

Remote and On-Site Monitoring FAQs

Remote Monitoring

• What is the provisioning process for a new monitor/study?

The study team must submit a request for access via the Qualtrics application form.

For access to HealthLink, once the Remote Monitoring Agreement has been executed with <u>Clinical Trial Contracting &</u> <u>Strategic Relations (CTC-SR)</u>, please complete the following forms and submit them via Qualtrics application form <u>https://uclahs.az1.qualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI</u>:

- 1. Monitor HealthLink Request Form
- 2. User Agreement UCLA Health EHR Access Agreement
- 3. Confidentiality Statement
- 4. Instructions for Completing Monitoring Forms

Requests will only be accepted via Qualtrics. Please do not submit forms via email.

For access to eBinders, please complete the following forms and submit via Qualtrics application form <u>https://uclahs.az1.qualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI</u>:

- 1. Monitor eBinders Request Form
- 2. <u>eBinders</u> Training Certificate

???? Requests will only be accepted via Qualtrics. Please do not submit forms via email.

- What is the remote monitoring set up fee for the combination of HealthLink and eBinders? For Industry (for profit) funded studies the cost is \$3150 per study. The \$3150 cost covers the provisioning of a study and one monitor for that study. For each additional monitor to be provisioned for that study, it is an additional \$2625.
- Is the \$3150 a one-time fee, or is it per remote monitoring visit (RMV)?
 Yes, the \$3150 is a one-time fee. It is the study set up fee and also covers provisioning one monitor for that
 study. For each additional monitor to be provisioned for that study, it is an additional \$2625. An additional
 \$2625 will be charged each time a new monitor comes onto the study. The cost is not per RMV. If there is staff
 time on your end, you will need to discuss those charges separately.
- What is the remote monitoring set up fee for studies using only eBinders? For Industry (for profit) funded studies the cost is \$1050 per study. The \$1050 cost covers the provisioning of a study and one monitor for that study. For each additional monitor to be provisioned for that study, it is an additional \$525.
- We have already been provisioned and paid for access to HealthLink, do we need to pay an extra fee to now access eBinders?

No, it is one fee for access to both systems.

 Are the signed forms (HealthLink user access form, confidentiality statement form, eBinders user agreement, and Individual user access form) a one-time requirement or do they need to be provided prior to each RMV? The signed forms are a one-time requirement only.

- Our monitors have already been provisioned for HealthLink, how do we give them access to eBinders? For access to eBinders, please complete the following forms and submit them via Qualtrics application form <u>https://uclahs.az1.gualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI</u>:
 - 1. ????Monitor eBinders Request Form
 - 2. <u>eBinders</u> Training Certificate
- If a monitor has already been provisioned for a study (eg. study A) and is now requesting access to another study (study B), are they required to provide the signed forms again? Maybe.
 - 1. ????If the sponsor of the two studies is the same, then the forms do not need to be signed again. Please submit a Qualtrics application requesting access to the new study.
 - 2. If the sponsors are different, then yes, completion of the forms will be needed for the new study.
- Do clinical research coordinators need to be trained to provide access to specific patients during the specified time frame?

Once the CRAs EMR and eBinders access is provisioned, the study team will be provided with a tip sheet that the clinical coordinators can refer to, for help releasing subjects in HealthLink and study documents in eBinders.

- Who on the study team can release subject records to CRAs for remote review? Only certain study personnel like research nurses or clinical research coordinators are able to release subject records. Data managers are not able to do so. The system has been set up in this manner based on a study personnel's job description.
- Will monitors only have access to the subject records they are assigned to review or all the subjects. For example, if monitor A is assigned to review subjects 001 and 002 on a study and Monitor B is assigned to review subjects 003 and 004 on the same study, will both monitors have access to all 4 subjects on the study?

Yes. Coordinators release patients to a specific HL (Healthlink) patient list (the Patient Group), which is built by study. The research monitors are given access to specific studies (the User Context, which is linked to the Patient Group). A research monitor who has been provisioned with a User Context for a specific study will have access to all the patients who have been released to the study. In this scenario, if a monitor should not access specific patient charts, this should be a training point to instruct the monitor to not open the charts they should not open. Every access is fully auditable, so if anything ever gets called into question there is an audit trail that the Healthlink team can look back on.

• How long is each remote monitoring visit (RMV)?

Each RMV is capped at 5 days. The system will generate an error message if the coordinator tries to release subject records for longer than 5 consecutive days. After 5 days (or shorter if set for less time by the study team), the subject records will no longer be able to be seen by the monitor. This ensures the CRAs' access is limited to the dates specified for the RMV.

• Is there a way to undo release of a subject for monitoring? For example, if we learn that a monitor doesn't need to review screen fails, how would we remove their access from those patients, so that we can minimize PHI access?

Yes, if you need any records unreleased prior to the expiration (duration when remote access to the subject records is available to the CRA) please e-mail the CTSI ORA at <u>ctsiora@mednet.ucla.edu</u>.

How long is the EMR and e-regulatory access valid?

Once provisioned, the monitor will have approved access to the system for up to one year, that can be renewed annually for the life of the study or up until the monitor is no longer associated with the study, whichever happens first.

How often can monitors schedule these RMVs?

Monitors can schedule RMV as many times as necessary depending on the study teams' availability. Once the monitor has access to the study, they should communicate with the study team to schedule RMVs. The study team connects the subject records to the study monitor and sets the remote review dates based on the mutually agreed upon remote monitoring dates.

