

Consolidated IRB Guidance Related to COVID-19

(Version 07.17.2020)

BACKGROUND:

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). This guidance updates, consolidates, and replaces previously issued IRB guidance related to the COVID-19 public health emergency. .

The IRB is committed to providing timely guidance to support response efforts to this pandemic. This and future updates of this guidance will be posted on the RF Office of Administration [COVID-19 Updates](#) website.

NEW SUBMISSIONS & TRIAGE FOR IRB REVIEWS:

To meet the requirements of the April 4, 2020 [Temporary suspension notice](#), for any new human research submitted to during the COVID-19 pandemic, please provide the following information within the IRB application or as a cover memo to the IRB: 1) Compelling reason to initiate new research 2) Explain how the benefits of the research outweigh the risks of exposure of research participants and others (e.g., investigators, staff, family members of research participants) to COVID-19, 3) Procedures to mitigate the risk of COVID-19.

Please send all e-mails regarding new IRB applications related to COVID-19 to the [Executive Director of the IRB](#). E-mails related to new COVID-19 applications will be returned as soon as possible but usually within 24 hours.

In general, the [IRB guidance for triaging reviews](#) will be followed when the daily workload is extremely high. This guidance includes information on the following: a) New Studies b) Triage Priority c) Rapid Response (COVID-19) IRB d) Review Process and e) Table of Triage Priorities.

RAMP-UP (Phase 1):

- Refer to the [Ramp up Plan for SUNY Downstate Activities](#) website for details.
- In general, to lift the temporary suspension of in-person face-to-face activities during Phase I of the Ramp-Up, there must be a prospect of therapeutic benefit (as determined by the IRB).
- Although it is not required, the PI may submit an [Application for Acknowledgment](#) for the IRB to acknowledge the approval of a ramp up plan for each study. This may be particularly important if a sponsor requires documentation from the IRB.

AMENDMENTS:

- The following items **do not require** an amendment to the IRB:
 - Pausing the research when it does not impact the integrity of the study or participant safety.
 - Conducting COVID-19 screening procedures mandated by the site, unless the PI or Sponsor is incorporating the data collected as part of a new research objective.
 - Adding safety requirements mandated by the site, provided the changes do not impact the integrity of the study or participant safety.
 - Following safety requirements, disinfecting procedures, using PPE, following social distancing measures, using a Class II Biosafety Cabinet or other safety equipment for handling specimens, as mandated by the site.
Note: Downstate clinical PPE supplies cannot be used for research activities. If the research team needs to obtain funding or support for an extramurally funded study for PPE supplies, advertising, or other required modifications for a sponsored project, please contact the [Director of Sponsored Programs Administration](#)

- Consolidating several protocol modifications in a single protocol amendment is acceptable but should be submitted expeditiously. Submit an [Application for Amendment](#) in IRBNet (include Ramp-Up Plan, if approved), if a previously approved IRB study **must be** amended for any of the following reasons:
 - Changes in a protocol, data management and/or statistical analysis plans (including any changes that significantly affects the safety of research participants, the scope of the research, or the scientific quality of the research).
 - Changes to the research that impact the informed consent process or form (including modification of signature lines for remote consent), study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigator(s), site staff, and/or monitor(s) secondary to travel restrictions, quarantine measures, or COVID-19 illness itself.
 - A switching from dispensing drugs on site to home delivery (subject to state and federal laws).
 - Changing protocol to permit alternative sites for infusions, including home infusions.
 - Using alternative facilities (e.g., laboratory, imaging center)
 - Replacing on-site visits with home visits by nursing or health aides to conduct study related procedures.
 - Converting in-person face-to-face visits to virtual visits (e.g., phone, e-mail, webinar, telemedicine) where possible.
Note: The IRB may approve tele-visits involving Protected Health Information via HIPPA compliant software (e.g., Zoom For Healthcare, Doxy.Me). Include description of any telephone or video contact visits that would likely result in some protocol-required procedures not being conducted (e.g., vital signs, blood samples for safety laboratory studies) and include any steps to mitigate risks to participants, including the need to discontinue study drugs.
 - Establishing new procedures to securely transfer data files (consistent with Downstate security requirements).
 - Additional safety monitoring.
 - Converting from on-site sponsor/CRO monitoring to remote study monitoring.
 - Changes in recruitment or advertising.
 - Modifications required to address protocol deviations.
 - Adding additional safety monitoring of research participants who no longer have access to the research site or investigational product or if they are withdraw from a clinical trial.
 - All other changes not described above.

PROTOCOL DEVIATIONS/CHANGES TO ELIMINATE IMMEDIATE HAZARD

Modifications to a previously IRB approved research activity in order to eliminate any apparent immediate hazard due to COVID-19, 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](#).

Changes to a clinical trial that are needed prior to IRB approval (e.g., changes to eliminate immediate hazard) represent protocol deviations until a study is amended.

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 participating 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 using the FDA's [COVID MyStudies App](#) for clinical investigations.
- Consider whether the consent discussion can be facilitated through a conference call or video conference. It is acceptable to use Zoom For Healthcare or Doxy.Me for tele-conferencing involving health information; however, Investigators are 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.

