-567-8250

OCR: OCRMail@uthscsa.edu; 210-567-8555

CTO: VPRCTO@uthscsa.edu; 210-450-8532



Join the VPR Research Administration Email List

Sign up for our email list so you can stay up to date with news and announcements from our offices.

Quicklinks

Human Study Submissions

- Clinical Trial
- UTHSA IRB Review
- External IRB Review
- Amendment/Modifications
- Progress Report/Update Report
- Prompt Report
- Exception Request

Logins

- ORCA
- Velos
- iDisclose
- CITI

Events

- Upcoming Events

Find

- Training for Animal Studies
- Training for Human Studies
- Glossary
- Forms
- Guidance & Policies
- Trending Information

Contact Us

- IRB
- OCR
- CTO
- COI
- IACP
- LAR

More

- Investigator Registry
- Find-A-Study
- Remote Monitoring Request

✕ Close Quicklinks

Research Monitor Visit Request

Resize font:



[Returning?](#)

Welcome!

Use this online form to request access to **UT Health San Antonio's** instance of EpicCare Link for Research Sponsor's monitors.

- Remote and On Campus visits involving access to Epic
- Requests can only be made by UTHealthSA research team members
- As a general rule, requests should be submitted at least 30 calendar days before the visit start date.

What information do you need to complete the request form?

- Basic study information (CTMS number, title, etc.)
- Monitor's information (name, email, **whether a current EpicCare Link user**)
- Coordinator/Data Manager's information & EpicCare Link permissions
- Monitoring start and end dates
- Copy of monitor's visit request (letter, email or optional form)

Save & Return - see the instructions at the bottom of the form on how to save your work and return later to complete the submission.

Security -- This questionnaire uses UT Health San Antonio's instance of REDCap. REDCap is a secure web authentication application that is HIPAA compliant. Access is through centralized two factor authentication, all data are encrypted meeting FISMA security standards, physical, network, and computer security is third-party monitored and enforced through the university's Information Assurance Division.

Cancer Related Research?

* must provide value

Cancer Related Research

Non-Cancer Research

res

ECL Visit Tasks

Request Type

* must provide value

Housekeeping

- New Visit
- Change dates of scheduled visit
- Setup EPIC research account
- Assign Coordinator role
- Remove Coordinator role
- Link Coordinator to study
- Remove Coordinator from study
- Remove Monitor from study
- Suspend Monitor's ECL access



res

Cancer Related Research?

* must provide value

Cancer Related
Research

Non-Cancer
Research

Request Type

* must provide value

New Visit

Change dates of scheduled visit

Setup EPIC research account

Assign Coordinator role

Remove Coordinator role

Link Coordinator to study

Remove Coordinator from study

Remove Monitor from study

Suspend Monitor's ECL access

Housekeeping

Study Information

CTMS #*	<input type="text" value="YY-XXXX"/>	UTHSA PI	<input type="text" value="First Name Last Name"/>
Study Title	<input type="text"/>		

Expand

Has a Research account previously been set-up in EPIC for this study?

* must provide value

UTHSA Coordinator Information

Name*	<input type="text" value="Joseph Schmelz"/>	UTHSA email*	<input type="text" value="schmelz@uthscsa.edu"/>
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Housekeeping

Does Joseph Schmelz have an Epic account?

* must provide value

 Yes No

reset

Is Joseph Schmelz's EpicCare account connected to this study?

* must provide value

 Yes No

reset

Has Joseph Schmelz been granted special permission for managing monitor visits in EpicCare Link?

* must provide value

 Yes No

reset

Special permission is referred to as the "Coordinator/Data Manager Role"



Monitor's Information

First Name*	<input type="text" value="Joseph"/>	Last Name*	<input type="text" value="Schmelz"/>
Employer	<input type="text"/>	Email*	<input type="text" value="schmelz@uthscsa.edu"/>

Housekeeping

Visit Information

Type*	<input checked="" type="radio"/> Remote <input type="radio"/> On-Site	<input type="text"/>	<input type="text"/>
	<input type="button" value="reset"/>		
Start Date*	<input type="text" value="2021-05-23"/> <input type="button" value="31"/> <input type="button" value="Today"/> Y-M-D	End Date*	<input type="text" value="2021-05-23"/> <input type="button" value="31"/> <input type="button" value="Today"/> Y-M-D

Uthsa EpicCare Link Cridentials

Is Joseph Schmelz a current UTHSA EpicCare Link user?

* must provide value

Yes

No

i.e., already have a username

Has Joseph Schmelz previously monitored this study (21-0001X) using UTHSA EpicCare Link?

* must provide value

Yes

No



Step-by-step instructions & EpicCare Link Agreement

Important Instructions for Research Monitors - UT Health San Antonio

vprcto@uthscsa.edu <vprcto@uthscsa.edu> Mon 5/24/2021 2:41 PM

To: [Study Coordinator], [Sponsor Monitor]

Attachments Research Guide - Step by step MONITOR ONLY.pdf; EpicCare Link Agreement.pdf;

Dear Joseph Schmelz,

Brandi Weaver has submitted your request to perform a Remote monitoring visit of study number CTMS 20-0202 starting 2021-06-03 and ending 2021-06-06.