Once approved to remote monitor, how would monitors go about scheduling these RMVs?
The local team would handle the scheduling of the monitoring and connecting of subjects with the monitoring
visit. Once the CRA has EMR access, they should reach out to the study team to schedule remote monitoring
visits. Once they mutually agree to the dates, the study personnel authorized to release subject records will go
into the system to release subject records for that particular remote visit. Subject records may be released for



review for up to a max of 5 days. If the remote visit is only scheduled for 2 days, the release of records can be restricted to only those 2 days or as many days as the visit is scheduled for, but may not exceed 5 consecutive days. The system will generate an error message when attempting to release records beyond 5 days.

- Once in-person monitoring visits are re-instated, will CRAs lose access to the remote EMR? There are no current plans to stop remote visits.
- What does the HealthLink monitoring training for CRAs entail? It is an online training for CRAs on navigating HealthLink. It is pretty quick and easy to complete. The study team will be provided with a tip sheet that they can use to link the subject to the RMV and release records to the CRA for remote review.
- What does the eBinders monitoring training for CRAs entail? It is an online training for CRAs on navigating eBinders. It is quick and easy to complete. The study team will be provided with a tip sheet that they can use to release study documents to the CRA for remote review.
- Does the Remote monitoring access include the use of Box or any other systems to share files that wouldn't normally be in CareConnect (such as questionnaires or regulatory files)? Documents that are not in CareConnect can be redacted for subject identifying information and uploaded to the UCLA Health Box system. You must limit the monitor's view to read only. The ORA office is not involved in this process. If there is staff time on your end for setting this up, you will need to discuss those charges separately with the sponsor.
- If a monitor has already been provisioned for a study (eg. study A) and is now requesting access to another study (study B), are they are required to provide the signed forms again? Additional signed forms are not needed. However, the \$2625 additional monitor fee will apply to this type of request.
- Do the additional monitor fees still apply to CRAs that are being replaced/no longer with the company? Yes, the fee applies even if the CRA is being replaced for the study.
- How long does the remote monitoring provisioning process take? The process typically takes 8-12 business days once the remote monitoring agreement has been executed.

On-Site Monitoring

Health System Space

• What is SEC³URE GO!?

SEC³URE GO! is a wearable, digital badge that combines mobile check-in with visitor identification. It visually displays the user's compliance status for all facility staff to see.

• Who can use SEC³URE GO!? Any commercial and clinical visitors to your facility can use it, including sponsor monitors, clinical contractors, physicians, and nurses. However, they will need a current SEC³URE Passport to be eligible for the badge.

• What does the SEC³URE GO! check-in process look like for the monitor?





- I didn't receive the email to set up my login to the SEC³URE GO! platform. What do I do? Contact customer service at 817-SEC3URE or 817-732-3873
- Additional monitors need access to the SEC³URE GO! platform. How do I get them set up? Contact customer service at 817-SEC3URE or 817-732-3873
- What is the SEC³URE GO! cost per monitor? \$334/year
- If a monitor works at more than one facility, do they have to register at all locations, or does one registration cover all locations? One registration covers all locations.
- What is the Contact/Support Information? Customer service – 817-SEC3URE or 817-732-3873
- What are the standards and requirements for all users:



Research Personnel - no patient area access (Emp/Staff interactions only) with access to Facility

Vaccination & Medical Credentials Required		Community %	Kiosk Enforcement Date
Chicken Pox [?]		11%	2022-05-11
COVID-19 Vaccine [7]	Accept Declination: COVID-19 Vaccine Declination Form	44%	2021-09-01
Hepatitis B [?]	Accept Declination: Hepatitis B Declination Form	10%	2022-05-11
MMR - Measles, Mumps and Rubella [?]	Accept Declination: MMR Attestation of pre-1957 birth date in lieu of shots	11%	2022-05-11
Seasonal Flu Vaccine [?]	Accept Declination: Influenza Declination Form in lieu of Flu Shot	34%	2020-10-31
🗹 Tdap [?]		7%	2022-05-11
Tuberculosis [?]	Low Risk (Single TB Test)	26%	2022-05-11
Insurance & Legal Credentials Required		Community %	Kiosk Enforcement Date
General Liability Insurance [7]		27%	2022-03-15
Competency & Certification Credentials Required		Community %	Kiosk Enforcement Date
COVID-19 Attestation [7]		13%	2022-05-13
Employer Competency Statement/Skills Checklist [?]		24%	
Background Check Credentials Required		Community %	Kiosk Enforcement Date
Criminal Background Check [?]	Accept Company Attestation [7]	26%	2022-05-11
Drug Screen [7]		7%	2022-05-11
Coffice of Foreign Assets Control (OFAC) Check [7]		20%	2022-05-11
Coffice of Inspector General (OIG) Check [?]		27%	2022-05-11
Profile Photo [7]		78%	2013-07-01
System Award Management (SAM) Check [7]		25%	2022-05-11
Training Credentials Required		Community %	Kiosk Enforcement Date
Aseptic Techniques Training [7]		22%	2022-05-11
Bloodborne Pathogens Training [7]		7%	2022-05-11
Electrical Safety Training [?]		3%	2022-05-11
Fire Safety Training [?]		3%	2022-05-11
HIPAA Training [7]		28%	2022-05-13
National Patient Safety Goals Training [?]		4%	2022-05-11
Environmental Exposure Credentials Required		Community %	Kiosk Enforcement Date
Radiation Safety Training [?]		3%	2022-05-11

Non-Health System Space

- What are the links for non-health system requirements for visitors?
 - UCLA Information for Visitors
 - UCLA Safety and Masking Guidance
 - UCLA Patients/visitors/vendors Visitation Guidance
 - UCLA Visitor Guidance
 - UCLA Health Temperature and Symptom Screening Guidelines

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