Recent Updates

The University of Cincinnati is committed to facilitating and protecting your research, but safety is our top priority. As the COVID-19 outbreak expands and the impact evolves, the Office of Research is working closely with the UC leadership team, other universities, and government agencies to identify best practices and establish guidance specific to research operations. This guidance is intended to help the campus research community limit the impact and potential risk associated with the growing COVID-19 pandemic.

Laboratories and research facilities should begin to plan for the possibility of significant disruptions to routine operations. Your plans should assume that there will be disruptions to facility/laboratory access and personnel. If you have not already done so, we urge you to develop a continuity of operations plan for your research program. The guidance below is provided to help assist you in this process.

We are facing an unprecedented challenge and must all do our part to "flatten the curve" to protect our community and to lessen predictable pressures on our public health infrastructure. **Understanding that we have essential research that may continue, we should work to reduce the number of researchers on campus.** While we recognize the challenges, we must shift work habits to significantly reduce the number of physical interactions on our campus.

We ask research group leaders to identify contributions that individuals in their group can make while working remotely. To the extent possible, you, your students and other lab personnel should devote time to productive alternatives such as writing grant proposals, reviewing articles and papers, writing thesis chapters, conducting analyses, compiling data and/or synthesizing important research. This is a good opportunity to reflect and to work on books and research papers.

Research Continuity Planning Guidance Topics (Last Updated 16 March)

- What if I am doing research with Biohazards, Radioactive Materials (RAM) or Radiation Generating Equipment (RGE)?

The latest guidance and information will always be available at the UC Coronavirus website and the Office of Research site.

What actions can I take right now?

- Update your research group or lab member contact list (e.g., name, title; UC location, office phone, email and cell phone number). Share the list with each lab member and with your supervisor and/or department. Keep both hard copies as well as electronic versions of the list.
- If your research requires functions that must be supported on campus during a disruption, please identify key lab members, personal protective equipment, and equipment needed to perform these functions. As a PI, you should provide this information to your supervisor and/or department chair. Supervisors and department chairs should notify the College Associate Dean for Research.
- If required on-campus functions depend on vendor supplies for ensuring research facility or lab safety (e.g. liquid nitrogen), please plan ahead appropriately to meet this need.*
- Ensure that standard operating procedures and Materials Safety Data Sheets are available in a visible location and all safety procedures are being followed. Dispose of hazardous waste in a timely fashion, especially if working with time-sensitive materials (e.g., peroxide formers).
- Ensure you and your research team have remote access to files, data and software systems, while maintaining data control assurances.
- Develop plans for backing up data on university servers if you are working remotely or plan to work remotely.
- Continue to follow compliance guidelines for each project protocol. Be sure to submit modifications to the appropriate protocol review committee prior to making changes in protocols.
- Test and practice remote working arrangements as practical.
- Be strategic about how you plan and conduct your research at this time. Depending upon the nature of your research, you might consider:
    - Prioritizing work that can only be carried out in your research facility;
    - Advancing work in progress to the point that it could be paused if necessary;
    - Identifying the work that has the highest future potential; and
    - Considering the relationship of projects to graduate student theses and post-doctoral training objectives.
- REMEMBER to preserve whatever samples that you can now.

You may wish to put off work amenable to remote support, such as data analysis, planning, and writing, by stockpiling results and data now that could be analyzed remotely in the future. If you are carrying out a long-term experiment and if it is feasible to freeze or store samples at specific steps, consider doing this more often.

*UC has contracts with a number of vendors (e.g., Fisher Scientific) who have specific commitments to supply our research enterprise. If you encounter delays from those vendors, please contact your Associate Dean for Research (or equivalent) immediately

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What can I plan to take out of my lab or office?

Researchers should carefully evaluate whether on-campus research functions can be conducted off-campus. Many restrictions apply that are enforced by Federal, State and UC regulations, policies and guidelines.

