COVID-19 Information

DGSOM is pleased to announce the latest development in their COVID-19 research mobilization efforts: A universal intake process for registering COVID-19 research projects and requesting COVID-19 research funding and resources. The Universal Intake three-step process includes registering a project, confirming and saving the registration number and requesting resources. Begin registration here.

- COVID-19 - Updates 2020
- Scientific Prioritization and Feasibility Committee for COVID Clinical Research
- COVID-19 FAQs for Clinical Research
- COVID-19 Info for Monitors and CROs
- Clinical trial opportunities for COVID-19+ Patients

- The CTSI Clinical Research COVID-19 help desk mailbox is now live. This mailbox will help capture, facilitate, and answer questions related to COVID-19 research.
- For those of you who have studies interests related to COVID-19, please register them using the following link: Covid-19 New Study Registration
- For those of you who have some capacity and time to contribute to COVID-19 research, please register yourself using the following link: Covid-19 Study Staff Support Registration

EFFECTIVE MARCH 16, 2020

UCLA is issuing a temporary policy related to human subjects-related research visits. This policy is being implemented to protect participants, researchers, and the larger UCLA Health community from risk of infection from COVID-19 as well as to ensure ongoing access to research which may provide essential support and care to participants.

In-person research visits should NOT be conducted unless the specific research visit provides an immediate benefit to a participant's health and/or well-being.

- This policy does not apply to IRB-approved study activities that do not involve direct participant/subject contact (e.g. chart reviews, online surveys, remote interviews).
- This policy does not apply to IRB-approved study activities that occur during the course of ongoing clinical visits or care.

For these study designs:	Does the specific research visit *'provide an immediate benefit to a participant's health and/or well-being,'* thus supporting in-person visits?		
	These visit types LIKELY "provide immediate benefit" (supports an in-person visit)	These visit types MAY OR MAY NOT "provide immediate benefit" (Support for in-person visit will depend on specifics of the study)	These visit types LIKELY DO NOT "provide immediate benefit" (does not support an in-person visit)
Randomized controlled efficacy trial (e.g., phase IIb or III) of a potential drug or device or other intervention	New enrollments/Follow-ups		
Post-approval trial (e.g., phase IV) of a therapeutic drug, device, or other intervention to assess tolerability and/or long-term benefit	Follow ups	New enrollments	
Early phase (e.g., phase I or IIa) pharmacodynamic, safety, tolerability or feasibility trial a potential drug or device or other intervention	Follow ups	New enrollments	
Non-randomized interventional trial of a drug, device, or other intervention requiring safety monitoring	Follow ups	New enrollments	
Non-randomized interventional trial of a drug, device, or other intervention not requiring safety monitoring		New enrollments/Follow-ups	
Comparative effectiveness studies or other study types describing the natural history of disease or other clinical outcomes		Follow ups	New enrollments
Non-interventional qualitative study			New enrollments/Follow-ups
Non-interventional study with collection of clinical data and/or biological specimens for future research			New enrollments/Follow-ups

Participants

- Participant research visits should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible. Any deviation from an approved IRB protocol must be approved by the IRB unless such change is necessary to eliminate an apparent immediate hazard.
- Research visits that cannot be performed remotely and do not provide an immediate benefit to a participant's health and/or well-being should be postponed until further notice.
- Currently, the determination of whether or not a research visit provides an immediate benefit to the health and/or well-being of a participant is determined by the principal investigator of the research study, the participant, and the participant's care provider, and should be informed by current public health guidance regarding the COVID-19 outbreak.
- Research visits that cannot be performed remotely and are essential (provide immediate benefit) to a participant's health and/or well-being may be performed in person, with the following additional guidance:
- Research participants should be contacted a few days prior to their visit by study personnel to be (1) informed about measures being taken at UCLA to protect visitors/subjects against coronavirus https://www.uclahealth.org/coronavirus#what-you-should-know & https://mednet.uclahealth.org/n6-mednet/cfce1d3cb637a460/uploads/sites/5/2020/03/Nurses-RN_Script_COVID_19_030420.pdf, and (2) screened for fever, cough and recent travel (same screening being performed in clinics).
- Please evaluate the participant based on the CDC criteria for evaluating and reporting Persons Under Investigation (PUI). https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html Subjects who are PUI should avoid research visits until cleared by their primary care provider.
- If a study team encounters a study participant that they are concerned has COVID-19, they should follow the flow chart at the following web-site with regard to whether to contact the EID Physician On-Call: https://mednet.uclahealth.org/n6-mednet/cfce1d3cb637a460/uploads/sites/5/2020/03/Lab_Testing_Phase-3_COVID-19_Criteria_3-10-2020_updated.pdf
- Research studies may be halted if staff, protective equipment, or other required equipment is unavailable.

