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To: AUB and AUBMC Researchers

Subject: Human Subject Research during COVID-19 Pandemic

To best ensure the safety and health of subjects participating in research and research staff, please refer to 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 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 to reduce risk and burden for participants in the context of COVID-19.
- Modify research procedures to include 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; or exposure to a person diagnosed with COVID-19; **should not have** any 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.
- Researchers must pause on enrolling new research participants that require person - to - person contact unless there is a compelling reason that was communicated to the IRB prior to initiating this enrollment.

For studies with no potential therapeutic benefit (examples: observational studies, epidemiological studies and studies collecting non-time sensitive biospecimens):

- Researchers must not enroll new participants in studies requiring person - to - person contact nor continue to conduct face – to - face visits.
- Consider changing data collection from face – to - face interaction to telephone or online modalities. You can use Webex (**http://aub.webex.com**) or Zoom for this purpose (https://zoom.us/)

- 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 modifications to the protocol, submit an amendment to the IRB via irb@aub.edu.lb, 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 contact participants and contact with other research personnel should be minimized.

Research Staff: Principal Investigator should ensure cross-training of study staff as to fill in for research staff who may be sick or unable to come to work. The PI should have the emergency contact information for all critical study staff, including mobile phone numbers.

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