

Ramp up Plan for SUNY Downstate Human Research

Overarching Plan

The human research ramp-up guidelines outlined in this document are derived from the center-wide principles and protocols developed by the SUNY Downstate “Back To New Normal” committee (BTNN; www.downstate.edu/health-alerts/back-to-new-normal.html), a multidisciplinary working group of faculty and staff representing diverse research interests and settings from all Downstate schools, colleges, and medical facilities, faculty experts in infectious disease, and the Research Foundation. All centerwide BTNN rules and guidelines, such as building entrance and elevator usage policies, social-distancing definitions, and mask-usage requirements apply to human research ramp-up.

This plan applies to research in Downstate HSU buildings. Downstate trainees and staff performing research at affiliated sites (e.g., Maimonides, Kings County, ...) should adhere to the research restart policies of those institutions.

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

Current State

As of 6/25/20, the COVID-19 rules for human research are as defined in the 4/4/20 [memo](#) from Dean Brunicardi. The overarching policy has been that “all in-person face-to-face interventions in all human research studies without a prospect of therapeutic benefit to the research participants” are temporarily suspended unless an exception has been approved by the Institutional Review Board (IRB) or the Downstate Coronavirus Task Force along with the IRB Chair as described in the [IRB guidance for lifting the suspension](#).

New studies submitted to the IRB have needed to include the following: 1) compelling reason to initiate new research, 2) explanation on how the benefits of the research outweigh the risks of exposure of research participants and others to COVID-19, and 3) procedures to mitigate the risk of COVID-19.

Applicability

The temporary suspension as defined in the 4/4/20 [memo](#) and this Ramp-up plan apply to all human research (e.g., all human research approved via the full board, exempt or expedited review) as defined by Downstate [Policy IRB-01](#) (page 15-24) performed by the [Downstate workforce](#) in our on-campus research spaces and clinical buildings.

The following human research activities are excluded from this plan:

- In-Person Face-to-Face interactions in research studies approved prior to 4/4/20 that have the prospect of direct benefit to the research participant, provided [COVID-19 hazards are mitigated](#).
- In-Person Face-to-Face interactions that were granted an exception (or an IRB approved amendment) per the 4/4/20 [memo](#) by following the IRB guidance for [lifting the temporary suspension of research activities](#), as long the research continues to adhere to the stipulations of that exception.
- New studies (or amendments to mitigate the hazards of COVID-19) that involve In-Person Face-to-Face interactions approved by the Downstate IRB after 4/4/20 as long as the study continues to adhere to the stipulations of that approval.
- Any human research approved by the IRB after 4/4/20 under the stipulation that the research will not take place until after the pandemic ends or after the temporary suspension is lifted (as defined

in the 4/4/20 memo) if the suspension is lifted by the Downstate Coronavirus Task Force or the Pandemic ends as declared by the CDC.

Any studies for which applicability of this plan is unclear should adhere to the plan unless otherwise granted an exception in writing by the Senior Vice President for Research.

Downstate trainees and staff performing research at affiliated sites (e.g., Maimonides, Kings County, ...) should adhere to the research restart policies of those institutions.

Guiding Principles

With the gradual decline of new COVID-19 cases in New York, it is appropriate to initiate the ramping up of human research activities at SUNY Downstate. Research ramp-up must be a careful and deliberate process that considers three major overarching principles/values.

SAFETY - First and most importantly, the process must be **safe**. Our approach must protect the health and safety of our workforce. This is best achieved through a ramp-up that emphasizes social distancing and the use of masks. If it is not necessary to physically be on campus to perform specific duties, as determined by the research group PI, off-site work should be performed.

FLEXIBILITY - Second, the process must allow for appropriate **flexibility**. Flexible policies will permit PIs to ramp-up their research group's activities in the most appropriate manner. As noted below, each PI is required to develop a plan to ramp-up research activities that is based on these guidelines and customized for their group. Notably, because modification in timing may be required in the event that COVID-19 cases resurge, adjustments, including another ramp down, may occur.

COMMUNITY - Lastly, as we ramp-up research activities, we must **support** each other and work together, remembering that we are part of the larger Downstate community. We need each PI to be responsive to challenges faced by their research personnel and help manage their concerns in returning to work on campus, in concert with RF and/or Downstate Human Resources.

With these principles in mind, below are the guidelines for ramping up human research activities at Downstate. These policies cannot address every possible scenario, and for any issues not addressed in these guidelines, decisions should follow the spirit of these guiding principles. As national, state, local and institutional policies continue to develop, changes may be necessary to these guidelines.

Strategies for Continuing Human Research While Activities are Restricted

The following strategies are suggested until full human research activities can be resumed:

- To limit face-to-face interactions with research participants, investigators are encouraged to utilize remote methodologies including online surveys and/or videoconferencing applications and remote consent options with a witness.
- Consider utilizing commercial laboratories for acquisition of blood and other samples.
- Follow the IRB Guidance for [Eliminating hazards associated with COVID-19](#).

The Research Foundations Sponsored Programs Office can help facilitate such approaches, including working with research sponsors for supplemental funds, as necessary.

