

Ramp up Plan for SUNY Downstate Human Research

Addendum to 6/25/20 plan

This addendum supplements the 6/25/20 “Ramp up Plan for SUNY Downstate Human Research” plan ([here](#)), to enable the ramp up of on-campus studies that do not have a prospect of direct therapeutic benefit. Unless otherwise noted in this document, all aspects of the 6/25/20 plan apply. This addendum also lifts the suspensions described in this 4/4/20 Coronavirus Taskforce memo: https://research.downstate.edu/_pdf/irb/guidance/temporary-suspension%2004.04.2020.pdf

Any inconsistencies, ambiguities, or points of confusion should be clarified with the Office of the SVP for Research <SVP-research-office@downstate.edu>.

On-campus study without prospect of direct therapeutic benefit

This addendum applies to requests to ramp up of on-campus studies that do not have a prospect of direct therapeutic benefit. Such studies can be re-activated, effective immediately if approved (see below). Approval will require:

- 1) A suitable justification must be provided for why continuing to delay the study would adversely affect the research.
- 2) The number of study personnel participating in each visit is minimized. If that number is greater than one, an acceptable justification must be provided.
- 3) For the protection of study participants and all Downstate students and staff, every effort must be made to minimize the likelihood of participants coming into close proximity with anyone on campus other than the study personnel. Specifically:
 - a. The participant must enter/exit the campus entrance/exit that will minimize the number of individuals encountered in hallways and elevators/stairs.
 - b. The entrance/exit, stairwell/elevator, and study room number must be defined.
 - c. So that participants cannot wander around the halls, the participant must be escorted from the entrance directly to the study room by study personnel and upon completion of the study, escorted from the study room to the exit by study personnel. The exception to this is bathroom use, which is, of course, permitted. Waiting in a waiting room is not permitted unless approved as part of the group-specific ramp-up plan.
 - d. The study and room scheduling plan must be described, indicating how the schedule will minimize participant contact with others. If the study uses CTSC space, the plan does not need to be described, as room scheduling will be managed by CTSC staff to ensure compliance with these principles.

Human Research Group Ramp-up Plan

Each PI is required to provide a *Human Research Group Ramp-up Plan* ([here](#)), to be approved by the Office of the SVP for Research **before initiating ramp up of research operations**. The PI should work with their research group to develop a plan that facilitates an organized and staged ramp-up of research.

To submit the completed plan, please email the attachment to svp-research-office@downstate.edu with the subject line “Human Research Ramp-up Plan – last name, first name.”