Sponsor Monitoring and Auditing for Clinical Research Studies

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For clinical research studies where a study sponsor is obligated by the FDA to monitor study source records, sponsors may be provided monitoring capability through one of three mechanisms:

1. Remote monitoring through HealthLink (a module within UCLA's CareConnect Electronic Health Records System) for CareConnect related source records, eBinders for regulatory documents, and UCLA's secure instance of Box.com for source documents not stored in CareConnect;
2. Remote monitoring through UCLA's secured instance of Zoom video conferencing facilitated by the principal investigator and research team; and/or
3. Safe and compliant on-site monitoring facilitated by the principal investigator & research team as outlined by the following procedures and/or policies (links may require UCLA AD login):
    - UCLA Safety and Masking Guidance
    - UCLA Patients/visitors/vendors Visitation Guidance
    - UCLA Visitor Guidance
    - UCLA Health Temperature and Symptom Screening Guidelines

Remote monitoring through HealthLink requires both, a Remote Monitoring Agreement facilitated by Clinical Trial Contracting & Strategic Relations (CTC-SR), as well as budget allocations for applicable Remote Monitoring Set-Up and Provisioning Fees (referenced below) for each sponsor-monitor provisioned with remote monitoring access. The institutional remote monitoring agreement and applicable remote monitoring fees have been standardized to streamline remote monitoring setup and mitigate negotiation. The option for remote monitoring may be made available prospectively during contract negotiations for new clinical trial agreements received by CTC-SR as of October 1, 2020. For existing studies, a process has been established to prioritize study teams and sponsors requiring remote monitoring access with the limited resources available to support remote monitor contracting, set-up and provisioning. For more information, please contact CTSIORA@mednet.ucla.edu.

Remote monitoring of regulatory documents through eBinders requires budget allocations for applicable Remote Monitoring Set-Up and Provisioning Fees (referenced below) for each sponsor-monitor provisioned with remote monitoring access. The remote monitoring fees have been standardized to streamline remote monitoring setup and mitigate negotiation.

For source and study documents stored external to CareConnect, such documents should be redacted appropriately of participant Protected Health Information (PHI) and uploaded to UCLA secure Box.
Remote Monitoring for sponsors through Zoom is to be facilitated by the research team. Monitoring language in existing clinical trial agreements would typically not require modification to enable Zoom-based monitoring. Should you have industry clinical trial contract related questions please contact Tamika Merrick, Director of CTC-SR at TMerrick@mednet.ucla.edu.

On-site Monitoring has traditionally been the primary method for sponsor monitoring of clinical trials at UCLA. However, on-site monitoring should be limited to only rare instances when the remote monitoring arrangements referenced in (1) and (2) above cannot be achieved with sponsor(s).

- On-site monitoring can occur in space where the on-site monitoring access is deemed essential to comply with applicable laws and study teams and monitors strictly adhere to the appropriate UCLA health **visitor** requirements. Investigators must obtain Department Chair or Division Chief (or designee) written approval permitting the request for an on-site visit.

For research studies where a study sponsor is NOT obligated by the FDA to monitor/audit the study source records, sponsors are generally not allowed to conduct monitoring of study records. Sponsors may request a special exception with the Office of Compliance. If approved, sponsors may only conduct monitoring through the remote access process. **Remote monitoring set-up and provisioning fees may include, but are not limited to, facilitation of the following tasks:**

- Remote monitoring terms and obligations contract review and execution with study sponsor(s) and CRO(s) for each applicable clinical research study.
- Study-specific statement of work defining scope and effective timeline for provisioning.
- Individual study monitor terms and obligations agreement review and completion.
- UCLA Healthlink Electronic Health Record (EHR) user access application review and completion.
- Remote study monitor provisional access application completion.
- Remote study monitor online training – scheduling, facilitation, and completion.
- Remote study monitor approval and access provisioning.
- Remote study monitor virtual visit scheduling and research participant linking to Healthlink.
- Remote monitoring use and access compliance – tracking, auditing, maintenance and reporting.

Monitors may not in any way divulge, save, copy, print, record, photograph, download, export, screenshot, release, sell, loan, alter and/or destroy any PHI except as permitted by law and properly authorized by the policies of the Participant. Any breach of the responsibilities and/or conditions of the terms of access may be subject to access suspension, employer notification and disciplinary action, and may be subject to civil and/or criminal charges, as applicable. Reinstatement of suspended access will be subject to the requirements, training and fees associated with new user access, as determined at UCLA's discretion.

Please see the "UCLA Clinical Research External Monitoring & Auditing Policy HS 9207" for more information.

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

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 https://uclahs.az1.qualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI:

1. Monitor eBinders Request Form
2. eBinders Training Certificate

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

Please see the charge master for current rates for access provisioning.

***Provisioning cannot be completed until all forms and certificates are submitted. Please submit all documents at one time. Incomplete applications will be returned.**

****Monitors will only be provisioned for studies listed on the application form.**

*****Monitors provisioned for eBinders only first, will be charged the full monitor rate should they later need access to HealthLink.**

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