Guidelines for UC Davis Research Ramp-Up/Ramp-Down

Revised: August 24, 2020

IMPORTANT: The following guidelines outline a plan for ramping up on-campus research. At this time, we are recommending entering Phase 2 effective June 1, 2020. Approval to move from one phase to another will be issued by the vice chancellor for research and will be based on guidance provided by county and state health officials. Updates will be made to this page to reflect the latest guidance.

Outline

Goal: To enable all UC Davis research to resume as soon as possible while maintaining adherence to public health guidance and maintaining appropriate hazard mitigation strategies.

This document refers only to research that must be conducted in university research and office spaces, such as the physical campus, astronomical observatories, field stations, agricultural lands, and nature reserves, field operation at non-university-owned facilities or requiring direct contact with individuals (human subjects). On-campus research includes physical presence in campus libraries, archives, and museums to access any university material that cannot be accessed remotely, as well as performance work (arts) or other studio access that must be done on campus.

All phases of the Research Ramp-Up/Down plan are subject to ongoing review. Mitigation of the ongoing pandemic is taking many different forms across the country and globe. We will monitor the ongoing performance and results of our plan through the campus mandatory reporting process. If you are aware of or are otherwise concerned about an individual exposure to COVID-19, please follow the campus process. The campus response includes fact gathering, communication support, and mitigation response guided by our Medical Directors, Legal, EH&S, and Human Resources.

Notes:

- The following guidelines recognize persons who self-identify as within one of the high risk groups. Students, staff, and researchers having need for accommodations should first

consult with their supervisor or professor for consideration. Human Resources and the Student Disability Center may also serve as a resource to help find mutually agreeable solutions.

- As the possibility remains that a new phase of public health emergency may create a renewed need to shelter-in-place, animal researchers should consider the ramifications on their animal subjects of another rapid ramp-down before resuming research.
- Many human, animal, plant, and microbial research studies are longitudinal and entail regular follow up of well-characterized cohorts. Delays in regular follow up may lead to data loss, loss of the cohort, and in some instances a failed study (i.e., lack of requisite data to address specific aims) after many years of investment. These efforts are included in the "time-sensitive" categories in this draft.
- Resource availability, procurement management, funding responsibilities, and other related issues are important, but not covered in this document. If the required protective gear cannot be provided at any point, not only can research not be ramped up to the next level, but it may also have to be ramped down, until required protective gear is available.
- Various units of campus may elect to introduce and enforce stricter guidelines as needed. Guidelines stated here have to be adopted as the minimum level of compliance.
- It is important to recognize that health care systems, including UCDH, have developed procedures for mitigating risk and these procedures can and should be incorporated into clinical research and human subject studies.
- *CONTINGENCIES:* If and when the County or State health officials provide limiting/restrictive guidance, research efforts will drop back to lower phases as appropriate and will be ramped up when the guidance changes. Additionally, we will leverage the learnings in earlier phases to make necessary updates in guidelines for the later phases.

Guiding Principles:

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- **Principle #1:** Follow local, State, and National Public Health Authority directives to shelter-at-home and maintain physical distancing.
  - Decisions on when we will begin to ramp up research (or if needed, to ramp down research due to guidance from public health officials), and at which phase research can be conducted (more on phases below), are guided by the State and the County Public Health Officer. The transitions to different phases will be communicated by the VCR.
  - Some research projects have successfully and safely transitioned to being fully remote, requiring infrequent or no access to university spaces. While also considered important and essential, they are not considered in the priority tiers discussed below. Those activities could continue at home until Phase 4.
- **Principle #2:** Protect the mental and physical health and safety of the research workforce, clinical patients and human research subjects.
  - We consider research as part of our essential business. We will continue research in a manner that recognizes and mitigates hazards to individual researchers and staff. We will maximize flexibility for researchers and staff when considering the functional requirements to complete essential research.

- Safe practices within laboratories must be rigorously maintained, with adequate access to PPE and other safety related supplies.
- When we are able to gradually scale up on-campus activities, it is clear that there will be many months ahead of us with the very real possibility of a resurgence of COVID-19 cases. Therefore, our ability to gradually and sustainably return all of our research and scholarly activities to 'normal' will depend on the discipline and dedication of everyone on our campus staff to remain committed to physical distancing and other safety measures at work and in our personal lives, to protect ourselves and all of those we care about at home and at work.

- **Principle #3:** To ramp up research activities in a way that recognizes and mitigates hazards and maintains compliance with public health guidelines, we highlight the following strategies.
  - The number of people in a workspace must be limited. We could permit 7-day/24-hour lab access wherever feasible, with workers using the lab in different work shifts or on staggered workdays. While physical distancing and low occupancy are critical, regulations regarding working alone must be adhered to, and the safety of all lab personnel must be ensured.
  - If the required PPE is not available and physical distancing cannot be maintained, the research cannot ramp up. Supply chain issues on restart could be a bottleneck. Ordering of items ahead of time may be prudent. Under no circumstances can safety be sacrificed due to lack of adequate supplies, type, and quality of PPE. For smooth ramp-up and acceleration of research activity, Deans, Department Chairs, PIs and their teams should plan for supply chain issues and prepare core and fabrication lines in advance of need.
  - Ensure Core Facilities, Shops, Wet Labs, and Fabrication Lines are engaged and ready to support work ramp up. Facilities will develop Standard Operating Procedures (SOPs) for lab access dependent on the Phase of Ramp-Up and will determine supply (including PPE) needs ahead of time.

