

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

(Updated 4.9.2020)

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 or Patients Under Investigation (PUI).
- Modify other studies that in response to lifting a suspension of research activities, during the pandemic.
- Modify existing informed consent documents, when anticipating the recruitment of participants with COVID-19 or Patients Under Investigation (PUI).

GENERAL 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).
- Consider whether product infusions can be switched to a home infusion.
- 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, supply disruptions, disruption in information technology systems or other technological tools needed for the research.
- Determine if additional safety monitoring is needed with research participants no longer have access to the research site or investigational product or if they are withdrawn from a clinical trial.

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

SAFETY CONSIDERATIONS:

Note: This section of the guidance is provided by Downstate EHS.

- Wear PPE when interacting with COVID patients, suspect COVID patients, COVID samples or suspect COVID samples. PPE selection should be based on the criteria established by the CDC guidelines. Follow all safety requirements, including physical distancing requirements.
- Where a feasible, a Class II Biosafety Cabinet can be utilized while handling samples.
- 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 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.
- If paper informed consent forms are retrieved, 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 (Recommended up to at least 21 days by Downstate EHS) before retrieving the form.

Reference resources:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

<https://www.vumc.org/safety/bio/emerging-infectious-agents>

INFORMED CONSENT PROCESS FOR PATIENTS WITH COVID-19:

General considerations:

- In general, unless they are caring for the patient or approved by the IRB, an investigator, witnesses, surrogate, or interpreter who participate in the informed consent process will not be permitted in the same room as a COVID-19 patient or a Patient Under Investigation (PUI) for COVID-19.
 - First, consider whether the study is eligible for a waiver of documentation of informed consent and a HIPAA alteration (to remove signature requirements) or a waiver of informed consent. If the study is eligible for such waivers, include these requests to the submission to the IRB.
 - Consider whether electronic consent may be incorporated into the process.
 - Consider whether the consent discussion can be facilitated 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.
 - When it is not possible to obtain informed consent electronically, consider the following process:
 - An unsigned consent form is provided to the patient by a health care worker who has entered the patient room. Include 2 copies if there are plans to safely retrieve the consent after it is signed. See above safety considerations.
 - Arrange a conference call with all parties involved in the consent process, when it is not be feasible or safe for all parties to have direct communication with the patient in the room.
 - To ensure potential participants are approached in a consistent fashion, follow the steps below:
 - Identify all who are on the call.
 - Review the informed consent with the potential participant and respond to any questions the patient may have.
 - Witness confirms all questions have been answered.
 - Investigator confirms the patient would like to participate in the study and that they have signed and dated the informed consent document(s) that is(are) in his/her possession.
 - If the consent document cannot be collected from the patient's location and included in the study records, the following two options are acceptable:
 - Attestation by a witness who participated in the call and by the investigator that the patient confirmed and agreed to participate in the study and signed the informed consent form(s).
- OR-**
- A photograph of the informed consent form(s) with attestation by the person entering the photograph into the study record that states how the

photograph was obtained and that it is a photograph of the informed consent signed by the patient.

- A copy of the informed consent document(s) signed by the investigator and witness should be placed in the research records with the source documents, with a notation by the investigator of how the consent was obtained, e.g., telephone. The research records at the site should document how it was confirmed that the patient signed the consent form (see above). The note should include a statement why the informed consent document was not retained, e.g., due to contamination of the document by infectious material.
- If the patient is unable to provide informed consent and surrogate consent (e.g., legally authorized representative) is obtained in accordance with IRB approval, the investigator must obtain consent from the surrogate, in accordance with the IRB policy and specific institutional policies of the site where the consent is obtained.

Surrogate Consent:

If anticipating surrogate consent, please amend the consent form to include the following sentence or something similar:

If you are deciding if an adult can be in this study, the terms “you” and “your” refer to the adult who cannot make the decision. Please consider the wishes and beliefs or the best interests of this person. If the participant’s ability to make decisions is regained after you give your permission for him/her to be in the study, he/she will be asked to provide his/her consent.

When planning for surrogate consent, please work with hospital administration before making plans to reach out to family members who are not able to be with their loved ones, to ensure contact is done in the most respectful manner.

Additional Consent Signature lines:

Consider using the additional signature lines within the informed consent document, as necessary for the research:

<hr/> Print the Name of the Adult Research Participant (18 years of age or older)	<hr/> Signature of the <u>Adult</u> Research Participant I have read this form and all my questions about this research have been answered to my satisfaction. I volunteer to participate in this research study.	<hr/> Date Signed
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<p>_____</p> <p>Print the Name of the Adult Research Participant for whom you are providing permission to be in the study</p> <p>(18 years of age or older)</p> <p>_____</p> <p>Print Your Name as the Surrogate and indicate your relationship to the research participant:</p> <p>_____</p>	<p>_____</p> <p>Signature of Surrogate</p>	<p>_____</p> <p>Date Signed</p>
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<p>_____</p> <p>Print Name of Witness</p> <p><i>(Required when obtaining surrogate consent or when obtaining remote consent)</i></p> <p>() Check here, if consent was obtained remotely through a conference call or video conference.</p> <p>() Check here, to confirm the participant agreed to participate in the study <u>and</u> signed the informed consent form(s) <u>and</u> all questions were answered.</p>	<p>_____</p> <p>Signature of Witness</p>	<p>_____</p> <p>Date Signed</p>
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<p>_____</p> <p>Print Name of Investigator Obtaining Informed Consent</p> <p>() Check here, if consent was obtained remotely through a conference call or video conference.</p> <p>() Check here, to confirm the participant agreed to participate in the study <u>and</u> signed the informed consent form(s) <u>and</u> all questions were answered.</p> <p>() Check here if the informed consent document was not retained, due to contamination of the document by infectious material.</p>	<p>_____</p> <p>Signature of Investigator Obtaining Informed Consent</p> <p>In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions.</p>	<p>_____</p> <p>Date Signed</p>
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OTHER IMPORTANT CONSIDERATIONS:

- For FDA regulated clinical investigations, consult the [FDA Guidance on Conduct of Clinical Trials of Medical Products during 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.
- Anticipate other challenges and circumstances such as quarantines, site closures, travel limitations, supply chain interruptions, and considerations for site personnel and research participants. Consider each circumstance to ensure the safety of research participants and others, including investigators and study staff. It is critical to keep research participants and others informed of changes that impact them.

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.