Study Title: Demonstration of NonCancer Visit by a New Monitor

Brandi Weaver indicated that you are not a current user of our instance of EpicCare Link and will need a new user account. If this is not correct, contact us before proceeding.

In order to access our electronic medical records, please navigate to our EpicCare portal and submit a request as follows:

URL for new user request

Automatic email to Monitor

1. Select "Request New Account"
2. Select "Request access for a new research monitor"
3. Fill out the required fields (indicated by a **red exclamation icon**) on the User Information form.
4. **Special Instructions for this form:**
 1. Ensure that the use site address box is unchecked
 2. Insert our study number (20-0202) in the Study Title field
 3. Answer "NO" to the question, "Do you currently have a UT Health San Antonio EpicCare Link login"?
 4. Enter "Self" in the Requested by field

Reply to this email when finished

Detailed instructions with screenshots are attached to this email.

Important* In order to use EpicCare Link, you are required to download and install the Epic Authenticator app from the App Store (iPhone) or Google Play (Android). Please notify us immediately if you are unwilling or unable to comply with this requirement.

Please notify us when you have completed the form by replying to this message or sending an email to: vprcto@uthscsa.edu

Once the request has been approved, you will receive another notification with instructions how to log on and conduct the review.

If you are not notified regarding the status of your request, please contact the study coordinator or the VPR Monitoring Administrator. **DO NOT submit another request in EpicCare Link!**

Respectfully,
UT Health San Antonio
VPR Clinical Trials Office (VPR/CTO)

Name of CTO Administrator

VPR CTO Administrator Assigned to Monitoring Visit Request

vprcto@uthscsa.edu <vprcto@uthscsa.edu>

Mon 5/24/2021 3:23 PM

To: [Study Coordinator], [Sponsor Monitor]

Jason Bates (email: batesjr@uthscsa.edu) has been assigned to process the monitoring visit request (details below).

You can contact Jason Bates via email at batesjr@uthscsa.edu if you have any questions.

Request Details

Monitor: [Joseph Schmelz](#)

MCC Coordinator/Data Manager: [Brandi Weaver](#)

Start Date: [2021-06-03](#) - End Date: [2021-06-06](#)

CTMS #: [20-0202](#)

Title: [Demonstration of NonCancer Visit by a New Monitor](#)

Automatic email to Monitor

The background is a solid blue color. In the four corners, there are decorative white line-art elements that resemble circuit traces or data paths. These lines connect to small white circles, some of which are larger than others. The lines are thin and have a clean, minimalist aesthetic.

COORDINATOR ACTIONS:
NEW MONITOR, NEW STUDY & REPEAT VISITS

Automatic email to Coordinator

Link to smart form



From: Sent automatically via Automated Invitations
from schmelz@uthscsa.edu

To: weaverb@uthscsa.edu

Subject: **[Reminder] Final Step to Complete Monitoring Visit Request**

Dear Brandi Weaver,
The monitoring visit request for Joseph Schmelz is ready for the final step in EpicCare Link. Please use the link in this message to document completion of this step.

You may open the checklist in your web browser by clicking the link below:

[Document Completion of ECL Monitoring Request](#)

If the link above does not work, try copying the link below into your web browser:

<https://redcap.uthscsa.edu/REDCap/surveys/?s=2ufpSpfGyo>

This link is unique to you and should not be forwarded to others.

Monitoring visit information:

Monitor	Joseph Schmelz	CTMS #	20-0202
Start Date	2021-06-03	End Date	2021-06-06

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COORDINATOR ACTIONS IN ECL

LIVE DEMO BY STEVEN CHESSHER

Coordinator smart form to document completion of ECL tasks

Instructions

EpicCare Link Instructions:

Attachment:  [Research Guide - Step by step.pdf](#) (2 MB)

Document completion of the tasks in the EpicCare Link "[Remote Research Study Monitoring](#)" Dashboard

Select patients for review and release to study monitor

- Navigate to Remote Research Study Monitoring dashboard
- Select "Patients associated with my studies"
- Select the patient(s) to be released
- Click "Release to Study Monitor"
- Locate and select the applicable study
- Click the magnifying glass in the Patient Group field
- Select the group that has been auto-populated as a match for the study

Completed

reset

Steps from the Instructions

Set Dates

- Enter the Release From Date by clicking the calendar icon and selecting the date or by manually typing it in (Start Date: 2021-06-03)
- Enter the Release To Date by clicking the calendar icon and selecting the date or by manually typing it in (End Date: 2021-06-06)
- Select "Release"

Completed

reset

Submit

Save & Return Later

SUMMARY

- MCC launched May 10; VPR CTO (non-cancer) scheduled launch June 1
- Management program consists of three applications
 - EpicCare Link [Monitor, Coordinator, Administrator]
 - ECL Access for Research Monitoring (REDCap) [Coordinator, Administrator]
 - On-Base Request form (Housekeeping) [Administrator]
- Consider any your studies require any housekeeping ahead of a specific visit request, this will save time later
- Documentation in the REDCap management application triggers standardized messaging to all parties involved. It is not connected to ECL.

The image features a solid blue background with white decorative circuit-like lines in the corners. These lines consist of straight segments and small circles, resembling a stylized PCB or network diagram. The lines are positioned in the top-left, top-right, bottom-left, and bottom-right corners, framing the central text.

QUESTIONS?