Research Personnel

- Study team-participant interaction should be restricted only to essential staff.
- Volunteers should avoid direct patient or study participant interaction (please check with the volunteer office)
- The use of work-study students should be minimized to reduce the community risk.
- Principal Investigators should have plans in place to manage their studies should their research staff be placed in isolation.
- Research PIs and staff should follow the Information for staff and providers on the UCLA Health website: https://www.uclahealth.org/coronavirus
- Please contact your departmental CAO. If departmental resources are unavailable, please contact the CTSI Office of Clinical Research to determine if there are resources to help backfill if staff are unavailable.
- Please work with any study monitors/auditors traveling from a US state where a state of emergency has been declared and/or from a CDC Level 2 or 3 country to either postpone the visit or conduct remote reviews.

Changes to Approved Research

All changes/modifications to any research protocols continue to require review and approval by the IRB except for the incorporation of screening for exposure to COVID-19 as well as any measures needed to avoid an immediate apparent hazard to a patient/participant. The incorporation of a COVID-19 screening procedure does NOT require IRB approval. If a research protocol requires a modification, due to COVID-19 implications, that needs to be submitted to the IRB for review and approval, please contact the UCLA OHRPP office directly so those submissions can be triaged in an expeditious manner.

Last updated: 22 May 2020

Section 1: Review Scope: For COVID studies that require UCLA Health System Resources:

(1)Access to the suspected and confirmed UCLA Health COVID-19 patients

(2)Access to the electronic medical record chart or data of those patients

(3)Access to the remnant or research biospecimen collection of those patients

(4)Planning any clinical research interventional trial (drug/device) for those patients

(6) COVID Population-based studies that overlap the UCLA Health population or UCLA healthcare workers.

Rationale: UCLA Health will require a rapid review to assess scientific priority, operational feasibility, and data/specimen centralized coordination. This review is required given:

(A)The increasing number of competing and overlapping studies being submitted to the IRB.

(B)The desire to protect the privacy of our COVID-19 patients, many of whom are UCLA employees.

(C)The limitation on personal protective equipment.

(D)Reduced operational resources during this crisis.

(E)Limited bio-specimen availability.

Section 2: Procedure

1.The IRB will flag COVID-19 trials for review at the time of submission. Studies with existing IRB approval should complete the study submission form:

2.The committee will be asked to review material by email and meet ad-hoc as needed to ensure the most expedited review possible.

3.The scientific review committee will review and prioritize the study assessing operational feasibility as well as population, data and biospecimen requirements.

4.Recommendations will be made to the COVID-19 Clinical Research Task Force

5.Initial Issues and concerns associated with the review can be escalated to Drs. Currier and Naeim who are heading the COVID-19 Clinical Research Task Force.

6.Further escalation and final decision-making authority will rest with the Research COVID Oversight Committee

General scientific review committee	**Clinical Trial Prioritization Subgroup**	**Ex-Officio**
1. John Belperio: **Chair** (Pulmonary)	(A)Judith Currier	Arash Naeim (Operations)
2. Jennifer Fulcher (Infectious Disease)	(B)Steve Dubinett	Dawn Ward (Lab)
3. Noah Federman (CTSI)	(C)Otto Yang	Eric Cheng (ISS/Data)
4. Paul Boutros (Cancer Center)	(D)Tisha Wang	Pamela Miller (Nursing/Hospital
5. Clara Lajonchere (IPH)	(E)Steve Chang	Kristin Craun (IRB)
6. Holli DeVon (Nursing)	(F)Paul Krogstad	
7. Chris Denny (Pediatrics/Lab)		
8. Moira Inkelas (Public Health)		
9. David Elashoff (Biostatistics)		
10. Joann Elmore (GIM-HSR)		
11. Neil Wenger (GIM-HSR, Ethics)		

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PLEASE DO NOT CONTACT COMMITTEE MEMBERS DIRECTLY TO AVOID A PERCEPTION OR REAL CONFLICT OF INTEREST. Please contact ctsisrc@mednet.ucla.edu if you have questions.

Last updated: 10 Apr 2020

1. Are investigators with clinical trial protocol violations due to their own institution's research policy changes (e.g., required remote visits, required postponement of non-essential visits) required to report these violations to the IRB?

For protocol deviations, that are due to Institutional policy changes, that do not impact subject safety, compromise the integrity of study data and/or affect the subjects willingness to participate in the study do not require prior IRB review and approval or reporting. For example study visits needs to be cancelled, postponed or rescheduled, performing adverse event assessments for the phone or online, or having labs drawn at a local facility do not need to reported individually, but should be documented on a protocol deviation log and submitted at the time of continuing review. Please see updated PAR guidance for additional information. If reporting of the above is required, how is the IRB requesting reporting of violations be performed? For protocol deviations/violations that do not impact subject safety should be documented on a protocol deviation log and reported at the next continuing review.

