

Research

Return to Campus Plan

The health, safety and well-being of our students, faculty, staff, and research community are our top priority, along with our commitment to the missions of the university and academic medical center. In developing this plan, six (6) guiding principles were considered. Those principles empower us to set priorities based upon a common set of goals:

1. We will follow applicable local, state, and national public health authority current and future directives for institutes of higher education. We will hold the safety and health of research participants, students, employees paramount. We will support the integrity of research and the careers of early-stage researchers.
2. Undergraduates are students first, researchers second.
3. Implement a fair and transparent process for granting access to research facilities.
4. As public health conditions permit, allow as rapid a research restart as possible.
5. Prioritize support for participation in finding cures and preventions for COVID-19, and in assessing and addressing the economic, political, and cultural impacts of the virus.
6. Risks and potential benefits (if any) to participants taking part in human subject research must be a top priority when restarting studies.

Additional observations and conclusions regarding these principles are listed at the end of this document.

All faculty, staff and students returning to research on campus must observe the requirements issued by VCU Human Resources, VCU Safety and Risk Management, or Environmental Health and Safety including: physical distancing, use of cloth face masks in public spaces, use of personal protective equipment (PPE) as required from a pre-existing job safety analysis in laboratory spaces and animal facilities/rooms, and flexibility as new information is available or situations arise. In addition, completion of training and agreements to properly clean/disinfect appropriate areas will be mandatory.

School/Unit Return to Campus Coordinators, Building Managers, and Managers will work together to identify and notify employees when facilities are ready for the return to research activities. Individuals may not return to campus until specifically authorized.

Additional considerations for research return revolve around use of core facilities and shared resources, use of animals and animal facilities, and human subjects research.

- Core facilities and shared resources will work under similar constraints as comparable laboratories with respect to distancing and occupancy, but have special additional considerations which may, in some cases, further constrain capacity and availability during the ramp-up period.
- Investigators with projects involving animals must understand that new animal orders will be ramped up gradually over time and capabilities for immediate animal delivery will be limited. At no time will DAR expand animal deliveries beyond its staffing capacity. In

addition, breeding colonies must be re-established gradually to prevent a synchronized wave of new litters being weaned that would tax the laboratory's colony management capabilities or DAR's caging and staffing capacity. DAR will require physical distancing in all animal facilities.

- The involvement of human subjects in face-to-face research activities must be evaluated for safety and risk and re-assessed on a regular basis.

In accordance with VCU's plan for a phased return to campus, most on-campus research will return in Phases II and III. The dates provided in the table are based on the external conditions listed, and are subject to change. Research that can be conducted remotely may continue through Phase IV if desired and approved.

| PHASE | EXTERNAL/ INTERNAL CONDITIONS | SUMMARY | CRITERIA | PROPOSED TIME PERIOD |
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| I | Governor's Executive Order 55 and 61 (referring to institutions of higher education) in place | <p>On-campus access allowed to maintain research capability or prevent catastrophic disruption</p> <p>COVID-19 related research encouraged</p> <p>Approved Tier 1 and Tier 2 human subjects studies continue</p> <p>Researchers/staff must be Designated to be on site</p> <p>On-campus research activity transitions to an estimated maximum of 15% of normal</p> | <p><i>Research access limited to physical-distanced essential personnel only for critical research activities and essential functions:</i></p> <p><u>Critical Research</u>: Finish up critical projects - no "new" projects, except for new COVID-19 projects, can be initiated on campus.</p> <p><u>COVID-19</u> related rapid response activities (e.g. testing, ventilators, etc.)**</p> <p>Prioritize core facilities that support COVID-19 research</p> <p><u>Field Research</u>: Prioritize seasonal data collection or experiments close to completion where pause or deferral would lead to "catastrophic loss" of research results. Undergraduates are not approved to participate.</p> <p><u>Human subjects research</u>: Research projects designated as Tier 1 (probability of high potential for direct health benefit); Tier 2 (moderate potential for health benefit); Tier 3 (limited or no direct health benefit) and Tier 4 (research involving no in-person interactions with participants). Tier 1 research and previously approved Tier 2 research can continue. Tier 1 and Tier 2 research that has not yet been approved can be assessed for approval. All other face-to-face research is on pause or must convert to remote interactions.</p> | March 23, 2020 through June 14, 2020 |
| II | Governor's Executive Orders 55 and 61 restrictions to critical research and essential | All research that is possible to be done remotely should continue remotely including all seminars, group meetings, etc. | <u>Animal Research</u> : Investigators with projects involving animals must understand that new animal orders will be ramped up gradually over time and expectations for immediate animal delivery will be limited. At no time will | June 15, 2020 – June 30, 2020 |

