

SPECIAL IRB UPDATE

DATE: March 12, 2020
TO: Research Community
FROM: SUNY Downstate Health Sciences University IRB & Privacy Board
RE: COVID-19: Impact on Human Research

Dear Research Community:

The following update provides key information regarding the Downstate IRB. If you have questions, suggestions, or wish to request training, please contact the IRB Office at (718) 613-8480 or IRB@downstate.edu

COVID-19:

The Downstate IRB is monitoring the situation with **Novel coronavirus (COVID-19)** and is providing this special update to inform our research community on its possible impact on new and ongoing human research operations. This special IRB Update has been reviewed by the Downstate Coronavirus Task Force.

MINIMIZING RISK OF RESEARCH INTERVENTIONS:

Each PI should monitor the COVID-19 situation and consider whether to take a pause in the research procedures that involve in-person interactions with participants at Downstate or within the greater NYC area, when such interactions involve the participant traveling to study visits and for studies that have little or no direct benefit to participants. Please consider slowing enrollment or stopping studies, when applicable. In making this determination, consider whether study visits occur at a time of a clinically indicated visit as those would most likely continue.

If there is a need to voluntarily suspend the research or amend a study, please submit this request in IRBNet.

CHANGES NECESSARY TO ELIMINATE APPARENT IMMEDIATE HAZARDS OR TO PROTECT THE LIFE OR PHYSICAL WELL-BEING OF THE RESEARCH PARTICIPANT ENROLLED IN PREVIOUSLY APPROVED RESEARCH:

The Downstate IRB encourages sponsors and investigators to take any necessary steps to eliminate any apparent immediate hazard to protect the life or physical well-being of research participants. Such changes in a previously IRB approved research activity may be initiated without IRB review and approval. **However, the Principal Investigator must report any such change to the IRB within 5 days.**

**450 Clarkson Avenue, Box 1284, Brooklyn, NY 11203-2098
(718) 613-8480 • FAX: (718) 613-8497 • IRB@downstate.edu**

These changes may include, but are not limited to the following, in response to COVID-19:

- Decreasing or changing the schedule of study visits,
- Adjusting the research procedures to conduct the research over the phone, e-mail, webinar, or telemedicine,
- Shipping investigational products to the study participant (subject to state and federal laws),
- Providing medically necessary care to study participants who are placed in quarantine or isolation,
- Incorporating screening questions for COVID-19 to avoid exposure before in-person interactions and identifying resources to direct a participant if they answer affirmatively to the questions,
- Establishing home visits from nursing or health aides to conduct study related procedures,
- Conducting remote monitoring activities,
- Establishing new procedures to securely transfer data files (consistent with Downstate security requirements), or
- Establishing back-up plans for staff shortages.

HIPAA PRIVACY & DATA SECURITY:

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.

ENROLLMENT GOALS AT THE TIME OF CONTINUING REVIEW:

If a study team is having difficulty with enrollment due to COVID-19, please describe this issue at the time of continue review. The IRB will be mindful of these concerns during the review.

POSSIBLE SUSPENSION OF RESEARCH ACTIVITIES:

Several institutions are suspending certain types of research activities throughout NYC. Downstate has not issued broad suspensions but reserves the right to do this in the future if it becomes the best interest of the research participants, patient care, the Downstate workforce, or others.

If the IRB suspends a study, Downstate must notify FDA, OHRP, sponsor, or external IRB, as applicable to the study.

DOWNSTATE IRB ACTIVITIES:

To help accelerate research and treatment of COVID-19, the Downstate IRB will give priority to any review activities related to COVID-19 (e.g., expanded access to investigational agents for

treatment, approvals of research activities related COVID-19, determinations of non-human research activities related to COVID-19 including surveillance activities, etc.).

The IRB has noticed an update in request for more rapid approvals for other activities due to anticipation of staffing issues in response to a wider pandemic. The IRB will review these on a case by case basis and try to accommodate whenever possible.

IRB MEETINGS:

IRB meetings may take place via teleconference in the foreseeable future. If you are expected to present a new project, the IRB will provide instructions on how to participate in the meetings.