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2. If my study is minimal risk and not subject to continuing review how should protocol deviations/violations be reported?

For protocol deviations/violations on minimal risk studies do not impact subject safety those should be documented on a protocol deviation log which should be maintained and available for IRB review as requested.

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3. If I want to submit a proposal involving treatment protocol for COVID-19 population what additional information should I include in my protocol for the IRB to consider?

Given the potential for multiple trials and alternative therapies in completing clinical protocols, please provide in your protocol defined inclusion and exclusion criteria, clear instructions regarding how you intend to identify and recruit potential participants, how the researcher will determine to which protocol a potential participant may be enrolled, what potential alternative treatments are available, how these potential treatments are communicated to the potential participant, any potential inclusion of the treatment provider in making determinations regarding enrollment, and how enrollment into one study or another may be prioritized within a department or research group. Depending on the inclusion criteria (the stage of disease progression at enrollment), consider whether or not a potential participant may be temporarily incapacitated (for example, intubated in the ICU) necessitating the use of a legally authorized representative for consent. The IRB must review (in advance) the possible inclusion in research of adults with impaired decision-making capacity.

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4. I received a memo from the Sponsor indicating they will allow flexibility on how follow-up visits are conducted. Do I need to submit this to the IRB?

No. The memo itself does not need to be submitted. However, if you plan to operationalize these flexibilities AND these flexibilities are disallowed in the study application, the changes should be submitted/reviewed/approved in advance of operationalizing via an amendment application. If there is insufficient time (check with the administrator for the IRB reviewing your application for timeframes) AND the change is needed to avoid immediate hazard to participants, the change should be made and notification provided to the IRB within 5 working days after the deviation (via PAR application).

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5. Should any clinical research activities cease or suspend related to COVID-19?

Existing studies that meet the definition of an NIH Clinical Trial (https://grants.nih.gov/policy/clinical-trials/CT-Definition-Case-Studies_1.7.19.pdf) **should proceed if the benefit to study participants continue to outweigh the risks** of participation. Principal Investigators can reach out to the Office

of Human Subjects Protection if they have questions about participant risk and benefit.

Principal Investigators should identify what procedures will be implemented for participants that become a COVID-19 Person Under Investigation and how the study will be amended to address these procedures.

Recommendations around this issue are fluid so please check frequently for updates.

Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)

6. Should I continue to have my research subjects come to UCLA for their study visits?

PIs are urged to discuss with study Sponsors whether study visits for enrolled patients can be conducted through telephonic or video-conferenced methods without increased risk or compromise to the safety of research subjects.

- If a visit needs to be performed in person to ensure research participant safety, including to renew supply of study medications, research participants should come to UCLA for their study visits just as they would for routine clinical care. For most people, the immediate risk of being exposed by an outpatient UCLA visit to the COVID-19 virus is thought to be low. This situation is being assessed daily by UCLA Health. https://www.uclahealth.org/coronavirus
- Initial potential new study patient visits for screening and enrollment that are typically done in person, and may continue at present. However, use of social distancing, minimizing direct contact (avoid shaking hands), and frequent washing with soap and water is recommended. Also, if possible, try to schedule these at the same time as the patient's clinic visit to reduce research-only visits. When appropriate, randomization visits should be conducted over the phone or telemedicine and provide study drug and patient-facing documents via email/fax/overnight delivery service.

7. Should any changes be made to the clinical trial study team?

Study team-participant interaction should be restricted only to **essential staff.**

8. Volunteers should avoid direct patient or study participant interaction (please check with the volunteer office)

The use of work-study students should be minimized to reduce the community risk. Principal Investigators should have plans in place to manage their studies should their research staff be placed in isolation.

9. What do I do if my study participant reports having a fever and cough?

1. Research participants should be contacted a few days before their visit by study personnel to be (1) informed about measures being taken at UCLA to protect visitors/subjects against coronavirus https://www.uclahealth.org/coronavirus#what-you-should-know & https://mednet.uclahealth.org/n6-mednet/cfce1d3cb637a460/uploads/sites/5/2020/03/Nurses-RN_Script_COVID_19_030420.pdf, and (2) screened for fever, cough and recent travel (same screening being performed in clinics).
2. **Please evaluate the participant based on the CDC criteria for evaluating and reporting Persons Under Investigation (PUI)**. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html Subjects who are PUI should avoid research visits until cleared by their primary care provider.
3. If a study team encounters a study participant that they are concerned has COVID-19, they should follow the

flow chart at the following web-site with regard to whether to contact the EID Physician On-Call: https://mednet.uclahealth.org/n6-mednet/cfce1d3cb637a460/uploads/sites/5/2020/03/Lab_Testing_Phase-3_COVID-19_Criteria_3-10-2020_updated.pdf

10. What precautions do I/my staff need to take to protect research subjects and staff from COVID-19 during study visits?

