PROCEDURES FOR MODIFICATION OF ONGOING STUDY PROTOCOLS TO ELIMINATE IMMEDIATE HAZARDS DUE TO COVID-19:

This guidance and future updates will be posted on the RF Office of Administration website at: https://research.downstate.edu/covid-19-updates.html

Please direct any questions regarding this communication to the IRB Office at IRB@downstate.edu

BACKGROUND:

Modifications to a previously IRB approved research activity in order to eliminate any apparent immediate hazard due to COVID-19, such as those listed above, may be initiated immediately without IRB approval. However, the Principal Investigator must report any such change to the IRB in IRBNet within 5 days in IRBNet using the Application Form for Reportable Event.

This guidance may also be used to develop new studies when anticipating the recruitment of participants with COVID-19.

CONSIDERATIONS:

Alternative options to in-person face-to-face study activities including interactions amongst study staff and/or between staff and research participants:

- Consider slowing enrollment or stopping research, even if there is a direct benefit
- Postpone, minimize or eliminate visits/procedures that do not impact the integrity of the study or participant safety
- Convert in-person face-to-face visits to virtual visits (e.g., phone, e-mail, webinar, telemedicine) where possible
- Ship investigational products to the study participant (subject to state and federal laws)
- Establish home visits by nursing or health aides to conduct study related procedures
- Conduct remote monitoring activities
- Establish new procedures to securely transfer data files (consistent with Downstate security requirements)
- Establish back-up plans for staff shortages

When in-person face-to-face interactions are necessary, prior to scheduling these visits you must first:
1. Pre-screen for signs and symptoms of COVID-19 (see below for details) and if positive, you must identify and direct a participant to the appropriate resource for care
2. Screen for and respect staff and study participant willingness and comfort in travelling to the study site
3. Ensure that hand sanitizer, hand washing facilities and other personal protective equipment are readily available and encouraged for both staff and study participant
4. Establish a rigorous disinfecting protocol for any equipment, manipulative, or other study equipment that will be used with multiple participants

**DRAFT GUIDANCE for Informed Consent Process for patients with COVID-19:**

**CAUTION: THIS SECTION IS UNDERGOING REVIEW AND WILL BE UPDATED AS SOON AS POSSIBLE, AFTER RECEIVING ADDITIONAL GUIDANCE FROM VARIOUS GROUPS, INCLUDING INFORMATION SECURITY, PRIVACY OFFICER, OCAS, EHS, OR OTHERS**

- In general, an investigator (unless caring for the patient), witnesses, surrogate, or interpreter who participate in the informed consent process will not be permitted in the same room as the COVID-19 patient.
- Consider whether the study is eligible for a waiver of documentation of informed consent and a HIPAA alteration (to remove signature requirements). If the study is not eligible for such waivers, consider whether it will be necessary for a participant to “signal” consent and document the affirmation of his/her consent on the consent document. Alternatively, a photograph may be taken of the signatures on the consent form, provided the study is not an FDA regulated clinical investigation because such studies require original source documentation.
- Consider whether electronic consent may be incorporated into the process.
- Consider whether the consent discussion can be facilitated over through a conference call or video conference. It is acceptable to use the standard tools that we use at Downstate for tele-conferencing; however, Downstate care providers are still encouraged to notify study participants that these third-party applications potentially introduce privacy risks, and they should enable all available encryption and privacy modes when using such applications. To utilize a telehealth platform to enable remote study visits, please contact Downstate’s HELP Desk at 718-270-4357 to request assistance.
- Any equipment removed from the room of a patient with COVID-19 or a patient under investigation (PUI) for COVID-19 must be appropriately disinfected using Downstate EHS approved procedures, including any equipment that is used for the purposes of obtaining informed consent, including any phones or cameras that might be used to take an image of the signed consent.

Safety considerations for paper consent forms:
- If paper informed consent forms must be used, please seal the paper forms in one or more zip lock/bag for external wiping with disinfectant prior to removal from the participant’s room. Keep the forms stored for a safe time-period (currently considered to be a minimum of 72 hours by [Downstate EHS](#)) before retrieving the form. If copying the form is desired, it is recommended that all signature pages be placed on the side facing outward and use multiple zip lock/bags, if needed. The form may be copied (unless source document is needed for an FDA regulated clinical investigation) in order to obtain additional required signatures, or a separate form can be used for all other signatures. It is recommended that a note be placed on the form(s) to link the two or more separate forms.
Other Important considerations:

- For FDA regulated clinical investigations, consult the March 2020 [FDA guidance](#) which provides general considerations in assuring the safety of trial participants and minimizing risks to trial integrity during the COVID-19 pandemic.

- Before implementing changes to sponsored research, consult with the RF [Sponsored Programs Administration](#) for guidance.

- Any changes to the research must comply with applicable IRB regulations and requirements, including HIPAA privacy and data security requirements. Click here to review IRB guidance on Data Security and other IRB policies and guidance materials. General questions may be directed to the [Downstate IRB & Privacy Board](#). Specific questions regarding data security may be directed to Igor Gorelik, Information Security Officer. Specific questions regarding HIPAA privacy may be directed to Shoshana Milstein, Privacy Officer.

- Investigators who elect to work off campus (e.g., home), whether the study has been shifted to an alternate schedule or not, must follow HIPAA privacy and data security requirements, including any required protections for data transfer and secure data storage.

**COVID-19 SCREENING LANGUAGE & ADVOCACY**

Research participants are expected to be asked to complete a short screening for exposure to COVID-19 prior to any in-person interactions and when calling them for any reason (e.g., to complete a research survey, to reschedule a study visit, etc.). The incorporation of this screening procedure does not require IRB approval. The following screening questions or something comparable may be used based on the current COVID-19 situation:

- Have you traveled to China, Iran, Italy, Japan, or South Korea in the past 14 days?
- Have you had any of the following symptoms (even if minor) in the past 14 days without confirmation as something other than COVID-19 (such as a positive flu test, chronic medical condition, etc.)?
  - Fever greater than 100.4 degrees Fahrenheit
  - Cough
  - Difficulty breathing
  - Sore throat
- In the last 14 days, have you lived with, visited, cared for, or been in a room with someone who is a patient under investigation for COVID-19 or someone who is confirmed to have COVID-19?

Refer individuals to call their local community health care provider if they answer any questions in the affirmative.

If an investigator has any questions about care of an individual with suspected COVID-19 infection they should direct their questions to both Dr. Charles Brunicardi and Dr. Michael Augenbruan for advice. Please mark any e-mail communications “Confidential” if they include the name of the individual or other Protected Health Information.