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| <p>functions lifted/revised</p> | <p>On-campus research activities transition to a maximum of 25% total personnel capacity, with physical distancing. Shift work can maintain this percentage while allowing more researchers to work.</p> <p>School/Unit Return to Campus Coordinators, Building Managers, and Managers are responsible for faculty and research staff return. Human Resource and Health and Safety requirements must be followed.</p> | <p>DAR expand animal deliveries beyond its staffing capacity. In addition, breeding colonies must be re-established gradually to prevent a synchronized wave of new litters being weaned that would tax the laboratory's colony management capabilities or DAR's caging and staffing capacity. DAR will require physical distancing in all animal facilities.</p> <p><u>Core facilities:</u> Core facilities will reopen, but availability will be constrained by reduced availability of staff and occupancy limitations for shared instrumentation or other shared-use spaces. Cores involving animal research will have policies coordinated with those of animal research generally. Core use and sample submission will be restricted to those investigators approved for on-campus research activity. Special procedures for sample submission, enhanced PPE, and high contact surface/instrument decontamination will be implemented. Users should anticipate that Instrument availability/sample processing/ turn-around time, etc. are likely to be significantly reduced/ lengthened during this phase.</p> <p><u>Field research:</u> Field research is limited to VCU and state travel restrictions currently in place.</p> <p><u>Basic Science labs:</u> Prioritize return of bench-level employees such as graduate students and postdoctoral scholars who cannot work remotely. Unit-level decisions about population density adhere to 25% maximum. For research labs, this should take into account 25% of normal space capacity but must allow 250 square foot per person minimum.</p> <p><u>Human research:</u> All departments and study teams should assess the risk of being on campus and taking part in face-to-face research. Research interactions with participants that can be done remotely should continue being done remotely. Amendments must be prospectively submitted and approved by the IRB for any new or altered procedures. The study's risk/benefit ratio needs to be evaluated by departments and study teams on a project-by-project basis prior to restarting and then reassessed on a weekly basis based on the changing status of the COVID-19 pandemic.</p> <p>Considerations:</p> | |
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| | | | <ul style="list-style-type: none"> • If a participant or research personnel is already on campus or in a clinic for non-research reasons and there would be no additional COVID-related risk for participating in/conducting the research, this could be taken into account. • Health system guidelines must be observed as the minimum required standards for clinical research conducted in the health system. • Research at off-site locations and in participants' homes should follow the most conservative guidelines for physical distancing, cleaning, and cloth face covering use (state, VCU/VCU Health, or off-site location guidelines). • The study's on-site participants, use of space and resources and its impact on other units and organizational operations should be taken into consideration. | |
| <p>III</p> | <p>VPRI, in consultation with VP for Administration, and considering available public health information, will make the determination to proceed to this phase.</p> | <p>All research that is possible to be done remotely should continue remotely including all seminars, group meetings, etc.</p> <p>On-campus research activities transition to a maximum of 50% total personnel capacity, with physical distancing. Shift work can maintain this percentage while allowing more researchers to work.</p> <p>School/Unit Return to Campus Coordinators, Building Managers, and Managers are responsible for faculty and research staff return. Human Resource and Health and Safety requirements must be followed.</p> | <p><u>Animal Research:</u> Investigators with projects involving animals must understand that new animal orders will be ramped up gradually over time and expectations for immediate animal delivery will be limited. At no time will DAR expand animal deliveries beyond its staffing capacity. In addition, breeding colonies must be re-established gradually to prevent a synchronized wave of new litters being weaned that would tax the laboratory's colony management capabilities or DAR's caging and staffing capacity. DAR will require physical distancing in all animal facilities.</p> <p><u>Core facilities:</u> Core facilities will remain constrained by reduced availability of staff and occupancy limitations for shared instrumentation or other shared-use spaces, but capacity should increase commensurate with the increase in staffing/occupancy. Cores involving animal research will have policies coordinated with those of animal research generally. Special procedures for sample submission, enhanced PPE, and high contact surface/instrument decontamination will remain in place. Users should anticipate that Instrument availability/sample processing/ turn-</p> | <p>July 1, 2020 – July 15, 2020</p> |

