COVID-19 Information for Clinical Research - March 13, 2020 Update

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

A. Existing studies that meet the definition of an NIH Clinical Trial 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.

B. 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.

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

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

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

A. PI's 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.

B. 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

C. 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.

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

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

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

C. The use of work-study students should be minimized to reduce the community risk.

D. Principal Investigators should have plans in place to manage their studies should their research staff be placed in isolation.

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

A. 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
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performed in clinics).

B. 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.

C. 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/cfcea1d3c637a460/uploads/sites/5/2020/03/Lab_Testing_Phase-3_COVID-19_Criteria_3-10-2020_updated.pdf

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

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

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

A. Biospecimens of study participants without concern for COVID-19 exposure, not PUI, collect normally.

B. 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

C. 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


7. 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.

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

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

9. 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.

10. 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.

11. 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.

12. 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 OCRAadminTeam@mednet.ucla.edu
For general questions or help with navigation, please email OCRNavigation@mednet.ucla.edu

Last updated: 16 Mar 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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