COVID-19 Information

DGSOM is pleased to announce the latest development in their COVID-19 research mobilization effort and UCLA's ongoing response to the coronavirus pandemic. Included here is information for Faculty, Staff, and Patients. The Universal Intake requesting COVID-19 research funding and resources is a three-step process includes registering a project, confirming and saving the registration number and requesting resources. Begin registration here.

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: 15 Oct 2020

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. U**CLA 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/

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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

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.

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COVID-19 Information for Research – Onsite Ramp-up

a. **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

b. Onsite ramp-up resources and FAQs - https://medschool.ucla.edu/coronavirus-information/ramp-up-faqs

c. 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. U**CLA 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/

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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. I**nformation 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

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- Group 1
  - Clinical Research Information Systems
  - Clinical Research Business Partners
- Group 2
  - Office of Research Administration
  - Jonsson Comprehensive Cancer Center
- Group 3
  - Office of Human Subjects Protection
  - CareConnect Website

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

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