Human Research Group Ramp-up Plan

Purpose

The following plan should be completed and approved by each research group's PI. The plan must be approved by the Office of the Senior Vice President for Research before ramp-up can commence.

Objectives

The objectives of this plan are:

1. Facilitate safe and orderly restoration of Downstate human research activities.
2. Minimize potential transmission of COVID-19.
3. Restore human research to full capacity as soon as possible.

Research group Ramp-up Considerations

Careful attention should be given to the types and duration of research following reopening. Researchers should plan accordingly:

1. Which, if any, research-group personnel need to work on campus opposed to remotely?
2. Can a staggered start be implemented?
3. Can the research group operate with fewer staff onsite at any given time, perhaps with extended hours?
4. Can the research be easily halted if another ramp-down is necessary?
5. Are additional accommodations required in order to restart your research?
6. Is there sufficient study-specific PPE, handwashing stations, or hand sanitizer?
7. Are there sufficient BSL-2 hoods, if required, with appropriate room configuration for processing specimens?

Personnel. Research group members must be granted a safe workspace. Social distancing and mask usage in common spaces are required. Research groups must consider how they can:

1. Create staffing rotations.
2. Limit staffing numbers to help with social distancing.
3. Implement frequent disinfecting protocols for research group spaces, including frequency.

Plan submission

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."

Research group Ramp-up Plan

1. PI Name (last, first): _____
2. Other persons responsible for the research group (if other than the PI): _____
3. Total number of research group personnel (faculty, trainees, staff, administrators): _____ (if only one person, questions 5, 6, and 7 can be skipped.)
4. Research group room info (add new rows as needed):

Building and Room # (if CTSC user, write "CTSC room TBD")	# of work locations within the research location that can be used simultaneously while maintaining at least 6' between workers	# of personnel proposed for Phase 1	Comments

5. Social Distancing Plan: Please provide a description of your strategy for achieving social distancing of your research group personnel, referencing specific room numbers. Attach sketches if helpful. If CTSC user, write "Scheduled CTSC Room TBD". *(e.g., one study coordinator in the research space at any given time - UHB 6-10; limit the number of personnel needed to obtain informed consent, etc.)*

6. Staff Scheduling Plan: Please provide a description of the scheduling strategy, including days, hours, and number of people per shift. Include links to scheduling calendars if available. *(e.g., staff schedules can be adjusted to alternate days; alternate times; some remain working from home, rotation of schedules, etc.)*

7. Cleaning and Disinfection Plan: Provide a description of how the research group will maintain a clean working environment throughout the day and between shifts (if applicable). Include information on responsibilities and techniques. Please note that Downstate cleaning staff will NOT be available to clean rooms more than once per day. *(e.g., each person is responsible to clean their own work space; everyone will clean shared equipment (printer, scanner, etc.) before each use.)*

8. Prospect of direct therapeutic benefit: If requesting an in-person face-to-face interaction with a study participant during Phase 1, please provide the IRBNet # for each study that has a prospect of direct therapeutic benefit to study participants. The prospect of direct therapeutic benefit plan will be confirmed by an IRB Member before the ramp-up plan is approved.

9. In-person face-to-face interactions that occur during clinic visits: If applicable, describe the ramp-up of research involving clinical inpatients, where 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, that does not involve any personnel in addition to those required for the clinical visit.

10. On-campus study that does not have prospect of direct therapeutic benefit: If the study requires on-campus participation of subjects and does not have prospect of direct therapeutic benefit to study participants: a) justify why the study should re-start on campus at this time; b) specify how many study personnel will participate in each visit, and if the number is greater than one, why; c) using specific campus entrance address, hallway descriptions, stairwell or elevator description, and room numbers, describe the procedure for meeting subjects, escorting them to the study room, and then escorting them out of the building upon study completion; d) unless the study will use CTSC space, describe the scheduling plan and how it will minimize likelihood of participants coming into close proximity with anyone on campus other than study personnel; e) if waiting room use is essential, please explain why and how participants will not come in close proximity to others while in a waiting room.

11. PPE Plan: If interacting with human subjects, provide a PPE plan to safely interact with research participants or others who may be infected with COVID-19. Contact the IBC or EHS for guidance.

12. Site monitors, Government inspectors, Vendors, and Outside Services: Provide a list of any known site monitors, government inspectors, essential outside vendors, or other outside services that will need to come into your research space, and the frequency/duration anticipated for those visits. These should be kept to an absolute minimum. As described in the guidelines, PPE and social-distancing protocols must be followed.

Name/Company/Institution	Frequency of visit (approximate)	Email or Phone Number

Office of SVP for Research comments:

Research group PI:

Plan approved as is: ☐

Plan approved as modified as described above in comments: ☐

Modification of plan required as described above in comments: ☐

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David Christini, PhD, SVP for Research Date