**GUIDANCE:**

1. **Contacting Sponsors:** If the study needs to be paused due to suspension of in-person non-essential research participant visits, or modified to allow for remote study visits, it is a mandatory requirement to notify the sponsor as soon as feasible. Utilize the standard process for informing sponsors of changes to the research. Please maintain a copy of all communications with sponsor regarding this notification process and sponsor responses in the study regulatory binder. Considerations for communicating with study sponsors should include the following:
   a. Contact study sponsors/industry for study-specific information on how to continue the study by using remote visits or pause the research
   b. Obtain sponsor guidance for study conduct, including:
      i. Changes in reporting requirements
      ii. Sample storage and shipping
      iii. Drug shortages or delays in shipping and use of MFA’s courier service to deliver investigational product to research subjects’ homes
      iv. Alternative safety assessments due to delays
      v. Delayed or missed participant contacts/visits
      vi. Changing the study procedures with appropriate IRB approval: You should inform the study sponsor of the modified procedures and what documentation requirements will need to be modified (e.g., changes to CRFs, etc.). The sponsor will seek FDA waiver as applicable for changes to Protocol and IRB approval should be sought for the modifications. Any deviations that occurred prior to IRB approval should be reported per standard IRB guidance based on the significance of the deviation.
   c. If you are conducting FDA-regulated research for which GW/MFA and MFA physician PI are the sponsor of an IND or IDE, the FDA will need to be notified as soon as feasible. Contact Holly Liu at hliu@mfa.gwu.edu for guidance and information on the FDA notification process.
   d. For NIH Funded clinical trials, please see additional guidance attached in Notice Number: NOT-OD-20-087 “Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19”.

2. **Study visits:** Researchers should cancel or make alternate arrangements for all scheduled non-essential visits as soon as possible. Every effort must be made by the study team to minimize visits and perform evaluations remotely if at all possible. Any study patient who should be seen must go through the standard clinical screening at the South Entrance of the MFA building. Study teams should review the study protocol and try to minimize the number of visits or make alternate arrangements to complete the visits without in person meetings (Skype, Zoom, phone call, etc.). All in-person research participant visits should be limited to “essential” visits.
**Essential visits:** Visits that require assessments that cannot be performed by phone or video conferencing. Visits that require blood draws for vital safety monitoring information, or visits that will pose an additional risk for the patient if not performed.

**Non-essential visits:** Visits that will not add risk to the patient if not performed, or visits that can be delayed or performed remotely (with sponsor approval).

The site research staff should call the subject to collect adverse events (AEs) address concomitant medication changes as applicable, ensure subjects are compliant with IP and address any additional questions the subject might have. Research staff should follow the MFA telephone protocol regarding COVID-19 screening and dissemination of critical information regarding the virus per standard protocol.

3. **Investigational medicine product:** Please contact your sponsor and confirm whether or not a protocol has been put in place to allow IP site-to-subject delivery. Sponsors will need to modify their Protocol to allow for this modification and apply for a FDA Waiver. If so, IP will be delivered to the site from the depot by courier service according to the study Pharmacy Manual. An IP courier will pick up the IP from the MFA and deliver to the subject’s home. The site study staff will work with the Sponsor to coordinate pick-up and delivery times. Please contact Melanie Bossi at mbossi@mfa.gwu.edu to confirm contractual requirements with courier prior to arranging for any shipments. Documentation of the shipment will need to be retained for filing. The researcher’s department shall incur all fees associated with courier delivery of investigational product.

4. **IRB Considerations.** For industry trials using Western IRB as the cognizant IRB, please access WIRB website at https://www.wcgclinical.com/changes-to-research-made-in-response-to-covid-19/ for procedural instructions regarding amendments or other required reports.

For studies overseen by the GW IRB, the GW IRB always encourages investigators to take such steps as necessary to eliminate apparent additional risks to participants. If you **must modify study procedures immediately in order to protect researchers and/or study participants,** you may implement changes without prior IRB approval, but must report such action as Promptly Reportable Information in iRIS as soon as possible. This report should include a description of the changes, why they were implemented, an anticipated timeline for the changes (e.g. through the end of the COVID-19 outbreak), and enough information to allow the IRB to assess risks from the changes. You can submit this information as a memo or other form of documentation, or as a protocol revision — that is up to the study team and sponsor. If you **must temporarily suspend research due to concerns about participant safety,** you should submit this suspension as Promptly Reportable Information in iRIS as soon as possible. If you **decide to voluntarily suspend study activities,** but that decision is not immediately related to participant safety and there is no increased risk to human subjects from that suspension, then the IRB does not need to be notified. If you **decide to modify study procedures to make non-urgent changes,** submit a modification in iRIS prior to implementation. Please note: It may not be necessary to modify your IRB-approved procedures if they do not specify whether interaction will occur in person or remotely. The GW IRB website is https://humanresearch.gwu.edu/ and the GW IRB specific COVID19 guidance is available at https://humanresearch.gwu.edu/covid-
The IRB of Record (WIRB or GW IRB) may require review/approval prior to resumption of study procedures. If changes are needed for the immediate health and safety of participants and staff that require modifications from protocol, not only a pause, you may implement changes without prior IRB approval, but must report such action to the cognizant IRB as soon as possible. IRB approval is also not required for communications to study subjects explaining the pause in research activities due to COVID19, or to implement procedures to ask research participants about questions related to recent travel, contacts, and current symptoms prior to study visits.

GW OHR staff are available for consultation. Please see the Contact Us section of the GW OHR website for more information. IRB submission volume is likely to be high at this time due to increased questions and modifications related to COVID-19. Please plan accordingly and contact GW OHR for urgent issues.

5. Monitoring visits:
All monitoring visits should be changed to remote monitoring visits or delayed until further notice. If there are specific records that need to be reviewed by the monitor, this should be arranged with the research staff and PI.