- Your Associate Dean for Research is a valuable resource in determining appropriate approaches to remote research operations.
- Specific questions regarding what can be taken from your research space can be directed to integrity@uc.edu.

All research must continue within the confines of the appropriate research space. In evaluating your options for remote work, please note the following:

- Researchers are not allowed to set up an off-campus laboratory site.
- Under no circumstances is it appropriate to remove animals or other materials from UC-approved housing or research spaces.
- Researchers may arrange with their PI or lab manager to take notebooks, data storage devices, or computers for remote work.* **No other materials, equipment or laboratory supplies are allowed offsite.**

Transfer and/or transport of Controlled Unclassified Information (CUI) or other data that requires a controlled environment requires prior approval from the Export Controls Office and must be in accordance with UC Data Security Policies.

How can we prepare for a potential shortage of crucial supplies or vendor disruption?

- Assess which supplies or services are truly critical.
- Please follow your vendors guidance on information regarding the potential for disruption. Identify alternative sources.
- For supplies or services that would be needed even in the event research would be interrupted, work with your research group, department and/or building manager to plan appropriately ahead of time to meet this need.

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My work involves core facilities or shared usage space. What should I do?

Updated March 17th – detailed information provided for mitigating disease spread

All researchers should immediately observe the 6' social distancing guidance in any shared usage space. Proper personal hygiene is critical to mitigating the spread of the disease.

- This can be accomplished by instituting a practice of cleaning share equipment and space before and after individual use.
- If planning to submit samples to a core are shared facility do not take samples without first contacting the Core Manager/Director to confirm they are operating and able to accept samples. If they are operating, provide experimental and sample details remotely (email, telephone) and arrange to drop off the samples to the lab in a designated area to minimize any personal contact.
- Upon receipt of samples, core personnel should wipe down the samples with a suitable disinfection prior to further sample processing.

As a core director/manager what are some specific thing I can do now to mitigate the impact if the situation escalates?

- Prepare and share the designated point of contact for each core laboratory and at least one backup with your college's Associate Dean for Research. Please indicate who needs critical access to the laboratory. This will initially be to maintain a minimal level of research continuity and secondly if a further escalation requires the cores to be shuttered. This latter category might include designated personnel for maintaining critical equipment that cannot be readily shut down (e.g. system that require cryogen fills). This would also be a good time verify that your emergency contact placard posted for your lab space is current.
- Be prepared with a process to shut down or "park" core equipment in a state that can be safely maintained for a period up to 6-8 weeks, if needed.
- Delay the initiation of any longitudinal study that will require time-dependent core activities or analyses be completed over the next 6-8 weeks. This is particularly relevant for animal studies.
- For existing longitudinal studies, communicate with the customer/collaborator to determine if the project can be truncated to a useful point earlier in the study or if it needs to go to completion. Every attempt will be made to complete the study if the conditions allow.
- Secure any chemical or hazardous materials in the appropriate longer-term storage areas rather than the active use areas (e.g. flammables in flame cabinets instead of out in the fume hoods).
- Verify your offsite connectivity to IT resources that may be needed for remote working opportunities.
- Consider adjusting workflows to maximize those activities that need to be done on site (e.g. data collection) for the short term, with those activities that can be done remotely (e.g. data processing, report generation), being reserved for when remote activities may be the only option.

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Will SRS still be submitting proposals?

Sponsored Research Services is providing support for proposal submissions and award negotiations. PI's should continue to monitor funder websites for updates on proposal submission deadlines or changes due to COVID-19. The Office of Research website will continue to list updated guidance from our major federal funders.

SRS pre- and post- award staff will continue to be available during normal operating hours, although they may be working remotely. PI's working in colleges with submission authorization (COM, CEAS, A&S, CECH, CON, Pharmacy) should check with their college offices for any details

regarding proposal submission. If colleges with submission authorization are unable for any reason to submit proposals during this time, Sponsored Research Services will work directly with PIs in these colleges to provide support.

