

RESEARCH RECOVERY PLAN

Guiding Principles

The health and safety of our researchers, i.e., faculty, staff, and students, during this pandemic is of utmost importance. However, there is also a need to return to research productivity to ensure continued discovery, extramural funding, and student training. Thus, a plan to phase in increasing research activity is needed that reduces potential exposure to COVID-19 virus. The decision to move through each of the phases will be dependent on the up to date situation with COVID-19 cases and the ability to manage the risk of exposure and infection.

If the nature of laboratory-based and/or human subject research is challenging to conduct remotely, additional technical and operational procedures must be rigorously applied. Accountability will be critical; all personnel should remind one another of the need to conduct research safely in proximity to one another.

Preliminary Steps

The general plan has several stages:

- Appropriate training of all personnel in proper use of personal protective equipment (PPE) and COVID-19 related risk management guidelines
- Assigned re-entry approval for individual researchers. The prioritization and determination for specific return-to-campus will be made as follows:

The Dean of each college/school prepares a list of the order of re-entry for research faculty based on the following criteria:

- Externally-funded sponsored research with near-term deadlines for completion or progress reports (this category may involve graduate students or postdoctoral fellows named as research staff on that project)
- Other externally-funded research
- Research involving graduate trainees nearing completion of degree-program

This priority list is provided to the Vice President for Research for review and approval; if approved, the respective Dean shall be notified in writing of the approved researcher(s), designated research space to be accessed, and any specific terms and conditions for the return to research and continued access. Upon approval, the individual investigator will be notified of these specific assignments and approvals.

Deans and the VPR will regularly consult with the leadership in Environmental Health & Safety (EHS), the Department of Laboratory Animal Medicine (DLAM), Facilities Management, and other campus officials as needed.

NOTE: Researchers engaged in animal research must take the additional step of describing to their Dean the number, species, and type of animals needed, along with the title and date of an approved IACUC protocol. If the project involving animals is cleared for “return to research,” this information will be shared with DLAM to arrange for timely ordering, delivery, and receipt of animals.

- As circumstances develop, additional research personnel may be allowed back on campus in phased orderly stages.

Phases of Return

The plan to “Return to Research” for animal and human subject studies will occur in phases:

Phase 1:

- On-campus
- Wet laboratory and animal studies
- Human Subject Research (HSR) not requiring direct in-person contact with research subjects (e.g., online data collection; virtual visits, etc.)
- HSR studies in which subjects can receive direct benefits from participating in research (and this requires specific permission from appropriate office – IRB etc.)

Phase 2:

- On-campus and off-campus
- HSR projects involving healthy research subjects requiring direct contact or close proximity (not able to maintain a 6’ distance)
- Clinical trials where the intervention is of potential benefit to the participant, even if the participants are at increased risk; subject to review by Office of Environmental Health and Safety and/or IRB based on special considerations (see below for HSR Guidance)

Phase 3:

- On-campus and off-campus
- HSR studies which involve vulnerable populations (children, prisoners, pregnant women) of any health status
- Physical access to the performance site where “research” is conducted needs to be controlled (e.g., hospitals or UNTHSC facilities).
- Requiring reviews by the Office of Environmental Health and Safety and/or IRB based on the special considerations (see below for HSR Guidance).

Special Note on Trainee research

HSC is committed to creating a safe environment for students, medical residents and postdoctoral fellows to conduct their research. Students, medical residents and postdoctoral fellows should follow all relevant guidelines. All students, residents and postdoctoral fellows who can perform their research remotely should do so with approval from their direct supervisor.

Postdoctoral fellows should follow the HSC guidelines and Standard Operating Guidelines (SOGs) created for faculty and staff (see attached SOGs). Postdoctoral fellows’ return to research activity on campus will be determined by their research mentor with approval from their college/school Dean.

Graduate students who are Ph.D. or MS Candidates and Medical Residents can apply through their supervisors and Department Chair to conduct on-campus, lab-based research or research with human subjects. Other students (traditional graduate students, medical science research track students, medical students, pharmacy students) can apply for on-campus access during Phase II.

Students who matriculate in the Fall Semester of 2020 can begin laboratory rotations/activity on the census date of that semester (September 1st, 2020) or as otherwise determined and authorized by the President of HSC.

RETURNING TO RESEARCH

The overall strategy will include restricted access to campus labs, new procedures to reduce potential exposure [minimize on-campus time, social distancing, usage of personal protective equipment (PPE) and disinfection], training of research personnel, and clear consequences for non-compliance with these procedures. Furthermore, on-campus research activities will be restricted to those that must use HSC facilities/labs. Data analyses, meetings/discussions with lab members, etc., can and should be done remotely. If any researchers demonstrate non-compliance, this will significantly impact their access to and use of campus research facilities.

Restricted access to campus labs

All researchers returning to campus will be required to comply with all relevant HSC guidelines regarding personal protective equipment, social distancing, decontamination, and self-monitoring. This includes completing required HSC COVID-19 related training (educational course) and adhering to CDC guidelines about self-quarantine following travel, or exposure to COVID-19 positive individuals. Researchers who study an “at-risk” population, live with, or care for people in high-risk groups, should follow CDC and HSC guidelines about working remotely and reducing their own risk and exposure.

Development of a list of labs with priority to restart research activity

Departments and schools prioritize which laboratories and researchers will be allowed to have limited activity on campus. In general, funded research, particularly those with clear deadlines/completion dates without any flexibility, should have the highest priority. However, there may be additional criteria used to further prioritize when research labs and projects can resume research activity.

