

# SUNY Downstate Health Sciences University Coronavirus Task Force

## UPDATE

FROM: F. Charles Brunicardi, MD  
Chair, SUNY Downstate Coronavirus Task Force

DATE: April 4, 2020

TO: Downstate Research Community

RE: Temporary Suspension of In-Person Face-to-Face Interactions for Human Research without Direct Therapeutic Benefit to Study Participants

Dear Research Community:

In order to protect research participants and others, including the Downstate workforce, from the threats of the Coronavirus Disease 2019 (COVID-19) pandemic, the Downstate Coronavirus Task Force is suspending all **in-person face-to-face interventions** in all human research studies **without a prospect of therapeutic benefit** to the research participants.

Due to the urgent nature of this notice, each PI is expected to evaluate the following for each study:

- 1) Does the study involve an in-person face-to-face interaction?

*In-Person Face-to-face interaction* includes any in-person activity that may require the study participant to travel to and/or from the study site and/or involve any in-person interaction with study staff or other study-related personnel or study participants.

- 2) Does the study provide a direct therapeutic benefit to the research participant?

*Direct therapeutic benefit* includes any intervention that may benefit the research participant's health or well-being.

*If a study:*

**INVOLVES IN-PERSON FACE-TO-FACE INTERACTION AND DOES NOT PROVIDE A DIRECT THERAPEUTIC BENEFIT TO THE RESEARCH PARTICIPANT**

The In-Person Face-To-Face interactions must be suspended until further notice unless:

- an amendment is approved by the IRB to mitigate the risk of COVID-19 and the IRB lifts the suspension for a specific study.

OR

- an exception is granted by the IRB Chair, Dr. Clinton Brown and the Chair of the SUNY Downstate Coronavirus Task Force, Dr. Charles Brunicardi.

Guidance for this process is provided on the Downstate RF ORA COVID-19 Updates website at: <https://research.downstate.edu/covid-19-updates.html>

If a study:

*INVOLVES IN-PERSON FACE-TO-FACE INTERACTION AND **DOES** PROVIDE A DIRECT THERAPEUTIC BENEFIT TO THE RESEARCH PARTICIPANT*

This research may continue at the discretion of the principal investigator however actions should be taken to modify the study to eliminate, when possible, or at least minimize any apparent immediate hazard to protect the life or physical well-being of research participants, staff, and other members of the community, including the use of appropriate Personal Protective Equipment (PPE).

Guidance for this process is provided on the Downstate RF ORA COVID-19 Updates website at: <https://research.downstate.edu/irb/electronic-submission.html>

#### **Notification to the Sponsor:**

The Downstate IRB currently oversees over 1,300 projects and will formally evaluate each non-exempt study that is either open to enrollment or sponsored to determine if the study meets the criteria for the temporary suspension of in-person face-to-face activities. The PI must evaluate all studies as noted above. Please be patient during this process as it may take some time to evaluate each study and issue the determination. We hope to have this completed by April 15<sup>th</sup>; however, this could be delayed due to unforeseen circumstances.

Sponsored Programs Administration will be notified of any formal suspension determinations for purposes of reporting the suspension to the sponsor. The PI must not make these notifications. The PI will receive a copy of all communications.

#### **New Studies:**

New studies submitted to the IRB must include the following:

- Compelling reason to initiate new research,
- Explanation on how the benefits of the research outweigh the risks of exposure of research participants and others to COVID-19, and
- Procedures to mitigate the risk of COVID-19.

For more information, see: <https://research.downstate.edu/irb/electronic-submission.html>