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| | | | <p>around time, etc. are unlikely to have returned to normal during this phase.</p> <p><u>Field research:</u> Field research is limited to travel restrictions currently in place</p> <p><u>Basic Science:</u> Return to work for technicians and hourly workers, each shift to be between 25-50% of capacity but must adhere to a 2 person per 250 square foot.</p> <p><u>Human Research:</u> All departments and study teams should assess the risk of being on campus and taking part in face-to-face research. Research interactions with participants that can be done remotely should continue being done remotely. Research can begin after being reviewed and approved by the department chair and research dean. Amendments must be prospectively submitted and approved by the IRB for any new or altered procedures. The study's risk/benefit ratio needs to be evaluated by departments and study teams on a project-by-project basis prior to restarting and then reassessed on a weekly basis based on the changing status of the COVID-19 pandemic.</p> <p>Considerations:</p> <ul style="list-style-type: none"> • If a participant or research personnel is already on campus or in a clinic for non-research reasons and there would be no additional COVID-related risk for participating in/conducting the research, this could be taken into account. • Health system guidelines must be observed as the minimum required standards for clinical research conducted in the health system. • Research at off-site locations and in participants' homes should follow the most conservative guidelines for physical distancing, cleaning, and cloth face covering use (state, VCU/VCU Health, or off-site location guidelines). • The study's on-site participants, use of space and resources and its impact on other units and organizational operations should be taken into consideration. | |
| III | VPRI, in consultation with VP for Administration, and | All research that is possible to be done remotely should continue remotely | <p><u>Animal Research:</u> Investigators with projects involving animals must understand that new animal orders will be ramped up gradually over time and</p> | July 16, 2020 – July 31, 2020 |

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| | <p>considering available public health information, will make the determination to proceed to this phase.</p> | <p>including all seminars, group meetings, etc.</p> <p>On-campus research activities transition to a maximum of 85% total personnel capacity, with physical distancing. Shift work can maintain this percentage while allowing more researchers to work.</p> <p>School/Unit Return to Campus Coordinators, Building Managers, and Managers are responsible for faculty and research staff return. Human Resource and Health and Safety requirements must be followed.</p> | <p>expectations for immediate animal delivery will be limited. At no time will DAR expand animal deliveries beyond its staffing capacity. In addition, breeding colonies must be re-established gradually to prevent a synchronized wave of new litters being weaned that would tax the laboratory's colony management capabilities or DAR's caging and staffing capacity. DAR will require physical distancing in all animal facilities.</p> <p><u>Core facilities:</u> Core facilities will remain constrained by reduced availability of staff and occupancy limitations for shared instrumentation or other shared-use spaces, but capacity should begin to approach normal. Cores involving animal research will have policies coordinated with those of animal research generally. Special procedures for sample submission, enhanced PPE, and high contact surface/instrument decontamination will be re-evaluated for this phase. Users should anticipate that Instrument availability should begin to stabilize, but are cautioned that sample backlogs accumulated during earlier phases are likely to impact processing / turn-around times on an ongoing basis.</p> <p><u>Field research:</u> Field research is limited to travel restrictions currently in place.</p> <p><u>Basic Sciences:</u> The number of individuals present can gradually be increased to 85% of capacity.</p> <p><u>Human Research:</u> All departments and study teams should assess the risk of being on campus and taking part in face-to-face research. Research interactions with participants that can be done remotely should continue being done remotely. Amendments must be prospectively submitted and approved by the IRB for any new or altered procedures. The study's risk/benefit ratio needs to be evaluated by departments and study teams on a project-by-project basis prior to restarting and then reassessed on a weekly basis based on the changing status of the COVID-19 pandemic.</p> <p>Considerations:</p> <ul style="list-style-type: none"> • If a participant or research personnel is already on campus or in a clinic for non-research reasons and there would be no additional COVID-related risk for | |
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| | | | <p>participating in/conducting the research, this could be taken into account.</p> <ul style="list-style-type: none"> • Health system guidelines must be observed as the minimum required standards for clinical research conducted in the health system. • Research at off-site locations and in participants' homes should follow the most conservative guidelines for physical distancing, cleaning, and cloth face covering use (state, VCU/VCU Health, or off-site location guidelines). • The study's on-site participants, use of space and resources and its impact on other units and organizational operations should be taken into consideration. | |
| IV | No or minimal state restrictions | All types of on-campus research are allowed | Restart normal research operations, including open museums and libraries, field research, and human subjects research. | ??Future?? |

VCU Guiding Principles for Research Return to Campus

Overarching Goal: To keep everyone safe, while increasing research activity in a phased approach as safety becomes easier to maintain.

