

Updated Guidance for VUMC Research Enterprise Functions

On March 25th, 2020 VUMC provided guidance intended to minimize the risk of COVID-19 for employees performing non-clinical functions, including those working in the research enterprise. All principal investigators, supervisors and managers were instructed to enable work-from-home arrangements for individuals not performing COVID-19 research or essential research functions on campus (e.g. animal care, core facility functions, and maintenance of critical equipment operations). We appreciate the manner in which you are successfully adapting and meeting the challenges associated with new ways of working both on campus and at home.

All VUMC employees and activities are essential for the ongoing success of the medical center. While VUMC has restarted elective clinical care and is preparing to increase nonclinical activities over the coming weeks, it is clear that COVID-19 will be pose a health risk to our employees and patients for many months. In order to reduce exposure to all employees, work from home will continue to play a major role in our operations. This approach limits the occupancy of our facilities, improves safety for patients and employees involved in direct clinical care as well as in crisis management and support.

As research enterprise activities are resumed, uncertainties are to be expected and close monitoring will be needed; this will not be an immediate return to business as usual.

Key Principles:

VUMC research enterprise operations will resume activities on campus in four phases that are coordinated with those of the Roadmap for Reopening Nashville – <https://www.asafenashville.org/roadmap-for-reopening-nashville/>

- Infection control practices will align with the metro Nashville Roadmap guidelines
- Research enterprise activity protocols will also be aligned with VUMC clinical enterprise policies covering COVID-19 infection control and monitoring
- VUMC-wide communication will accompany progression between phases
- Any negative trends in COVID-19 infection in an area of the enterprise will be addressed rapidly with appropriate biosafety measures; and, that area may be required to return to practices associated with a more restricted phase
- If metrics of COVID-19 infection and health system capacity change significantly, VUMC in coordination with city and state officials may be required to return to a prior phase and re-impose restrictions on non-clinical activity. All principal investigators, supervisors and managers must develop a shutdown contingency plan in case it becomes necessary to rapidly reduce activities

The Research Enterprise activities will follow guidance that applies to all VUMC non-clinical functions. Below is additional guidance and/or specific variances for employees performing research activities. **VUMC will issue institution-wide notifications regarding the date for commencing each Phase.**

The following safety practices should be followed now and through all phases:

- Whenever working on-site, adhere to strict physical distancing (**defined as 6 ft**) and follow universal COVID-19 precautions (frequent hand washing with soap and water for 20 secs or hand sanitizer, including before and after eating)
- PIs, directors of cores and shared facilities, and research leadership will continuously assess personnel physical distancing relative to space design, type of work, nature of research activities and functions (**see Appendix for more details**)
- All employees must monitor themselves for COVID-19 symptoms, including new onset cough, fever, and other symptoms specified by the CDC (<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>). If you have symptoms immediately isolate yourself, contact your healthcare provider and notify your supervisor. VUMC will continue temperature screening and has begun COVID-19 symptom checks at employee entrances
- Cloth masks must be worn in public areas of the medical center including hallways, lobbies, meeting rooms, and cafeterias, and in shared workspaces. Research cores/shared facilities are considered public areas. Avoid touching your face or mask. If you touch your face or mask, wash or sanitize your hands. If performing human participants research and engaged with patient care, appropriate clinical PPE must be worn as per clinical enterprise protocols. In wet lab areas, paper masks may be worn with guidance/approval by Environmental Health and Safety. N95 masks will not be used in the research enterprise except as approved by Occupational Health for employee health/safety reasons. Each research unit/area/lab should procure and provide masks as needed
- Virtual meeting applications (such as Microsoft Teams and Zoom) are encouraged as an alternative to face-to-face meetings or work-related travel
- Employees 65 years or older, or those with high-risk factors related to COVID-19, should continue to work from home in a manner consistent with VUMC HR policy
- Current proposed guidelines apply to campus-based and off-site research activities. Community-based activities that require direct face-to-face contact with community members in the community setting are discouraged until further notice. Converting these research activities to remote approaches are encouraged
- Most “dry lab” research focused on computational and related activities, and research administrative support staff, should continue to follow “work from home” as much as possible
- Ramping up of clinical/human participant research in the inpatient and outpatient clinical environments will be dependent on the approval of the plan by specific medical director(s) of the impacted PCC, and administrative clinical site leadership (**see Appendix for more details**)
- Ramping up of non-COVID-19 clinical/human participant research in the CRC will be dependent on the approval of the plan by the CRC leadership