Notes:

- 1) *Retrieve paper informed consent forms and seal the paper forms in one or more zip lock/bag for external wiping with disinfectant prior to removal from a contaminated area. Keep the forms stored for a safe time-period (up to at least 21 days is recommended by Downstate EHS) before retrieving the form.*
- 2) *Other alternative methods for remote consent may be followed as outlined in [FDA guidance](#); however, any process for remote consent must be approved by the IRB.*

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 Form Signature lines and Remote Consent:

Consider using the additional signature lines within the informed consent document, as necessary for the research. See All-In-One Template which can be downloaded from [Step 8](#) on the IRB Electronics Submission Process webpage.

OTHER IMPORTANT CONSIDERATIONS:

- In addition to Downstate requirements, if changes are needed to study which has oversight by an External IRB, the External IRB needs to approve these changes prior to implementation.
- For FDA regulated clinical investigations, consult:
 - [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)
 - [Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry](#)
- Before implementing changes to sponsored research, consult with the RF [Sponsored Programs Administration](#) for guidance.
- For extramurally funded studies (sponsored research) please work with the [Director of Sponsored Programs](#) to communicate with your sponsor if any changes impact the *budget* or if is determined

by the Downstate Coronavirus Task Force or IRB or Administration that your existing and/or new study cannot continue as planned.

- 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.
- Refer to the RF Office of Administration [COVID-19 Updates](#) website for updates from Sponsored Programs Administration, including COVID-19 funding opportunities and updates from IACUC and DCM.
- Refer to the [Downstate COVID-19 Information and Resources](#) website for additional information.

APPENDIX: KEY EVENTS & PRIOR IRB GUIDANCE

- **January 31, 2020:** The US Department of Health and Human Services issued a [declaration](#) of a public health emergency related to COVID-19.
- **March 12, 2020:** A Special IRB Update memo issued regarding COVID-19 to inform our research community on its possible impact on new and ongoing human research operations. This special IRB Update was reviewed by the Downstate Coronavirus Task Force. This guidance is rescinded with this updated guidance.
- **March 13, 2020:** US President [declared](#) a national emergency in response to COVID-19.
- **March 2020, April 13, 2020, July 2, 2020:** The FDA issues guidance (and ongoing updates) for [FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic](#).
- **March 27, 2020:** The Downstate Coronavirus Task Force issued a memo for ramping down research.
- **March 30, 2020:** The IRB issued guidance for new IRB applications, including COVID-19 studies that will take place during the pandemic. This guidance is rescinded with this updated guidance.
- **March 30, 2020:** The IRB issued a call for information related to COVID-19 research. This guidance is rescinded with this updated guidance.
- **March 30, 2020:** The Office of Civil Rights at the US Department of HHS issued a [Notification of Enforcement Discretion for Telehealth](#).
- **April 4, 2020:** The Downstate Coronavirus Task Force [suspended](#) all **in-person face-to-face interventions** in all human research studies **without a prospect of therapeutic benefit** to the research participants, in order to protect research participants and others, including the Downstate workforce, from the threats of the Coronavirus Disease 2019 (COVID-19) pandemic.
- **April 9, 2020:** The Downstate IRB has issued guidance on **eliminating hazards associated with COVID-19**. This guidance is rescinded with this updated guidance.
- **April 9, 2020:** The Downstate IRB has issued guidance on **lifting a suspension of research activities** related to COVID-19. This guidance is rescinded with this updated guidance.
- **April 13, 2020:** OHRP issued "[OHRP Guidance on COVID-19](#)." OHRP offers guidance on the following topics: a) Public Health and Clinical Activities b) Excluded Public Health Surveillance Activities, c) Legally Required Reporting, d) Research Changes to Eliminate Apparent Immediate Hazards e) Proposing and Reviewing Study Changes, and f) Whether Suspensions of Research Must be Reported

- **April 13, 2020:** Based on the [suspension notice](#) that was issued on April 4, the Downstate IRB evaluated all sponsored research studies to determine if the research meets the criteria for the temporary suspension of in-person face-to-face interactions when there are no therapeutic benefits to the research participants. Sponsored Programs Administration has been notified of this determination so that the sponsor can be notified. The Downstate IRB published a [notice](#) for each of these studies in IRBNet.
- **April 17, 2020:** The IRB issues guidance [Triage for IRB reviews during the COVID-19 pandemic](#).
- **April 25, 2020:** The IRB issued [Guidance](#) for obtaining consent from a Legally Authorized Representative (LAR or Surrogate) or permission from a parent or legal guardian during the COVID-19 pandemic. The signature lines (based on FDA guidance) are available in the All-In-One Informed consent template posted at [Step 8 of the IRB Submission Website](#).
- **June 3, 2020:** [FDA Information on COVID MyStudies Application \(App\)](#) is released to make available to investigators an App as a free platform to obtain informed consent securely from patients for eligible clinical trials when face-to-face contact is not possible or practical due to COVID-19 control measures.
- **June 22, 2020:** The FDA issued [Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry](#).
- **June 26, 2020:** On June 26th, the Downstate Back to New Normal (BTNN) work group announced policies to ramp-up research activities. Each group is required to fill out and submit their group-specific ramp-up plan according to the process described in the [links](#).
- **July 17, 2020:** The IRB issues [Consolidated IRB Guidance Related to COVID-19](#).