Our framework is informed by the following principles and observations.

Principle #1: *We will follow applicable local, state, and national public health authority current and future directives for institutes of higher education. We will hold the safety and health of research participants, students, employees paramount. We will support the integrity of research and the careers of early-stage researchers.*

- Observation: As of the date of this publication, Governor Northam’s Executive Order 55 permits only critical research or essential functions through June 15. Nevertheless, higher risk groups—like older faculty and staff, or those with underlying health conditions—will likely need to shelter at home longer.
- Observation: Governor Northam’s plan was recently released: [Forward Virginia](#)
- Observation: President Trump has issued a similar set of criteria for reopening economic activity: [White House Plan for Opening up America Again](#)
- Observation: CDC guidance for reopening colleges and universities has been issued: Colleges and Universities: [Plan, Prepare, and Respond](#)
- Observation: No researcher should feel they are being compelled to work on campus or in the field during periods of broad shelter-at-home directives. Safety within laboratories must be rigorously maintained, with adequate access to PPE and other safety-related supplies. Labs will not be authorized for access unless adequate safety supplies are identified as being available.

- Observation: Limited access is likely to persist for some time, and researchers will need to adapt to longer term-limited access. State and National guidelines suggest that access should only be restored once there is more pervasive testing and contact tracing. Ultimately establishing immunity, through serological testing or an effective vaccine, will be a prerequisite for a full return to business as usual, but that could take many months.
- Observation: Given that the relaxation of access constraints is locally determined, it may be especially challenging to ramp-up projects that are distributed across sites or which depend on international collaborations.
- Observation: Lifting of travel restrictions, such as those that limit international travel, ban interstate travel by state employees, or restrict non-essential travel, are necessary before field research can recommence. This includes human subject-related field research that must be conducted in person.
- Observation: A number of research projects have successfully and safely transitioned to being remote, requiring infrequent or no access to university spaces. All research that is possible to be done remotely should continue remotely.
- Observation: To the extent that it is possible under the public health authority directives, as access restrictions are relaxed, priority to return to research spaces should be given to those researchers who cannot work remotely and are under time constraints to complete degrees, term appointments (e.g., postdoctoral researchers), or for tenure and other career reviews.
- Observation: Extension of the tenure clock should be considered for any researcher whose work has been affected.
- Conclusion: We can expect these State and National plans to influence the local decisions of City and County Public Health authorities based on local and regional conditions. It is fair to expect that between “only essential/minimal activity outside of the home” and “return to business as usual,” there will be intermediate phases of increased access, with two to four weeks or more between phase changes, with the possibility of returning to a more restricted phase should COVID-19 infections again rise. Researchers should plan as best they can for the inherent uncertainty regarding when a return to research spaces will be safe. VCU should be sensitive to the consequences of reduced access to research spaces, including on-campus offices, and the dramatic impact this will have on careers, particularly of young researchers.

Principle #2: *Undergraduates are students first, researchers second.*

- Observation: Engagement of undergraduates in research should only be permitted under the most exceptional of situations. These may include the situation in which (1) the undergraduate student is an essential team member for the project, (2) the project itself has been authorized for access, and (3) the work of that student must be performed in person in the research space, and (4) no other work can be assigned to that student that can be performed remotely. These will be considered on a case-by-case basis.
- Conclusion: For their own safety, undergraduate student return to research should only occur on a case-by-case basis prior to the beginning of the fall semester.

Principle #3: *Implement a fair and transparent process for granting access.*

- Observation: The conditions and priorities for granting access should be rational, non-arbitrary, and made public.
- Observation: While the vast majority of people who have been granted access are following the physical distancing rules and maintaining low density within research spaces, a small number of abuses are inevitable. Managers should be aware of who has

access and the frequency of access and coordinate with HR to ensure access privileges are not being abused.

- Conclusion: Physical distancing and density limitation guidelines for must be followed by all.