Human Research Ramp-up Phases

Human research activity will be phased in according to:

Phase 1 (effective July 1) – Research without in-person face-to-face interactions: Downstate human research activities that do not involve in-person face-to-face interactions (e.g., individual or group work involving data processing or survey analysis) can resume, once the group leader has received a approval of a Human Research Group Ramp-up Plan (see below):

- Staff who can work remotely should continue to do so, in accordance with the effort to reduce the number of individuals in Downstate buildings. Designation of staff appropriate for return is to be made by the PI according to the guidelines of the COVID Taskforce. Funding agency policies, if they exist, may be taken into consideration.
- Any staff working on campus must adhere to Downstate's social distancing and mask usage rules.
- Research involving clinical inpatients, as long as the study is performed in conjunction with a visit required for clinical care, with the research intervention taking place in the same room as the clinical visit, and does not involve any personnel in addition to those required for the clinical visit.
- Site monitors may visit the research site, provided there are sufficient plans for study-appropriate PPE (supplied by the monitor) and available space for social distancing. Government inspectors may visit the site at the discretion of the agency in collaboration with the IRB or PI; however, the inspector should verify there is sufficient study-appropriate PPE in place and available space for social distancing.

Please note that even if adequate social distancing is feasible as proposed, the group-specific plan may be modified by the Office of the SVP for Research if doing so is necessary for Downstate to meet our overall NY State imposed personnel limitations.

Phase 2 (*start date to be announced*) – Research (inpatient or outpatient) with in-person face-to-face interactions without out the direct prospect of therapeutic benefit: The same guidelines and procedures must be followed as detailed for Phase 1.

Phase 3 (*when all NYS and NYC restrictions are lifted*) – Research activities with complete staff: Research groups may resume full-density research activities. Mask usage and/or other policies will be determined according to government regulations and the local situation at that time.

The launch of each phase will be announced. Launches of phases 2 and 3 will depend on the success achieved in the previous phases, epidemiologic data, and state and local restrictions. If data indicates a resurgence in COVID-19 cases and as restrictions are ramped up, we may have to reimpose restrictions.

Human Research Ramp-up Guidelines

1. Social Distancing and Mask Policies

As noted above, social distancing and mask usage are central to the ramp-up plan:

- Stationary work positions must be located more than 6' (in radius; i.e., in all directions) from the nearest other stationary work positions. When transitioning between work positions, staff are allowed to pass closer than 6' to another staff member but must minimize such occurrences and not congregate.
- **Masks must be worn at all times inside any room if there are more than 1 person present, even if those present are more than 6' apart.**

If necessary, staggered shifts may be required to ensure proper social distancing. Lunch, breakroom, and conference room usage must adhere to all centerwide rules.

2. Developing Work Shifts — Considerations

- a) If shifts are necessary to maintain social distancing, research groups should develop calendars to schedule work shifts that follow the maximum personnel guidelines.
- b) The structure of schedules and length of shifts are determined by the PI. Personal circumstances and outside obligations should be considered when developing shifts. PIs should be flexible with assigning shifts. If a suitable arrangement cannot be made, please contact your Human Resources Business Partner for assistance. Shifts can be scheduled in a variety of ways, including time of day (morning, afternoon) or days of week (i.e. Mon-Wed, Thur-Sat), and spread

within the facility (i.e. working in different rooms, different workstations, etc.) to avoid close interactions.

- c) When feasible, personnel should enter and leave Downstate buildings at non-standard times to avoid congestion coming into the building and using elevators. Personnel should take stairs, if possible, to reduce elevator traffic.
- d) Working alone between 8pm-6am is discouraged for safety reasons, but can occur with an approved safety plan.
- e) The schedule should be strictly followed. Everyone should complete work within their shift.

3. Sequence of staff return

The following should be considered to determine the order of scheduling returning staff:

- a) Consideration should be given to trainees and staff who need to complete their research projects in a timely fashion to meet deadlines for, e.g., a grant submission, a thesis, or a paper submission.
- b) Stagger personnel to accommodate as many as possible to ramp-up their research projects.
- c) PIs should consider grouping personnel into cohorts with shared research goals to work around the same time.
- d) Volunteers and visitors (including undergraduate and high school students) are not allowed in Downstate buildings, without special permission from the SVP of Research, until further notice by the BTNN committee.

4. Personal and Research-Group Protection

- a) All personnel should self-monitor for symptoms, including temperature, daily before coming on site. Any personnel feeling unwell should not come to the research site and should notify their supervisor.
- b) Diligently wash hands with soap upon entering and leaving the research site and frequently throughout the day. At a minimum, maintain a supply of hand sanitizer in work spaces without hand washing sinks; however, make this available for all work areas if feasible.
- c) Masks must be worn in all Downstate areas except when alone in a room or when eating.
- d) Research ramp-up may lead to personnel working alone at times. Research groups are encouraged to establish virtual buddy systems with a group member, member of a neighboring group, or supervisor who they can call or text to check in/out and ensure safety.

5. Research group communication

To ensure social distancing, all meetings – including group meetings, work/research-in-progress meetings, journal clubs, seminars, and faculty meetings – should be held virtually until further notice.

6. Compliance

All Research groups must adhere to these policies. It is the responsibility of the PI and other research group supervisors to enforce physical and temporal distancing measures, mask requirements, social distancing, and other safety regulations. We are confident that faculty, students, and staff understand the importance of these policies and will operate accordingly. An allegation of non-compliance may be reported anonymously to the confidential Compliance Line (877-349-SUNY or via [Compliance Line Website](http://www.compliance-helpline.com/downstate.jsp) www.compliance-helpline.com/downstate.jsp).

Human Research Group Ramp-up Plan

Each PI is required to provide a *Human Research Group Ramp-up Plan* ([Word template attached](#)), 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."