Process to Request Lifting of Temporary Suspension of In-Person Face-to-Face Interactions with Study Participants without the Prospect of Therapeutic Benefit

(Updated 04.04.2020)

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:

This process should be followed if the Downstate Coronavirus Task Force **suspends all in-person face-to-face interventions** in studies **without a prospect of therapeutic benefit to the research participants.**

NOTE: There are two processes described below (A & B). Chose the process which is applicable to the situation and take one approach (not both). Follow process B for urgent requests.

A: Request to Lift Suspension via an Amendment Request:

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.

Important considerations when requesting the amendment:

- Review the Downstate IRB Guidance for procedures for modifications of ongoing study protocols to eliminate immediate hazards due to COVID-19. This is update often as we learn more about COVED 19. Please download this document form the ORA COVED-19 website.

- For FDA regulated clinical investigations, consult the FDA Guidance on Conduct of Clinical Trials of Medical Products during coved-19 Pandemic. This guidance provides general considerations in assuring the safety of trial participants and minimizing risks to trial integrity during the COVID-19 pandemic and FAQs.

- 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.

B: Process for Requesting an Urgent or Immediate Exception:

If there is an urgent or immediate need to carry out in-person face-to-face interventions for this study, and the research is not overseen by an external IRB, please take the following actions, rather than submitting the amendment as described above (e.g., do not initiate both processes):

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.