Principle #4: *As public health conditions permit, ensure a rapid restart to research.*

- Observation: To implement physical distancing and to reduce density of research personnel in university research spaces, consider permitting 7 day/24 hour building and lab access, schedule staggered work days or work shifts, plan to extend EHS, janitorial, and facilities support to enable round the clock operation of laboratories, research facilities, libraries, archives, collections, etc.
- Observation: Plan in advance for supply chain issues on restart. Under no circumstances should safety be sacrificed due to lack of adequate supplies, such as the type and quality of PPE.
- Observation: Ensure Core Facilities, Shared Resources, Service Centers, Shops, and Fabrication Lines are engaged and ready to support work ramp up in advance of need.
- Observation: Researchers, EHS, and building managers must work in concert to ensure that local infrastructure and physical layout of research spaces within buildings are considered during ramp-up.
- Conclusion: Develop flexible work schedules, plan in advance for any supply chain issues, prepare research facilities in advance of need, and coordinate across with EHS and building management.

Principle #5: *Prioritize support for finding cures and preventions for COVID-19, and in assessing the economic, political, and cultural impacts of the virus, while increasing the safe access to all patients to clinical trials for their conditions.*

- Observation: Critical clinical research has continued, while non-critical research was suspended, which affected many researchers conducting both federally-funded and industry-funded research
- Observation: A great majority of available clinical research resources have been dedicated to COVID-19 studies. This is likely to continue in the near future and should be prioritized.
- Observation: Leaders involved in organized clinical trials have developed and endorsed guidelines for ramping-down clinical research, and are developing new rules for ramping-up clinical research while respecting physical separation and maximizing the telemedicine resources
- Observation: The clinical trial participants, research nurses, and research coordinators must respect all university health system precautions.
- Conclusion: There is important research taking place in our research units regarding the impact of COVID-19 on the workforce, and it should be prioritized as broader clinical research activities are resumed.

Principle #6: *Risks and potential benefits (if any) to participants taking part in human subject research needs to be a top priority when restarting studies.*

- Observation: COVID-19 risks are a type of environmental risk across all spaces, people (staff and subjects), and research types. Therefore, these risk considerations are equally applicable across all human research.
- Observation: The VCU IRB is responsible for evaluating risks and benefits to participants, but other space, resource and personnel considerations are determined by deans and department chairs.

- Observation: Poor conduct of in-person research activities may place participants at greater risk. To minimize COVID-19 risks and exemplify the ethical principle of Nonmaleficence, public health and safety guidelines must be followed with a mechanism for oversight to ensure compliance.
- Observation: In some research involving sensitive topics, privacy or psychological, social or relational risks might be best minimized in person rather than in remote interactions.
- Observation: As VCU's capacity to minimize COVID-19 risks increases, the risk/benefit ratio for conducting in-person research interactions and interventions will become more favorable. Research with a greater prospect of benefit will have a favorable risk/benefit ratio earlier than other studies for returning to campus and holding in-person interactions/interventions.
- Observation: In accordance with VCU's core value of Service and the ethical principle of Beneficence, research should be prioritized that has a reasonable prospect of directly improving the human condition and supporting the public good at home and abroad. Priority should be given to research with a reasonable prospect of direct benefit to individual participants and to research that aims to improve services, processes and systems at VCU and in the Richmond community.
- Observation: The risk of taking part in face to face research needs to be evaluated prior to restarting this research and re-assessed on a weekly basis based on the changing status of the COVID-19 pandemic. A study must pause immediately for re-evaluation (and potential reporting to the IRB as an Unanticipated Problem) if research staff or subjects who were on campus are discovered to test positive or are presumptively diagnosed with COVID-19.
- Observation: Off-site locations and research participants may have differing levels of comfort about allowing researchers into their spaces/homes. Researchers must carefully gauge the willingness of off-site locations to allow research in their facilities as well as subject willingness to enter the research location and respect any refusals. For home visits, researchers should inquire about and respect any participant requests regarding use of source control or cloth face masks and physical distancing while in their home.

Conclusion: Decisions about restarting individual human research studies should involve careful evaluation of the COVID-19 risks, risk minimization procedures, and the potential for benefit to individuals and the community. Human research occurring on- and off-site must adhere to the guidelines for health and safety laid out by VCU, VCU Health, the Commonwealth of Virginia, and any other applicable policies of off-site facilities. Researchers should be informed about and follow the most restrictive policy for the location where their research will occur.