Date: March 13, 2020

To: Keck School of Medicine Clinical and Community Researchers

From: Laura Mosqueda, Dean
Thomas Buchanan, Vice Dean for Research
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Keck School of Medicine of USC

Re: Human Subject Research during COVID-19

To best ensure the safety and health of our study participants and research staff, we issue the following guidelines regarding human subject research visits during the COVID-19 outbreak. The goal is to reduce unnecessary person-to-person contacts. Researchers should weigh risks of such contact against risks of foregoing study participation and/or visits – with their benefits.

For studies with potential therapeutic benefit (examples: most interventional studies with drugs, devices, procedures, behavioral interventions):

- The decision about in-person research visits for new or existing study participants should be made by the study Principal Investigator on a case-by-case basis, weighing risks of person-to-person contact against the potential benefits of the study intervention and monitoring.
  - Examine study procedures for modifications and accommodations that could reduce risk and burden for participants in the context of COVID-19.
  - Develop a plan for screening for symptoms and/or diagnosis of COVID-19 before any in-person visits occur. Participants with symptoms of fever, cough, congestion, or respiratory distress should not have contact with research staff and should be referred for medical care.
- If the Principal Investigator is not the participant’s physician, the decision should be made in consultation with the participant’s physician whenever possible.

For studies with no potential therapeutic benefit (examples: most natural history studies, observational studies, epidemiological studies and studies collecting biospecimens):

- In-person contact should be avoided for such studies, unless such contact is part of a scheduled visit for clinical care.
- Consider changing data collection from in-person to telephone or online modalities. Zoom is available for this purpose (https://usc-hipaa.zoom.us) with help available at https://itservices.usc.edu/zoom/
- We are exploring other options for data collection and will share them as they are identified.
Additional Information

- **IRB Amendments**: If compliance with these guidelines requires a protocol change, submit an amendment to the IRB via iStar, using the word “COVID” in the title of the amendment. This will allow the IRB to prioritize the amendment for rapid processing.

- **Study Monitoring**: Study monitoring visits should continue only as required for study integrity. Monitors should not have participant contact; contact with other personnel should be minimized.

- **Cross-Training of Staff**: Investigators should cross-train study staff to fill in for research staff who may be sick or unable to come to work. Ensure you have emergency contact information for your critical staff, including cell phone numbers.

- **Remote Access**: Ensure that research personnel have access to information they need to carry out work remotely (e.g. research databases, literature, Zoom). However, under no circumstances should researchers take materials other than their laptops or data storage devices to their homes or other offsite locations.

These guidelines are specific to in-person research encounters. Separate guidance regarding staffing can be found here ([https://research.usc.edu/coronavirus/#labstaffing](https://research.usc.edu/coronavirus/#labstaffing)). Additional information is also available through the USC Office of Protection of Research Studies OPRS Memorandum and the Office of Research website ([https://research.usc.edu/coronavirus/](https://research.usc.edu/coronavirus/)).