

[COVID-19 Information](#)

- [General Information for UCLA Faculty and Staff](#)
- [Information for Faculty](#)
- [Sponsor Monitoring for Clinical Research Studies](#)
- [Information for Research](#)
- [Information for Patients and Visitors](#)
- [Remote Monitoring FAQs](#)

COVID-19 General Information for UCLA Faculty and Staff

- a. General Information for Faculty** - <https://medschool.ucla.edu/coronavirus-information/faculty>
 - b. General Information for staff** - <https://medschool.ucla.edu/coronavirus-information/staff>
 - c. The CTSI Clinical Research [COVID-19 help desk mailbox](#)** for general research questions
 - d. Strategic mobilization to address a global pandemic** - <https://medschool.ucla.edu/coronavirus-information/research>
 - e. CDC link for Healthcare workers testing overview**
(https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Fclinical-criteria.html)
 - f. UCLA Health Sciences COVID-19 Onsite Training Guidelines** - <https://medschool.ucla.edu/workfiles/COVID-19%20Onsite%20Training%20Guidelines%202020-08-15%20Clean%20PDF.pdf>
 - g. UCLA Requirements for COVID-19 Symptom Monitoring** - <https://medschool.ucla.edu/coronavirus-information/ramp-up-faqs>
 - h. Universal Masking guidance** - <https://mednet.uclahealth.org/n6-mednet/faa2a7d789f7cd49/uploads/sites/6/2020/04/Universal-Masking-WEB-4-15-20.pdf>
 - i. UCLA Requirements for COVID-19 Symptom Monitoring for Staff and Faculty**
<https://www.adminvc.ucla.edu/covid-19/ucla-employee-faq/symptom-monitoring>
-

j. DGSOM Town Halls and Task Forces -

<https://medschool.ucla.edu/coronavirus-information/covid-communication/town-halls-and-task-forces#TH>

k. IRB Guidance - COVID-19 (SARS-CoV-2) and Human Subjects Research FAQ -

<https://ohrpp.research.ucla.edu/covid-19-human-subjects-research-faq/>

l. COVID-19 Policy Governance at UCLA - <https://medschool.ucla.edu/coronavirus-information/covid-19-policies>

Last updated: 26 Aug 2022

COVID-19 Information for Faculty -

<https://covid-19.ucla.edu/information-for-faculty/>

a. Funding Information

i.

COVID-19 Research Grant Program: Health Equity, Clinical, Translational, and Basic Science Research - <https://medschool.ucla.edu/coronavirus-information/covid-19-research-grant-program>

ii.

Funding channels to support COVID-19 research -

<https://medschool.ucla.edu/coronavirus-information/covid-19-research-funding>

iii.

UCLA Office of Contract and Grant Administration COVID-19 Updates Related to Sponsored Research - <https://ocga.research.ucla.edu/covid-19/>

iv.

UCOP FAQs - Extramural sponsors and UC have issued various guidance and policies related to the impacts of COVID-19 on sponsored projects - <https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/coronavirus/frequently-asked-questions.html>

v.

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

b. Oversight Committees

i.

COVID-19 Oversight Research Committee (OCRC) -

<https://medschool.ucla.edu/coronavirus-information/operations-and-governance>

ii.

Scientific Prioritization and Feasibility Committee for Approval of COVID 19 Research (SPFC)-

<https://medschool.ucla.edu/coronavirus-information/research/governance/spfc>

iii.

ORA COVID-19 - <https://medschool.ucla.edu/oraCOVID-19>

Policy Governance at UCLA - <https://medschool.ucla.edu/coronavirus-information/covid-19-policies>

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

Last updated: 26 Aug 2022

Sponsor Monitoring for Clinical Research Studies

For clinical research studies where a study sponsor is obligated by the FDA to monitor study source records, sponsors may now 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, and UCLA's secure instance of Box.com for source/study 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 Research Ramp Up Plan and UCLA Health Visitor Policies](#)
 - [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. 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, as a result of the COVID-19 pandemic and the remote monitoring mechanisms referenced above, 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 only occur at this time in Non-UCLA Health (Departmental or School 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 health and safety precautions and expectations as outlined by the

[UCLA Research Ramp Up Plan and UCLA Health Visitor Policies.](#)

Remote Monitoring Fee Schedule (Direct Costs)
Fee Classification
Per Study, Per Monitor, Per Visit
Industry Funded Clinical Research Study

"Please note: all fees above are subject to the applicable UCLA indirect rate(s)."