PI's conducting sponsored research should inform their appropriate Program Officer of any changes in research plans or progress as a result of COVID-19 impacts to UC.

Updated 04/06/2020

SRS Contracting staff will be emailing you directly to determine if your active industry agreements are in jeopardy of missing deliverable deadlines or otherwise need extensions because work is delayed due to COVID-19. Please expect to receive an email requesting additional contract specific information.

In the meantime, if you have a follow-up question about your active industry award, or if you need for our contracting administrative team to request a modification or no cost extension from an industry partner, please email Aretha.abrams@uc.edu or Richard.Hatcher@uc.edu.

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What should I do about human-subject research?

Updated 3/23/2020

As we make decisions on how to respond to the COVID-19 outbreak we want to begin by stating that our primary concern is the safety of our research participants and the research team members who work for the University and UC Health. Our secondary goal is to preserve the scientific integrity of the research protocols.

As the need for social distancing increases, the number of UC faculty and staff on site is decreasing even in the clinical areas. Research participants may be less willing and facing even greater risks to come to our facilities. Demands for remaining clinical care resources continue to increase, making it more difficult to safely complete research. We must prioritize safe clinical care and practices that minimize spread of COVID-19. Informed advice about how long clinical research activities will be reduced is difficult to give, as the situation is changing rapidly. As you plan for what to do with your own research protocols, our current advice is to assume there will be no decrease in restrictions for at least two months. We will continue to reevaluate this timeframe.

COVID-19 research is a priority because of societal need for information. All COVID-19 protocols must still have IRB review and approval before starting enrollment. Please contact Dr. Linke before submitting a study involving COVID-19 linkemj@uc.edu

The latest guidance and information will always be available at the UC Coronavirus website and the Office of Research site.

Per the memo *Research Priorities during a Civil Emergency or Regional Crisis* from the Vice President for Research, the following criteria describe which UC research projects will be given priority for ongoing access to facilities during a university-wide emergency. For purposes of this determination, UC research projects are divided into three categories:

Level I Research: **Critical Research** efforts that are directed at responding to or mitigating the crisis that has caused the University closure, and which holds the potential for significant contribution in resolving the crisis; Medical research that if discontinued would endanger the lives of the human subjects participating in the research; and activities that require timely and regular attention to maintain essential functions that support critical research, including but not limited to critical research infrastructure and experimental conditions such as animal support, maintaining equipment that requires gas, cryogenic service, monitoring irreplaceable cell lines, maintaining unique or loaned collections, and other substantially similar treatments.

Level II Research: **Essential Research** efforts that involve a significant investment of University resources, agency sponsorship, or contractual obligation, or effort on the part of researchers and staff that cannot be interrupted without jeopardizing those investments or the research results and overall project outcomes;

Level III Research: **Standard Research** that is in the initial stages, does not require completion of imminent, critical milestones, or may be continued at an alternate site by reprioritizing or resequencing the research structure. Though there may be a loss of data, efficiency or early investment, current efforts can be recreated or resumed after minimal disruption, with little loss of investment.

These criteria are incorporated into the following guidance.

The Human Research Protection Program and UC IRB are operating on our normal schedule.

In an effort to minimize the risk of contracting or spreading COVID-19 in human participant research interactions, the university is placing temporary restrictions on human subjects research through May 1. We will continue to reevaluate this timeframe

The Human Research Protection Program (HRPP) staff are working remotely but are operating on our normal schedule. The UC IRB will continue to hold weekly meetings using remote access technology. Please contact the HRPP office at irb@uc.edu or 513-558-5259 with any questions.

Some Human Participant Research Studies or Activities Must Be Paused.

(New 3/24/2020) Effective March 24, 2020 the UC Cancer Center will alter its operations to temporarily halt research sample collections and processing that do not impact patient safety or the primary endpoint of the clinical trial. You can find the official announcement here.