- a) Deans, based on input from Department Chairs, prepare a phased plan for restarting research that is consistent with HSC safety and personnel guidelines.
- b) The Dean will review the Chairs’ list and invite investigators to submit a plan that includes:
 - i) the number of personnel,
 - ii) room numbers, and a
 - iii) schedule for the proposed activity.

In addition, the need for core and animal facilities should be included. Furthermore, there should be consideration of whether sufficient PPE is available or a plan to acquire needed supplies. Scheduling restrictions should be identified, which can influence the recommended plan.

- c) The Dean will review the plans and submit a recommended approach to the Vice President of Research that would allow the designated researcher(s) to return to activity safely. This approach can use 24-hour scheduling to ensure that the number of personnel in labs or on the same floor is consistent with social distancing.

Note that any research activity occurring in the clinical spaces of the Health Pavilion that involves patients must adhere to the policies and procedures associated with the UNTHSC clinical practice group.

Coordination of scheduling of laboratory/research activity

There is a need to coordinate scheduling of research activity at the level of labs or projects, a floor or building that maintains safety and accounts for people who will be in the same space for non-research essential institutional business. This includes scheduling and procedures to use services by core laboratories, e.g., confocal microscopy, flow cytometry, genomics core lab, DLAM, pharmaceutical analysis, human subjects research projects, and other multi-user research locations.

Coordination will be overseen by the relevant facility managers (Principal Investigator, Chair, Dean, or VPR, depending on the facility). The goal is to coordinate and schedule activity in each building to minimize potential exposures and maintain a safe working environment.

Note that the use of “Core” Research Instrumentation labs, managed by the Division of Research and Innovation will involve specific guidelines and procedures for accessing and conducting research in those labs/rooms: [RESTARTING DRI CORE FACILITIES AT UNTHSC](#).

As research team members arrive on campus (gradually) it is expected that eventually we will develop a pattern and rhythm to return to semi-normalized discovery activities. Please be patient throughout this evolving process and time.

Standard Operating Guidelines (SOGs) for managing COVID-19 Risk in Research

Refer to HSC published guidelines for hand washing, self-monitoring for symptoms of COVID-19, and social distancing and wearing masks; all personnel with access to campus will be required to follow related HSC guidelines for COVID-19 specific training, self-assessment and self-reporting. Further, researchers working off-site (so-called “field” research) should, whenever possible, limit time the field, and ensure physical distancing at all times and wear face masks when conducting research.

As for laboratory-based research, research involving in-person interactions with human subjects must be pre-approved by the relevant School/College Dean.

Each project director (i.e., Principal Investigator of a funded research project or a research lab director) will identify all personnel under her/his supervision and the physical space to be used for research, regardless of whether the research involves direct in-person human subject interactions.

The research space may include a designated individual office at UNTHSC or a suite of offices or classrooms at UNTHSC, and also off-campus locations for field-based work.

Project directors should ensure that, where possible, all research activities that can be done without direct face-to-face contacts, be done to limit such interactions. For the designated research space or any space temporarily used for research at UNTHSC that can be accessed by more than one person, project directors should develop a detailed plan restricting and monitoring access to that space, and ensuring physical distancing when necessary. The plan should include a protocol for situations where the guidelines are not followed.

For research involving human subjects and community partners recruited from and conducted at non-HSC locations (e.g., homes, homeless shelters, schools, clinics), it is recommended that researchers identify and adhere to any existing procedures and guidelines of that facility and agency (if different) in which it is conducted,

as well as those of the corresponding local authorities of the site (e.g., Dallas County, or City of Dallas). Also, the following procedures are to be considered:

- Screen all human subjects and their support persons (e.g., parents) for possible symptoms of COVID-19 and adopt a multi-step screening process
- Advise human subjects to check their temperature and monitor COVID-19 symptoms prior to a scheduled visit by research staff or coming in for an appointment
- Send instructions for subjects if they have fever or COVID-19 symptoms
- Schedule face-to-face visits in ways to ensure separation in time between appointments
- Plan to provide facial masks and hand sanitizer for subjects and their support persons if necessary
- After each participant visit (or session), sanitize any surface (e.g., table and chair, laptop or ipad) that the participant touched
- Upon arriving, screen again for fever and COVID-19 symptoms
- Include a plan for distancing those who come with or who are present with participants
- For all group-based activities (e.g., group-based interventions, focus groups or stakeholder meetings) that require direct in-person contact, limit the number of participants per session to ensure physical distancing, arrange space for physical distancing and clean the research space following each session
- Following the same protocol, screen all research personnel daily who are involved in direct contacts with participants and provide PPE (e.g., face masks, sanitizer, disposable gloves)

All project directors should develop a comprehensive plan based on their unique needs and circumstances and obtain approval by their Dean. This plan should include the identification of space utilization and monitoring of safe research activity; the protocol to ensure the safety of all research personnel including UNTHSC students and research subjects; and the procedures for handling any anticipated COVID-19 positive cases, including a plan to scale back the research if the proposed plan needs to be revised.

For field-based activities that require within-state or out-of-state travels, this must be pre-approved in writing by the appropriate Dean, the Provost, and the Vice President for Research. This also requires the removal of the “Stay-at-Home” order by the appropriate local authorities (e.g., both Tarrant County and destination County/State).