MEMORANDUM

To: **Principal Investigators and Study Coordinators for Clinical Research at GWSPH**
From: **Dr. Adnan Hyder, Senior Associate Dean for Research, GWSPH**
Date: **14 March 2020**
Subject: **Human Subjects Research in Clinical Research at GWSPH and COVID-19 Outbreak**

As we make decisions on how to respond to the COVID-19 situation, we want to begin by stating that our primary concern is the safety of our research participants and the research team members who work for GWSPH. Our secondary goal is to preserve the scientific integrity of research protocols. All changes to a research protocol still need to be reviewed and approved by the IRB *with the exception of the public health screening questions for COVID-19*.

Research teams involving patients and clinical protocols should take the following actions now.

Screening of Research Participants
All study teams should immediately implement procedures to screen research participants at any interaction and incorporate telephone screening prior to scheduled study visits. Research participants should be assessed for potential infectious risk or high risk exposures at any encounter and prior to any visit. The questions related to recent travel, contacts, and current symptoms are evolving; but the latest version of screening questions should be reviewed before each encounter and utilized to decide if a research encounter should proceed (https://www.cdc.gov/).

Develop Contingency Plans
Study teams should proactively prepare contingency plans for their active research protocols. Important considerations for contingency plans include:

A. Assess if the disruption of a research protocol might impact the safety of your research participants.

Investigational Drugs: If research participants are on investigational drugs, determine what the plan would be if the investigational drug could not be dispensed to your research participants. You might find a way to deliver investigational drugs to their home if this is consistent with site Standard Operating Procedures (SOP), chain of custody SOPs, and protocol team management. If the investigational drugs cannot be dispensed to your research participants, you should make plans to transition research participants back onto their most appropriate clinically available medications in concert with the protocol teams and guidance from the study sponsor. This transition should include consultations with the clinical team caring for the research participants and consent of the participant.

Research Procedures: PI's need to assess whether any reduction in staff makes it unsafe to complete the planned research procedures. Even starting phlebotomy or IVs might not be easy or safe if experienced staff are not available.

Timely review of research data: If research team members are not available, integration of research care such as reviewing lab results in a timely manner might not be possible and will require special attention under the direction of the study PI. Study teams should consider the availability of appropriate back-ups to the PI to make safety assessments.

B. *Utilization of alternate visit options including telephone or zoom visits for participants who are unable or unwilling to come to on-site visits*

Telephone or video conferencing: It would be wise to have up-to-date phone numbers for all of your research participants. You might also discuss videoconferencing or Zoom type of service. Consider use of secure servers for transfer of information or other methods to ensure the ongoing confidentiality of participant data. Also consider privacy for participants and safety for staff, if staff are required to do research activities at home. Staff may need training on personal protection and private areas, secure data storage, and low sound transfer areas to ensure confidentiality. It is imperative that methods to adapt to the COVID-19 situation do not inadvertently put staff or participants at risk of inappropriate disclosure of information.

Health Center or Home Visits: Some research visits may require blood draws or simple measurements like BP and BMI assessments that could be accomplished either at the facility or home or possibly telehealth. Before deciding on options, research teams need to consider: can the activity be done safely at the site proposed, as PI do you acknowledge that the research staff doing tests have been appropriately trained, does the research staff member have any health conditions or current symptoms related to the coronavirus, and does the research participant or other individuals (accompanying patient) have symptoms that would indicate a high risk of coronavirus transmission (see ORE memo: https://publichealth.gwu.edu/sites/default/files/MEMO_GWSPH%2C%20Human%20Subjects%20Research%20and%20COVID-19%2C%2011March2020.pdf). Up to date screening questions should be utilized to make the assessment about risk of coronavirus transmission.

The research encounters (at any location) must be documented and include the following information - did the research participant pass the screening questions about risk for infection, what times did the research team interact with the participant and for how long, and who else was present during the encounter.

Please remember changes to the research protocol, other than public health screening, require approval by the IRB.

As we confront the novel coronavirus pandemic, we have to balance continuing research with the risk to our students, staff and faculty as well as our study participants. We are entering uncharted waters with personal and work disruptions that are only likely to increase; please keep abreast of latest developments and visit the following site frequently: https://campusadvisories.gwu.edu/covid-19.

For questions please email ORE at gwsphresearch@gwu.edu.
Thank you for your patience and your hard work.

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.