DATE: March 24, 2020

TO: Kevin Nellis, MS
FROM: SUNY Downstate Health Sciences University IRB & Privacy Board

PROJECT TITLE: [1566379-1] IRB Demo
REFERENCE #: NIH Award: 1009189-25-58769
SUBMISSION TYPE: NOTICE
ACTION: TEMPORARY SUSPENSION OF IN-PERSON FACE-TO-FACE INTERACTIONS WITH RESEARCH PARTICIPANTS TO MITIGATE RISKS OF COVID-19

DATE: 03/22/2020

Notice:

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 IRB has evaluated this study to determine additional risks. We recognize that our investigators understand the gravity of the pandemic we are facing and are unlikely to take unnecessary risks with study participants or others. As you are aware, COVID-19 has made interventions previously considered by the IRB to be "no more than minimal risk" (i.e. in-person face-to-face interactions) to now be considered "more than minimal risk". To further minimize risk and to flatten the epidemic curve (e.g., slow the acceleration of the number of cases, reduce the number of case and related demands on hospitals and infrastructure, and reduce the number of overall cases and health effects), the Centers for Disease Control, World Health Organization, and NYS Department of Health, and NY Governor have issued mandates to minimize social and physical distance.

The IRB determined this study includes in-person face-to-face interventions without a prospect of therapeutic benefit to the research participants. Therefore, the Downstate IRB and the Downstate Coronavirus Task Force is suspending all in-person face-to-face interventions in this study, until further notice, unless plans are submitted to and approved by the Downstate IRB to mitigate the risks of COVID-19.

Request to Lift Suspension:

The PI may submit a request to lift this temporary suspension by submitting a cover letter request along with an Application for Amendment in IRBNet through the usual IRB Electronic Submission Process.
Please include the following with the request:

1. Compelling reasons to continue the research, and
2. Explanation on how the benefits of the research outweigh the risks of exposure of research participants and others to COVID-19

In addition, please include any of the following as applicable for the amendment:

1. Plans and additional protections to mitigate risk exposure to COVID-19,
2. Plans to eliminate or reduce face-to-face interactions,
3. Plan to conduct all face-to-face interactions remotely,
4. Plans to screen participants for COVID-19 with referrals of affirmative screens to a local community health care provider,
5. Waiver of documentation of informed consent form,
6. Partial HIPAA waiver to waive documentation of signature for a HIPAA authorization, or
7. Other plans or protections as determined by the investigator (or sponsor, if applicable)

Note: If the study is overseen by an External IRB, the External IRB must approve the changes, prior to submission to the Downstate IRB for acknowledgement.

The PI may submit a request to lift this temporary suspension by submitting a cover letter request along with an Application for Amendment in IRBNet. Please include any of the following as applicable for the amendment:

1. Plans and additional protections to mitigate risk exposure to COVID-19
2. Plans to eliminate or reduce face-to-face interactions
3. Plan to conduct all face-to-face interactions remotely
4. Plans to screen participants for COVID-19 with referrals of affirmative screens to a local community health care provider
5. Waiver of documentation of informed consent form
6. Partial HIPAA waiver to waive documentation of signature for a HIPAA authorization
7. Other plans or protections as determined by the investigator (or sponsor, if applicable)

Important considerations when requesting the amendment:

• 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.

Process for Requesting an Urgent or Immediate Exception:
If there is an urgent or immediate need to carry out an in-person face-to-face interventions for this study, please take the following actions:

1. Request an exception via email directly to the IRB Chair, Dr. Clinton D. Brown [clinton.brown@downstate.edu] and the Chair, SUNY Downstate Coronavirus Task Force, Dean F. Charles Brunicardi [charles.brunicardi@downstate.edu], with a copy to the Downstate IRB [IRB@downstate.edu].

2. Include the IRBNet #, Study title, and PI with the request and include the information requested above for the instructions for submitting an amendment to lift the suspension.

3. Clarify whether the exception is for a one-time intervention or one specific individual or whether the request is to completely lift the suspension of all in-person face-to-face interventions.

4. The in-person face-to-face interventions may immediately resume as specified in the request once the exception is granted and is documented in an e-mail from both Dr. Brown and Dr. Brunicardi with a copy to IRB@downstate.edu. However, the research team must adhere to any limitations or restrictions listed by either Dr. Brown or Dr. Brunicardi. Note: When granting the exception to suspension, Dr. Michael H. Augenbraun or his designate from the Division of Infectious Diseases will be included in the consultation when there is a need to weigh the importance of the specific research activity against the relative risk of infection that could result from the activity.

5. File a copy of the approval e-mail(s) with the research records. The IRB will publish a letter in IRBNet to acknowledge the approval e-mail(s) as soon as possible; however, do not wait for the formal IRB acknowledgment letter to implement the changes.

Additional Information:

The following is noted:

- The RF Office of Research Administration has created a COVID-19 Update website which posts potential impact of COVID-19 to researchers at Downstate. For more information, please see: https://research.downstate.edu/covid-19-updates.html

- The Downstate IRB will work with the Downstate Institutional Official to notify the FDA, OHRP, sponsor, or external IRB, as applicable to the study and will work with an external IRB to make these notices as outlined with the details of an IRB reliance agreement. When applicable, Sponsored Programs Administration will be notified 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.

- If a study team is having difficulty with enrollment due to COVID-19, please describe this issue at the time of continuing review. The IRB will be mindful of these concerns during the review. The IRB recognizes there may be unavoidable protocol deviations due to COVID-19 illness or control measures. These protocol deviations should be reported to the IRB in the usual manner, usually in summary format at or before the time of continuing review.

- 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 Augenbraun for advice. Please mark any e-mail communications “Confidential” if they include the name of the individual or other Protected Health Information.

If you have any questions, please contact the IRB staff by writing to irb@downstate.edu. Please include your study title and IRBNet reference number in the correspondence.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within SUNY Downstate IRB's records.

Reference for “flattening the curve”: https://www.livescience.com/coronavirus-flatten-the-curve.html