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.

Last updated: 26 Aug 2022

COVID-19 Information for Research – Onsite Ramp-up

- GUIDANCE & RESOURCES FOR THE UCLA COMMUNITY ABOUT HOW TO SAFELY RAMP UP ONSITE RESEARCH ACTIVITY DURING COVID-19** - <https://www3.research.ucla.edu/research-ramp-up>
- Onsite ramp-up resources and FAQs** - <https://medschool.ucla.edu/coronavirus-information/ramp-up-faqs>
- REGISTER YOUR COVID-19 RESEARCH PROJECTS** - <https://medschool.ucla.edu/coronavirus-information/universal-intake-process>

- d. **COVID-19 Oversight Research Committee (OCRC)** - <https://medschool.ucla.edu/coronavirus-information/operations-and-governance>

- e. **Scientific Prioritization and Feasibility Committee for Approval of COVID 19 Research (SPFC)**- <https://medschool.ucla.edu/coronavirus-information/research/governance/spfc>

- f. **ORA COVID-19** <https://medschool.ucla.edu/ora>

- g. **UCLA Office of Contract and Grant Administration COVID-19 Updates Related to Sponsored Research** - <https://ocga.research.ucla.edu/>

- h. **UCOP FAQs** - Extramural sponsors and UC have issued various guidance and policies related to the impacts of COVID-19 on sponsored projects - <https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/coronavirus/frequently-asked-questions.html>

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

- j. **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: 26 Aug 2022

COVID-19 Information for Patients and Visitors:

- a. **COVID-19 CLINICAL RESEARCH NAVIGATOR:** UCLA Health and DGSOM are pleased to announce the availability of a COVID-19 Clinical Research Navigator. The navigator is available to assist UCLA Health patients who have recently (**within 72 hours**) tested positive and would like to hear more about COVID-19 clinical trials and observational studies available to them and their exposed close contacts. Laurie Shaker-Irwin at ClinicalResearchC19@mednet.ucla.edu or call 424-440-3722.

 - b. **COVID-19 updates** - <https://covid-19.ucla.edu/updates/>

 - c. **Information for Patients & Visitors** - <https://www.uclahealth.org/coronavirus>

 - d. **Clinical Trials & Research Studies** - <https://www.uclahealth.org/coronavirus>

 - e. **COVID-19 Visitor Guidelines** - <https://www.uclahealth.org/covid-19-visitor-restrictions>
-

f. COVID-19 FAQs for the community - <https://www.uclahealth.org/covid-19-faqs>

Last updated: 26 Aug 2022

- **What is the Remote monitoring set up fee?**

For Industry (for profit) funded studies the cost is \$2500 per study. The \$2500 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 \$2000.

- **Is the \$2500 a one-time fee, or is it per remote monitoring visit (RMV)?**

Yes, the \$2500 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 \$2000. An additional \$2000 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.

- **Are the signed forms (healthlink user access form, confidentiality statement form 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.

- **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?**

No, It is not required. The study team/Sponsor/CRO contact should e-mail Uma Ganapati at uganapati@mednet.ucla.edu requesting access for the monitor for the additional study and provide the following information:

- i. Name of the previously provisioned monitor
- ii. IRB# for the study they are requesting access to.

If the study has a fully executed remote monitoring agreement, the provisioning process will be initiated immediately.

- **Do clinical research coordinators need to be trained to provide access to specific patients during the specified time frame?**

Once the CRAs EMR access is provisioned, the study team will be provided with a tip sheet that the clinical coordinators can refer to, for help releasing subjects. There is no additional training.

- **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' EMR 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 Uma Ganapati at uganapati@mednet.ucla.edu. A ticket will be opened and assigned to the CC Link team. It is a tool the Healthlink team can run on the backend.

- **How long is the EMR 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 RMV. 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 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.

- **Does the Remote monitoring access include the use of Box or any other systems to share files that wouldn't normally be in CC (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.

Last updated: 26 Aug 2022

Last updated: 29 Aug 2022

Source URL: https://www.researchgo.ucla.edu/covid-19-information?qt-view_vertical_tab_section_block_27=4

Drupal.jQueryUiFilter.globalOptions('accordion');