

MEMORANDUM

To: Principal Investigators and Study Coordinators at GWSPH
From: Dr. Adnan Hyder, Senior Associate Dean for Research, GWSPH
Date: 11 March 2020
Subject: Human Subjects Research at GWSPH 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 GWSPH 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 subject 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 and/or 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 below.

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 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.

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 immediately to the GW IRB*. 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 must be reported to the IRB as soon as possible*. 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 GW IRB always encourages sponsors and investigators to take such steps as necessary to eliminate apparent additional risks to participants.

At the current time, 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. We will work closely with the GW IRB and OVPR to monitor the situation.

Please refer to these useful sites for more on the outbreak:

- <https://campusadvisories.gwu.edu/covid-19>
- <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-083.html>

Please contact the Office of Research Excellence at GWSPH for any questions:
GWSPHResearch@gwu.edu

Cc: Office of the Dean GWSPH, Office of the Vice President of Research, Director GW IRB

References: This memo is heavily based on human subject materials and announcements from Universities of: Southern California, Columbia, Harvard and Johns Hopkins – thanks to all these institutions and colleagues for sharing materials.