Research PIs and staff should follow the Information for staff and providers on the UCLA Health website: https://www.uclahealth.org/coronavirus

11. Are there any additional precautions needed for the collection and processing of biological specimens from my study subjects due COVID-19 concerns?

1. Biospecimens of study participants without concern for COVID-19 exposure, not PUI, collect normally.
2. Biospecimens for study participants with COVID-19 exposure/concern collect following standard universal precautions for all patient samples. Please refer to the following links for changing guidance: https://www.uclahealth.org/body.cfm?id=3602&fr=true OR https://www.uclahealth.org/pathology/body.cfm?id=107&fr=true
3. Biospecimens from COVID-19 PUI enrolled in COVID research should be collected per research protocol and PUI laboratory protocol. If a study is planning on processing specimens from PUI, IBC approval will be needed. Please contact the IBC for further information: Phone: (310) 794-0262 or Email: ibc@research.ucla.edu
4. The CDC has provided interim laboratory biosafety guidelines for handling and processing specimens associated with Coronavirus disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

12. If my study staff are out sick, are there central resources (e.g., coordinator pools, laboratory technicians) to help me continue my study visits/research?

Please contact your departmental CAO. If departmental resources are unavailable, please contact the CTSI Office of Clinical Research to see if there are resources to help backfill if staff are sick due to Coronavirus.

13. Will the Clinical Translational Research Center (CTRC) stay open?

There are no plans currently to limit services through the CTRC.

14. Will the services for the Office of Clinical Research continue to be available?

Office of Clinical Research (OCR) units are fully capable of conducting day-to-day clinical research business services remotely (contracting, coverage analysis, coding, IT services, FDA support, regulatory support). Our Oncore submission, tracking and review system can be accessed anywhere an individual has internet access. We would also have the capability to conduct meetings via a web-based platform as well (e.g. zoom, WebEx, goto meetings). With advanced planning and consideration, we do not foresee a significant disruption in OCR operations if staff and committee members were unable to physically come to our office building. The one caveat to this is on-study coordinator support within the OCR and the nurses in the CTRC who will continue to be on-site to interact with study participants.

15. Changes to Currently Approved Research:

All changes/modifications to any research protocols still need to be reviewed and approved by the IRB except for the incorporation of screening for exposure to COVID-19 as well as any measures needed to avoid an immediate apparent

hazard to a patient/participant. The incorporation of a COVID-19 screening procedure does **NOT** require IRB approval. If a research protocol requires a modification, due to COVID-19 implications, that needs to be submitted to the IRB for review and approval, please contact the UCLA OHRPP office directly so those submissions can be triaged in an expeditious manner.

16. Clinical Research Monitor and Audit Visits:

Please work with any study monitors/auditors traveling from a US state where a state of emergency has been declared and/or from a CDC Level 2 or 3 country to either postpone the visit or conduct remote reviews.

17. For additional information of questions:

For questions related to the Clinical Translational Research Center, please call 310-825-5225 and/or email CTRCServices@mednet.ucla.edu
For questions related to the Office of Clinical Research, please call (310) 794-8119 or email OCRAdminTeam@mednet.ucla.edu
For general questions or help with navigation, please email OCRNavigation@mednet.ucla.edu

For those of you who have studies interests related to COVID-19, please register them using the following link: Covid-19 New Study Registration

For those of you who have some capacity and time to contribute to COVID-19 research, please register yourself using the following link: Covid-19 Study Staff Support Registration

Last updated: 16 Apr 2020

Please refer to Compliance Advisory Regarding Clinical Research Study Monitoring intended for research study sponsors and/or CROs who are inquiring regarding remote monitoring of UCLA Health Clinical Research studies during the COVID-19 Pandemic period.

Last updated: 25 Mar 2020

SUBJECT: Clinical trial opportunities for COVID-19+ Patients and their close contacts

UCLA is committed to providing the best possible care to our patients and their families. In order to achieve this goal we want to make sure you are aware of clinical trials that are specifically focused on patients that are COVID+ as well as studies that focus on prevention of COVID-19 disease in close contacts of COVID+ patients. Please note that some opportunities to prevent COVID-19 after an exposure are time-sensitive requiring more immediate attention if your close contacts are interested in participation.

Please note that the list of options will be likely growing and changing over the course of the next weeks and months. If you don't find something available or something that interests you, please check back frequently to see if there is an updated or new opportunity.

OPEN STUDIES for Close Contacts of COVID+ Patients

Efficacy of Hydroxychloroquine for Post-exposure Prophylaxis (PEP) to Prevent Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection Among Adults Exposed to Coronavirus Disease (COVID-19): a Blinded, Randomized Study

Last updated: 17 Apr 2020

Last updated: 22 May 2020

- 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

Drupal.jQueryUiFilter.globalOptions('accordion');