OVERVIEW

• Requirements
• EpicCare Link (ECL) Roles & Responsibilities
• ECL Use Cases
• Program Management
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
ECL: ROLES & RESPONSIBILITIES
MEET THE TEAM

Sponsor Monitor
CHASE

Study Coordinator
ROSA

CTO Administrator
ALEXIS
• **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**
  • 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

• **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
USE CASES
## FOUR USE CASES

<table>
<thead>
<tr>
<th>ECL Step [Role]</th>
<th>New Monitor</th>
<th>New Study</th>
<th>Repeat Visit</th>
<th>Change Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit new account request [monitor]</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assign new username [administrator]</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Link monitor to research study [administrator]</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Select subjects &amp; set dates [coordinator]</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>First ECL log on, change password &amp; setup dual authentication [monitor]</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Select existing request, applicable subject &amp; change dates [administrator]</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Review subject records [monitor]</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
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
Research Monitor Visit Request

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 UHealthSA 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?

<table>
<thead>
<tr>
<th>Request Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td>New Visit</td>
<td></td>
</tr>
<tr>
<td>Change dates of scheduled visit</td>
<td></td>
</tr>
<tr>
<td>Setup EPIC research account</td>
<td></td>
</tr>
<tr>
<td>Assign Coordinator role</td>
<td></td>
</tr>
<tr>
<td>Remove Coordinator role</td>
<td></td>
</tr>
<tr>
<td>Link Coordinator to study</td>
<td></td>
</tr>
<tr>
<td>Remove Coordinator from study</td>
<td></td>
</tr>
<tr>
<td>Remove Monitor from study</td>
<td></td>
</tr>
<tr>
<td>Suspend Monitor's ECL access</td>
<td></td>
</tr>
</tbody>
</table>

**ECL Visit Tasks**

**Housekeeping**
<table>
<thead>
<tr>
<th>Request Type</th>
<th>Cancer Related Research?</th>
<th>Non-Cancer Research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Visit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change dates of scheduled visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setup EPIC research account</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assign Coordinator role</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove Coordinator role</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Link Coordinator to study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove Coordinator from study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove Monitor from study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspend Monitor's ECL access</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* must provide value
### Study Information

<table>
<thead>
<tr>
<th>CTMS #*</th>
<th>YY-XXXX</th>
<th>UTHSA PI</th>
<th>First Name Last Name</th>
</tr>
</thead>
</table>

**Study Title**

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

* must provide value

Yes | No
<table>
<thead>
<tr>
<th><strong>UTHSA Coordinator Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Does Joseph Schmelz have an Epic account?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Is Joseph Schmelz's EpicCare account connected to this study?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Has Joseph Schmelz been granted special permission for managing monitor visits in EpicCare Link?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
</tbody>
</table>

*Special permission is referred to as the "Coordinator/Data Manager Role"*
### Monitor's Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*</td>
<td>Joseph</td>
</tr>
<tr>
<td>Last Name*</td>
<td>Schmelz</td>
</tr>
<tr>
<td>Employer</td>
<td></td>
</tr>
<tr>
<td>Email*</td>
<td><a href="mailto:schmelz@uthscsa.edu">schmelz@uthscsa.edu</a></td>
</tr>
</tbody>
</table>

### Visit Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type*</td>
<td>Remote, On-Site</td>
</tr>
<tr>
<td>Start Date*</td>
<td>2021-05-23</td>
</tr>
<tr>
<td>End Date*</td>
<td>2021-05-23</td>
</tr>
</tbody>
</table>

### EpiCare Link Credentials

- **Is Joseph Schmelz a current UTHSA EpicCare Link user?**
  - Yes
  - No
  - *must provide value*
  - i.e., already have a username

- **Has Joseph Schmelz previously monitored this study (21-0001X) using UTHSA EpicCare Link?**
  - Yes
  - No
  - *must provide value*
Step-by-step instructions & EpicCare Link Agreement

URL for new user request

Automatic email to Monitor

Reply to this email when finished

Important Instructions for Research Monitors - UT Health San Antonio
vprcto@uthscsa.edu <vprcto@uthscsa.edu>
Mon, 26 Apr 2021 16:24:29 +0200

To: [Study Coordinator], [Sponsor Monitor]

Subject: Request for a Remote Monitoring Visit [Request Number]

Dear [Name],

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:

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

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,

[Name]

UT Health San Antonio
VPR Clinical Trials Office (VPR/CTO)
VPR CTO Administrator Assigned to Monitoring Visit Request

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.

<table>
<thead>
<tr>
<th>Request Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor: Joseph Schmelz</td>
</tr>
<tr>
<td>MCC Coordinator/Data Manager: Brandi Weaver</td>
</tr>
<tr>
<td>Start Date: 2021-06-03 - End Date: 2021-06-06</td>
</tr>
<tr>
<td>CTMS #: 20-0202</td>
</tr>
<tr>
<td>Title: Demonstration of NonCancer Visit by a New Monitor</td>
</tr>
</tbody>
</table>
COORDINATOR ACTIONS:
NEW MONITOR, NEW STUDY & REPEAT VISITS
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:

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Joseph Schmelz</th>
<th>CTMS #</th>
<th>20-0202</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date</td>
<td>2021-06-03</td>
<td>End Date</td>
<td>2021-06-06</td>
</tr>
</tbody>
</table>
COORDINATOR ACTIONS IN ECL

LIVE DEMO BY STEVEN CHESSHER
Coordinator smart form to document completion of ECL tasks

**Instructions**

Steps from the Instructions

**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

**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"
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.
QUESTIONS?