USC University of Southern California

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS)
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Director

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To: Principal investigators and study coordinators

From: Julie Slayton
Director, Office for the Protection of Research Subjects

RE: Human subjects research at USC and the evolving COVID-19 outbreak

As we continue to grapple with the consequences associated with the COVID-19 coronavirus outbreak, the risk/benefit ratio for biomedical and social behavioral research participation must be carefully assessed. Both the ethical principles of research delineated in the Belmont Report and federal regulations for the protection of research participants dictate that we ensure the risk/benefit ratio be acceptable at all times. Universities such as Columbia have already paused certain types of human subjects research activities underway at their institutions and others such as the University of California system are considering their next steps. While we do not believe that such research at USC should be brought to a halt at this time, we do strongly recommend that investigators take steps to decrease the likelihood that they will put themselves, members of their study teams, or their study participants at risk of becoming infected with or spreading the disease. Below are guidelines to follow with respect to overall planning and data collection activities.

Establish Formal Plans

All investigators engaging in human subjects research should develop concrete and actionable plans for:

- Continuing or halting data collection.
- Regularly communicating with the following to ensure everyone is operating under the procedures recommended by the University: Team, study sites, participants and their caregivers.
- Managing data in the event the University Park and/or Health Science Campuses are closed for research purposes.

Investigators and study teams conducting research activities that involve medications and/or devices should create plans for patients who have had new devices or recent procedures and/or who require close monitoring because of the nature of the medications. These plans should include contingency plans for providing medications, cross training of staff, and ensuring access to required care.

Review Data Collection Procedures

As part of planning, investigators and study teams should revisit data collection procedures as well as the extent to which or circumstances under which data collection should be brought to a halt, either temporarily or permanently. Suggestions for biomedical and social behavioral research are provided here:

Specifically for biomedical studies, consider:

- Screening study participants or potential participants for their travel histories within the last 14 days and flu-like symptoms.

- Decreasing the number of protocol-mandated in-person study visits to healthcare facilities.
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine, allowing blood draws at remote or commercial laboratories.
- Shipping investigational products directly to research participants.

Specifically for social behavioral studies, consider:

- Ensuring that that the research staff is healthy and check with study sites to determine whether there have been any identified cases or if anyone at the site is or has been quarantined when collecting data from populations at higher risk of suffering severe health consequences if they contract COVID-19 (e.g., older adults or those designated at higher risk by the CDC) or in settings that bring large groups of people together in contained spaces (e.g., K-12 schools, close proximity living spaces).

Both biomedical and social behavioral studies:

- Avoid or minimize bringing groups of people together for data collection activities (e.g., focus groups, whole group interventions).
- Consider moving face-to-face data collections (e.g., interviews, surveys administered in person, some forms of observation) to telephone or online (e.g., Zoom) formats.
- Follow recommended guidelines for reducing exposure and, if prudent, pause study activities.
- Determine whether it is necessary to completely suspend research activities and if so, pause recruitment until the situation changes.

For full board and expedited studies, if an investigator or study team needs to alter data collection activities by shifting to phone or online, or another change needs to be made to a study protocol in order to protect participants or study personnel, an amendment should be submitted with the language "COVID" in the title. This will allow the IRB to flag the amendment and review and approve it quickly. If a sponsor or investigator needs to make a change to research plans and is unable to submit an amendment (e.g., immediate hazard or risk to research participants exists), these changes can be made and then reported to the IRB within 5 days, as a reportable event. Eliminating immediate hazards may include actions that reduce potential exposure to COVID-19, or to continue to provide medically necessary care (including study drug) to participants who have been placed in isolation or quarantine because of suspected or known exposure. The USC IRB encourages sponsors and investigators to take such steps as necessary to eliminate apparent additional risks to participants.

At the current time, the USC IRBs will continue to review and approve research protocols that have been or will be submitted, including those submissions that require full board review. However, any research team that has not yet begun research activities should ensure that doing so will not jeopardize members of the research team or participants. In addition, should the COVID-19 landscape change significantly, there may come a point when research activities including human research subjects will be restricted and application reviews might be paused in the interest of individual and public health.

Cc:

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