1. **Why must some human participant research studies or specific activities be paused?**

   The real or perceived risk of viral transmission, the risk/benefit ratio for in-person contact associated with research activities must be assessed for each protocol. Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio.

2. **Which studies or study procedures must be paused?** (updated 3/30/2020)

All human subjects research studies with in-person interactions must cease enrollment. UC IRB approval is required to continue enrollment in these studies. IRB approval is also required for currently enrolled subjects to continue participation in these studies. This is effective for all human subjects research conducted at UC, regardless of reviewing IRB. Cancer Clinical trials must be approved by the Chair of the UC Cancer Center Protocol Review and Monitoring Committee (PRMC).

Please carefully evaluate your studies to determine if it is in the best interest of patients and staff to continue enrollment in light of the COVID 19 pandemic. Studies must also be evaluated to determine if it is in the best interest of currently enrolled subjects to continue participation in a study.

To continue enrolling patients and/or participation of currently enrolled subjects, please send a request to Dr. Linke linkemj@uc.edu (if you have not already done so). This requirement is in addition to the College of Medicine approvals. The IRB must now consider how the risk of COVID 19 exposure and infection affects the risk:benefit determination for a study.

Please address the following concerns in your request.

1. Keep patients out of the hospital
   - Most studies that require participants to stay in the hospital or the Schubert Research Center should not continue to enroll.

2. Risk and benefits of study participation. The risk of COVID 19 exposure and infection must be considered in the risk:benefit determination for the study
   - What would happen to the potential participants if they were not in the study?
   - What advantages does the study offer to participants that they would not have outside the study?
   - What are the potential direct benefits to participants?

3. Describe your plans to minimize participant and study staff COVID 19 exposure, transmission, and infection. These plans should address,
   - Screening individuals for COVID 19 symptoms prior to study visits.
   - Screen individuals for COVID 19 exposure prior to study visits.
   - Potential transmission by asymptomatic infected individuals must be considered.

- The same precautions that are taken with patients being seen for the clinical care should be used for research visits.
- Could any in-person study visits be switched to remote visits?

4. Verify that the study,
   - Will not utilize resources that are needed to take care of COVID 19 infected patients.
   - Study procedures would not interfere with clinical procedures put in place to treat COVID 19 patients
   - Would not use limited resources such as PPE
   - Research staff will be used for the studies so that clinical staff are not taken away from clinical responsibilities that may be needed to respond to COVID 19.

3. May new enrollment into existing studies continue? (New Information 03/30/2020)

- All human subjects research studies with in-person interactions must cease enrollment (as described above)
- Studies with no in-person participant interaction may continue to enroll participants.
- Level I IRB approved studies on COVID 19 may enroll participants.

4. Which studies may continue? (updated 3/30/2020)

- Studies that do not involve face-to-face interactions with participants may continue.
- Studies conducted electronically or via telephone or involving secondary data analysis may continue.
- IRB approved studies on COVID 19
- Studies approved by the IRB as described in #2

5. How should research interactions go forward? (New Information 03/23/2020)

- For research interactions that cannot be done remotely, opportunities for exposure should be reduced as much as possible without reducing the efficacy of the treatment or increasing risk to the participant. Examples of exposure reduction may include: reducing non-essential visits, reducing the number of blood draws, eliminating non-essential visit time, or maximizing the use of remote technologies in lieu of "face-to-face" interactions.
- For cancer-related studies, interim guidance from the National Cancer Institute for clinical trials supported by the NCI, such as delegation of visits or procedures to local providers or mailing of oral study drugs, see https://ncicirb.org/announcements/memorandum-interim-guidance-patients-clinical-trials-supported-nci-cancer-therapy .
- For FDA-regulated clinical trials, refer to FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
- Limit study staff to be utilized to conduct visits to limit contact for study personnel, study participants and other individuals. Supervisory research personnel should discuss upcoming schedules in the next 6-8 weeks and how to limit the number of study personnel required to conduct visits that must be completed.

