COVID-19 Information

- General Information for UCLA Faculty and Staff
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- Sponsor Monitoring and Auditing for Clinical Research Studies
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- Information for Patients and Visitors
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COVID-19 General Information for UCLA Faculty and Staff

a. General Information for Faculty - https://covid-19.ucla.edu/information-for-faculty/

b. General Information for staff - https://covid-19.ucla.edu/information-for-staff/

c. **The CTSI Clinical Research** COVID-19 help desk mailbox for general research questions

d. CDC link for Healthcare Professionals https://www.cdc.gov/covid/hcp/index.html

e. **UCLA Health Sciences COVID-19 Onsite Training Guidelines** - https://covid-19.ucla.edu/training-required-on-covid-19-for-all-employees/

f. **UCLA Requirements for COVID-19 Symptom Monitoring** - https://covid-19.ucla.edu/covid-protocols-at-a-glance/

g. **Universal Masking guidance** - https://mednet.uclahealth.org/n6-mednet/faa2a7d789f7cd49/uploads/sites/6/2020/04/Universal-Masking-WEB-4-15-20.pdf

h. UCLA Requirements for COVID-19 Symptom Monitoring for Staff and Faculty https://www.adminvc.ucla.edu/covid-19/ucla-employee-faq/symptom-monitoring

i. IRB Guidance - COVID-19 (SARS-CoV-2) and Human Subjects Research FAQ - https://ohrpp.research.ucla.edu/covid-19-human-subjects-research-faq/

j. COVID-19 Policy Governance at UCLA - https://covid-19.ucla.edu/

k. **DGSOM Town Halls and Task Forces** - https://covid-19.ucla.edu/

Last updated: 12 Sep 2024

COVID-19 Information for Faculty -
https://covid-19.ucla.edu/information-for-faculty/

a. **Funding Information**

i. **Funding channels to support COVID-19 research** -
https://medschool.ucla.edu/coronavirus-information/covid-19-research-funding

ii. U**CLA Office of Contract and Grant Administration COVID-19 Updates Related to Sponsored Research** - https://ocga.research.ucla.edu/covid-19/

iii. **Charging grants and contracts costs to Federal sponsored awards during COVID-19** -
https://ocga.research.ucla.edu/covid-19/

b. **Information on classes, remote instruction, campus research, leave options and other faculty-related topics** - https://covid-19.ucla.edu/information-for-faculty/

Last updated: 29 Oct 2026

Sponsor Monitoring and Auditing for Clinical Research Studies

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.**

Last updated: 8 Jul 2026

COVID-19 Information for Research

a. **ORA COVID-19** https://medschool.ucla.edu/ora

b. U**CLA Office of Contract and Grant Administration COVID-19 Updates Related to Sponsored Research** - https://ocga.research.ucla.edu/

c. **Charging grants and contracts costs to Federal sponsored awards during COVID-19** - https://ocga.research.ucla.edu/covid-19/

d. **IRB Guidance** - COVID-19 (SARS-CoV-2) and Human Subjects Research FAQ - https://ohrpp.research.ucla.edu/covid-19-human-subjects-research-faq/

Last updated: 29 Oct 2026

COVID-19 Information for Patients and Visitors:

a. COVID-19 updates - https://covid-19.ucla.edu/updates/

b. I**nformation for Patients & Visitors** - https://www.uclahealth.org/coronavirus

c. Clinical Trials & Research Studies - https://www.uclahealth.org/coronavirus

d. COVID-19 Visitor Guidelines - https://www.uclahealth.org/covid-19-visitor-restrictions

e. COVID-19 FAQs for the community - https://www.uclahealth.org/conditions-we-treat/covid-19-info/faq

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Remote and Onsite 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 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.***

- **What is the remote monitoring set up fee for the combination of HealthLink and eBinders?**
  Please see the current charge master for the most up to date fees.
- **Is the fee a one-time fee, or is it per remote monitoring visit (RMV)?**
  Yes, it 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 fee. The additional fee 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?**
  Please see the current charge master for the most up to date fees.
- **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 https://uclahs.az1.qualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI:
  1. ????Monitor eBinders Request Form
  2. eBinders 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 ctsiora@mednet.ucla.edu.
- **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 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 Health System Space?**

  "UCLA Health System Space" is any location owned or operated by UCLA hospitals and/or UCLA outpatient clinics, managed by either the UCLA Hospital or UCLA Faculty Practice Group utilized to provide clinical care to UCLA patients. This includes, but is not limited to, Ronald Reagan UCLA Medical Center, Santa Monica Medical Center, UCLA Orthopaedic Surgery, Resnick Neuropsychiatric Hospital, ambulatory sites, and the UCLA Faculty Practice Group.

  More information to come.

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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Source URL:https://www.researchgo.ucla.edu/covid-19-information?qt-view__vertical_tab_section__block_27=2

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