Phases for Resuming Research Enterprise Operations

Phase 1

- In this phase, the first-step expansion of research, prioritizing extramurally-funded* wet-bench and human participant research activities can occur, which can be conducted safely with physical distancing and universal COVID-19 precautions (up to 50% capacity); **Inclusive of early career faculty supported on intramural funding sources*
- Continued implementation of training and programs that allow participants to meet remotely to the extent possible; creation of new programs as needed to foster remote learning
- Gatherings of up to 10 people are permitted if physical distancing can be achieved
- Avoid use of shared break areas and supplies and if utilized, disinfect supplies and all surfaces before and after use

Phase 2

- In this phase, a next-step expansion prioritizing extramurally-funded wet-bench and human participant research activities on and off campus can occur, which can be conducted safely with physical distancing and universal COVID-19 precautions (up to 75% capacity)
- Continued implementation of training and programs that allow participants to meet remotely to the extent possible; creation of new programs as needed to foster remote learning
- Gatherings of up to 25 people are permitted if physical distancing can be achieved
- Avoid use of shared break areas and supplies and if utilized, disinfect supplies and all surfaces before and after use

Phase 3

- In this phase, a further expansion of extramurally- and intramurally-funded research can occur, which can be conducted safely with physical distancing and universal COVID-19 precautions (up to 100% capacity)
- Continued implementation of training and programs that allow participants to meet remotely to the extent possible
- Larger gatherings are permitted with size limits to be determined, if physical distancing can be achieved
- Avoid use of shared break areas and supplies and if utilized, disinfect supplies and all surfaces before and after use

Phase 4

- In this phase, all research that can be safely conducted with universal COVID-19 precautions in place can occur. Physical distancing is encouraged, but is no longer required
- Work from home and use of masks in public are optional
- Larger gatherings are permitted with size limits to be determined
- Shared break areas and supplies should be disinfected before and after use

VUMC Multi-phase Plan for Research Activity Ramp Up

	Phase 1 [^]	Phase 2 [^]	Phase 3 [^]	Phase 4
Research capacity	First-step expansion, prioritizing <u>extramurally-funded*</u> , wet-bench and human participant research activities, which can be conducted safely <u>with physical distancing</u> and universal COVID-19 precautions (<u>up to 50% capacity</u>) *Inclusive of early career faculty supported by intramural funds	Next-step expansion prioritizing <u>extramurally-funded*</u> , wet-bench and human participant research activities, which can be conducted safely <u>with physical distancing</u> and universal COVID-19 precautions (<u>up to 75% capacity</u>) *Inclusive of early career faculty supported by intramural funds	A further expansion of <u>extramurally- and intramurally-funded</u> research, which can be conducted safely <u>with physical distancing</u> and universal COVID-19 precautions (<u>up to 100% capacity</u>)	<u>All research</u> that can be safely conducted with appropriate precautions
Remote training and programs	Continued implementation and creation to support remote activities	Continued implementation and creation to support remote activities	Continued implementation and creation to support remote activities	Continued implementation and creation to support remote activities
Gatherings	<u>If physical distancing can be achieved</u> , allow gatherings of up to 10 people	<u>If physical distancing can be achieved</u> , allow gatherings of up to 25 people	<u>If physical distancing can be achieved</u> , allow gatherings of size to be determined	Allow larger gatherings, <u>if safe</u> , and with size to be determined
Work from home	Most “dry lab” research should continue to take place remotely at home and administrative support staff should continue to work from home to the extent possible	Most “dry lab” research should continue to take place remotely at home and administrative support staff should continue to work from home to the extent possible	Most “dry lab” research should continue to take place remotely at home and administrative support staff should continue to work from home to the extent possible	Work from home is optional, and the use of masks in public is optional

[^]Cloth masks must be worn in public areas of the medical center. Research cores/shared facilities are considered public areas. If performing human participants research and engaged with patient care, appropriate clinical PPE must be worn as per clinical enterprise protocols.