- Limit the possibility that research staff will be too close to each other and unable to meet the social distancing needed to halt the spread of the COVID-19 virus.
- Essential research visits that cannot be performed remotely may be performed in person, with the following additional guidance:
    - All study participants should be contacted by telephone and asked about any respiratory symptoms or fever prior to their visits on the day prior to the scheduled visit. If study participants have any respiratory symptoms or fever they should be referred for appropriate testing before coming to a study visit. Upon arrival to UC Health or UC Medical Center, study participants should be asked again about respiratory symptoms or fever, and, if they report any, should be immediately moved to an isolated room and asked to put on a mask. Study personnel should wear appropriate personal protective equipment when conducting a study visit with a participant who is having respiratory symptoms or fever and refer the study participant for appropriate testing for infectious diseases.
    - Study investigators should use their best judgment to limit contact that is not absolutely necessary to ensure the safety of the study participant and ensure the integrity of the research.
    - Participants should be provided with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a telephone script and an in-person handout. If possible, this information should be shared before the research visit.

6. What if my study is reviewed by an external IRB? (New Information 03/23/2020)

This COVID-19 guidance is effective immediately for all human subjects research conducted at UC, regardless of reviewing IRB. If you need to make changes to your research, follow the reviewing IRB's procedures for submitting amendments or deviations.

7. What if a human research study needs to be modified in response to COVID-19? (updated 3/23/20)

Per UC SOP HRP-029 Review of Study Modifications "Modifications in approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards". If protocols must be modified to address immediate safety concerns to participants or study staff related to the COVID-19 epidemic, the UC IRB has determined that these modifications meet this exception. Any modifications made per this exception should be subsequently submitted for IRB notification using the Reportable New Information (RNI) function in RAP as an Unreviewed change: *Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.*

Protocol modifications to eliminate immediate hazards may include;

- Actions taken to reduce potential exposure to COVID-19
- Suspension of all or some research activities

- Decreasing the number of in-person study visits
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine
- Allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants

Protocol modifications that are not made to eliminate immediate hazards must continue to be approved by the IRB prior to implementation.

Please contact the HRPP office at irb@uc.edu or 513-558-5259 with any questions.

8. **Can I submit new studies for IRB review during the COVID-19 outbreak?** **(New Information – 03/23/2020)**

- Yes, you may submit new studies in RAP. New studies will be screened and forwarded for expedited or convened IRB review in accordance with standard UC HRPP procedures and timelines; however, enrollment of new participants must adhere to the following:
- Any research studies involving COVID-19 should include COVID-19 in both the Title and Short Title of the protocol submission. Please contact Dr. Linke before submitting a study involving COVID-19 linkemj@uc.edu
- Level I COVID-19 studies may commence after receiving appropriate approvals.
- Clinical trials approved the UC Cancer Center PRMC may initiate enrollment.
- Other studies with in-person interactions may not commence enrollment until further notice.
- Studies with no in-person participant interaction may commence after receiving IRB approval.

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How will animal care proceed?

Update March 30th – LAMS No Charge for Non-Urgent Health Issues
Update March 17th – Priority Animal Experiments

Effective Monday March 30th, LAMS staff will offer care for non-urgent health cases (e.g., dermatitis, hydrocephalus, malocclusion) at no charge. LAMS will notify researchers by email and provide their recommendations. If a response is not received within 48 hours, LAMS will treat or euthanize at their discretion. In addition, LAMS staff will automatically wean, separate and report offspring at no charge. If you do not want LAMS to perform this service, send an e-mail to lams@uc.edu. These no charge services will remain in effect, barring staffing issues, through the duration of the "Stay at

Home" order. For other health care or husbandry requests, please e-mail lams@uc.edu or submit a Service Request through RAP.

