

[COVID-19 - Updates 2020](#)

- [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

- 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](#)

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Drupal.jQueryUiFilter.globalOptions('accordion');