

SCI-CTO Monitoring Guidelines

****This general rule document refers to monitoring and audit****

MedLink Monitor Accounts (New and Renewal)

- 1. Monitor must have an approved MedLink account prior to making a Monitor Reservation for both Remote and On-Site monitoring.
- 2. Submit the MedLink attestation form for a new monitor through REDCap at least 30 calendar days prior to the monitoring event to ensure access is granted on time. Please note it takes up to 14 calendar days to process and approve a new monitor's MedLink account and another 14 calendar days for record release.
- 3. MedLink accounts for monitors must be renewed annually. A new attestation form must be signed and submitted as a "Renewal of Previous Monitor Application" through REDCap. Please submit 30 calendar days prior to the expiration date for no interruption to MedLink access for the monitor. Please note if a monitor does not sign in to MedLink for a year, their account is suspended.
- 4. There is no limit on how many monitors can be assigned to a study at a given time, as long as a MedLink attestation form has been submitted and the monitors have been approved for a MedLink account.
- 5. If a Monitor is no longer monitoring at Stanford please submit a request "Termination of Monitors Access". Once access to a monitor has been terminated it can be reinstated but submitting a "Renewal of Previous Monitor Application" through REDCap.
- 6. MedLink Monitoring Report available in OnCore with all current and previous monitor's contact information and MedLink account expiration date.
- 7. For log-in issues or to reset a monitor's MedLink account password, please contact the SHC IT Service Desk at 650-723-3333.

Record Release for Approved Monitor

- 1. 14-day window submission policy- All Record releases must be submitted 14 calendar days prior to the Monitoring event.
- 2. A maximum of 16 MRNs per Record Release. No More than a total of 16 MRNs per monitoring event.

SCI-CTO Monitoring Guidelines

****This general rule document refers to monitoring and audit****

- 3. For questions, concerns, or corrections to an already submitted Record Release please start a NEW email to scicto-monitoring@stanford.edu and provide your Record ID. Do not respond to automated email notifications.
- 4. SCI-CTO approval of Record Release can occur up to one month prior to the monitoring event. HIMS record release usually occurs anywhere between one to two business days prior to the monitoring event. Notifications will be sent once the record release has been approved and when records have been set to be released.

Monitoring

- 1. No more than 5 consecutive business days for a monitoring event, anything above 5 business days will require approval from SCI-CTO Monitoring.
- 2. No co-monitoring is allowed. All requests for co-monitoring must be approved by SCI-CTO Monitoring prior to making a monitor reservation and is case by case. No co-monitoring is allowed for oversight or training purposes.
- 3. If co-monitoring is approved and the monitoring event is on-site the additional monitor must monitor remotely. One co-monitoring session is allowed over a 3-month time period.
- 4. Visit Cancellations – If the monitoring event needs to be canceled, please submit a “Visit Cancellation” through REDCap. This notifies all teams involved in the record release process.

Routine Monitoring

- 1. Approved monitors will have read-only access to patients’ EMR through MedLink between 5:00 AM to 8:00 PM PST on their scheduled monitoring days.
- 2. No International monitoring is allowed. All EMR access through MedLink must be within the US. Access will be denied by SHC IT if an attempt is made outside the US.

SCI-CTO MedLink Guidelines

****This general rule document refers to monitoring and audit****

Audits

- 1. A maximum of 16 MRNs per Record Release. No More than a total of 16 MRNs per auditing event.

- 2. Co-monitoring is allowed for Audits with a maximum of two monitors on-site at any given time.

- 3. 14-day window submission policy- for audits if the 14-day submission window is unable to be met please contact us directly at scicto-monitoring@stanford.edu