COVID-19 - Update March 16, 2020

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.

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

March 13 Update >>

Last updated: 16 Mar 2020