During the COVID-19 emergency, the University asks investigators to pause any new experiments. Prior to submitting an animal order in RAP, send an email request along with justification to lams@uc.edu. You will receive a determination in one business day.

Every PI working with research animals should create a plan to manage animal experiments and ongoing care in case of decreased lab staffing or shortage of supplies. Every PI should create an emergency contact list and share that with the Attending Veterinarian and LAMS Director: tetensje@ucmail.uc.edu or lams@ucmail.uc.edu.

Other considerations:

- Research labs should prioritize ongoing essential research
- Consider delaying new projects and delaying acquisition of new animal subjects
- Reduce rodent breeding to only numbers required to maintain lines
- Do not use PPE to cover cages during transport outside of LAMS facilities; use LAMS provided drape material
- Minimize waste of feed and bedding supplies whenever possible

Lab Animal Medical Services (LAMS) has continuity plans in place to provide routine care (food, water, sanitation, health checks) and routine veterinary care. LAMS is stocked with essential items for animal care. Animal caretakers and Veterinarians are considered essential personnel and will continue to report to work unless they become infected with the COVID-19. LAMS emergency contact information is posted on the entrance door of each animal facility. The IACUC office is operating and IACUC meetings are continuing as scheduled. If changes occur, the IACUC website will be updated accordingly.

If you manage your own animals or conduct your work at an outlying facility your group should have contingency plans in place for who will provide daily animal checks and what to do if this person is unable to perform them. If help is needed providing care due to illness of all caretakers and PIs, the Attending Veterinarian should be contacted to arrange for emergency backup animal care.

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What if I am doing research with Biohazards, Radioactive Materials (RAM) or Radiation Generating Equipment (RGE)?

The **Biosafety** Office and Institutional Biosafety Committee are operating on our normal schedule. Laboratory inspections may need to be delayed. Please securely store your biohazardous materials and disinfect surfaces and workspaces in accordance with your approved IBC protocol. If you have questions or concerns please contact the Biosafety Office at inbiocom@ucmail.uc.edu

The **Radiation Safety** Office and Radiation Safety Committee are operating and will provide critical services.

- Please minimize RAM orders to those that are essential for clinical care or research continuity. Any service requests not deemed critical may be delayed.
- Questions and/or concerns may be directed to Radiation Safety Officer at Terry.Lindley@uc.edu or RadiationSafety@uc.edu.
- **For emergencies please call the radiation safety 24/7 pager at (513)249-6812**

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Student Researchers

Undergraduate Student Researchers

Consistent with the university's move to remote instruction and to minimize personnel on campus, undergraduates – whether for course credit or in paid/unpaid positions – should not be on campus working in labs or other research facilities. You should have those students focus on conducting analyses, reviewing data, mining the literature or other appropriate activities that are an important component of research, yet that can be completed remotely.

Graduate Student Researchers

Graduate students may continue to come to campus to work in labs or other research facilities to conduct essential research activities providing they **adhere and observe the necessary social distancing and personal hygiene directives**. Graduate students should remain supervised by their advisor/mentor, and in no circumstances should any advisor/mentor require graduate students to report to work if they are also not doing the same.

Faculty advisors/mentors should keep graduate student safety and well-being as their top priority and work with any students who are uncomfortable with the current situation. As with all researchers, there are many activities that can be completed remotely such as writing grant proposals, reviewing articles and papers, writing thesis chapters, conducting analyses, compiling data and/or synthesizing important research.

Please note: students who are being supported by sponsored research should be continuing to work on those sponsored projects even in a remote work environment. Appropriate documentation of those activities can always be requested by the sponsor to ensure appropriate use of funding. While certain funders are already making adjustments due to this pandemic, it still remains the responsibility of the PI for any sponsored award to follow funder guidance and make good faith efforts to continue work on the project until informed otherwise.

The Graduate School has updated guidance on the status of Thesis and Dissertation Committee Meetings on their web site. Please check there often for more information relating to degree progress and completion information.

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