APPENDIX

Additional guidance and practices that should be followed for labs and cores/shared facilities:

- a. Consult as needed with VEHS Biosafety Officer to ensure appropriate biosafety level is supported as research progresses, and/or to identify enhancements needed for working with specific sample types.
- b. Routinely monitor guidance from Division of Animal Care regarding status of animal care facilities, and plan for animal maintenance and experiments accordingly.
- c. Wash hands (or use hand sanitizer if soap and water is not available) before entering and exiting all labs and before consuming food/drink
- d. Disinfect lab (to include equipment/handles/work surfaces) at end of each shift. In the case of core facility, equipment and workstations should be disinfected in the transition between core users.
- e. Prohibit sharing of equipment such as goggles, safety glasses, face shields, lab coats, etc. that do not have to be shared.
- f. While practicing physical distancing, ensure others are aware of your activities in the event you need assistance.
- g. Monitor PPE, cloth masks (or other type of masks if approved for use) and disinfectant supplies to ensure the lab has enough to support lab activities.
- h. Users of core facilities/shared resources should contact the facility manager in advance to plan for additional core-specific guidance and restrictions.

Additional guidance and practices that should be followed for clinical/human participant research investigators:

- a. Formulate a plan to enable patient accrual to existing open clinical/human participant trials during phase 0 of the ramp-up plan. Each team should formulate and prioritize a list of trials they wish to be reviewed for this action by the relevant PCC. Approval from the PCC/local clinical site is required prior to re-initiating accrual of human subject participants in all phases.
- b. Clinical trials that offer curative or life-prolonging treatment in the absence of an acceptable standard of care should be prioritized.
- c. Do not open existing trials to new accruals that make use of ancillary services that may have limited capacity. Departments may have limitations based on relative COVID-19 clinical case load or other ongoing clinical operations.
- d. If possible, avoid opening accrual to existing trials that require or may lead to inpatient admission, given potential use of inpatient resources.
- e. In general, less complicated trials that use less human resource (i.e. PK draws no longer than 1 or 2 h post dose, no serial EKGs past 2 h, no observation longer than 2 h, etc.) would be favored for the first phase.

- f. Your team will want to determine if there is a waiting list of patients for a given existing trial to be re-opened for accrual, to manage resources.
- g. Keep in mind that COVID testing for asymptomatic patients in certain categories has started. Consider the implications of a positive COVID test on enrolling a patient in a given study, as such patients require PPE for all phases of their journey in VUMC.
- h. Limit in-person clinical/human participant research encounters. Tele-visits should still be encouraged whenever feasible.
- i. Changes in research protocols to accommodate COVID-19 related issues should seek approval from IRB and other regulatory oversight as needed (see Resources below)
- j. Study monitors should work virtually whenever feasible, and on-campus visits require approval of the PCC/clinical site. Vendor visits should not initiate until Phase 4.

Resources

VUMC Coronavirus information for employees:

<https://www.vumc.org/coronavirus/employee-only-information>

Office of Research Contingency and Continuity Planning:

<https://www.vumc.org/oor/contingency-and-continuity-planning-vumc-research-labs-and-cores>

Environmental Health and Safety – Biosafety:

<https://www.vumc.org/safety/bio/emerging-infectious-agents>

NIH and FDA guidance for research during COVID19 including “Considerations for New and Ongoing Human Subjects Research During the COVID-19 Public Health Emergency”:

<https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>

Animal Care and Use Program:

<https://www.vumc.org/acup/acup-covid-19-response>

CDC Guidance for Laboratories:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>