Requirements for Phases 1 – 3

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All research activities must maintain the following:

1. Only personnel with a need to access physical locations to advance research should be on-site. Even those personnel should minimize time on campus. All others should remain sheltered-in-place and/or off-site to help maintain physical distancing. Meetings should be conducted remotely.
2. Labs may not be authorized for access unless the following are defined and ready to be produced upon request by the Deans and/or VCR:
   a. How many individuals can be in a space at any given time
   b. A clear process to ensure work shifts do not accidentally overlap
   c. A listing of supplies provided to maintain safety and their storage location: face coverings, soap, hand sanitizers, cleaning materials, first aid kits.
   d. Procedures to clean/wipe down shared items, equipment, cars, and work surfaces prior to usage by others

e. A process to maintain access and activity logs in order to trace contact should someone become sick with coronavirus.

3. Physical distance between people should be maintained at all times unless other safety precautions are adopted.
    a. Maintain a distance of at least 6 feet between people unless PPE appropriate for the context is used. Laboratories and facilities with limited space that cannot ensure that personnel will meet these public health requirements must remain off-limits. Some locations may choose to reconfigure interior space to relieve bottlenecks and maintain space between research personnel.
    b. Do not gather in groups of size more than what is limited by the county officials. Research ramp-up should not result in crowded spaces or mass gatherings.
4. Cover your mouth and nose with a face cover when around others and when moving through common spaces. Please follow the Human Resources guidance regarding face coverings.
5. Wash your hands often with soap and water for at least 20 seconds. Routinely and regularly disinfect common contact sites.

Phases of Ramp Up (or Ramp Down):

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Phase 1: Current "Shelter-in-Place" phase. Only critical research activities may occur.

1. Research that must be maintained for the health and safety of human and animal subjects
2. Research for which discontinuation would cause effectively irreplaceable data and sample loss.
3. Maintenance of critical equipment and a safe standby mode of laboratories.
4. Maintenance of critical animal populations and/or ensuring the ethical care and conduct of research with animal subjects.
5. Maintenance and care of plant populations (includes immortal populations of trees, strawberries, etc.) that are hard to recreate and represent decades of research.
6. COVID-19 research with a timeline relevant to the current pandemic.
7. Core facilities can stay at a level of operational status that is adequate just for the ongoing research activities in this phase.
8. Exception granted by Deans, Directors, VCR.

Phase 1x (Effective May 11, 2020 – May 31, 2020): Facilitate an incremental and gradual ramp up of a few research activities

- To align to the continually-changing situation and make us better prepared for transitioning to Phase 2, we are introducing an intermediate phase beyond Phase 1 – Phase 1x – which was implemented effective May 11, 2020. You can view the guidelines for Phase 1x here.

Phase 2: (Effective June, 1, 2020) Time-sensitive research activities (~33% of research personnel on-site at any time)

- Seasonal data collection such as field and agricultural work, time-sensitive human subject research studies, experiments close to completion, or deadline driven, whose pause or deferral would lead to long delays or loss of research results.
- Generation-driven animal and plant experimentation must be carried out or the value of the animal colony or plant varieties for research will be lost.
- Lab and studio access for students and postdocs close to completing their degree/term of appointment. Research that is critical to meet thesis requirements for a final defense in the upcoming term, or requirements before a graduating student can start a new position that has already been accepted.
- Necessary core facilities should be staffed and operational to support only the ongoing research activities during this phase. Research activities dependent on core facilities may thus be having a gradual ramp-up during this phase and will be vetted through a process defined by the core facilities directors and the concerned Dean/VCR.
- Lab should be able to purchase necessary supplies, including proper PPE and those necessary for proper decontamination of surfaces.

Phase 3: Gradual restart of research (~66% of research personnel on-site at any time):

- Core research and fabrication facilities that cannot be operated remotely such as, machine/glass shops, imaging facilities, nano fabrication lines, etc. could expand their operations. Individual facilities should adhere to additional safety procedures imposed by the facility directors and follow their SOPs.
- In-person research where physical distancing may be maintained or risk mitigated to a minimal risk level. In general, this research can begin when clinical care settings open up and follow similar procedures. (Must follow the additional SOM guidelines for Phase 2).
- Field research can be resumed adhering to the relevant requirements and local guidelines.
- Gradual expansion on all research activities, while following the requirements and suggestions outlined in the next section. Public health will always be our top priority.

Phase 4: Restart a return to full research operations. The return to the new normalcy may be gradual and, in some cases, it may require additional sub-phases, which can be locally defined under the guidance of deans and directors.

Additional Guidance Clinical Research

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Additional guidance for restoration of clinical research at the SOM (Parts of these guidance are also applicable to clinical research at SVM)

To a large extent, clinical research should resume along the same timeline and phases as outlined earlier. With regards to risks to participants, research staff and investigators, clinical research involving human subjects can best be categorized by the nature of the research procedures in relation to the available risk mitigation approaches. Indeed, a basic principle of human subjects' protection is to compare risk to that encountered in the conduct of everyday life, which defines minimal risk.

Clinical Phase 1: Observational and clinical research that can be conducted at a distance.

Clinical research often involves record review, interviewing, psychological and cognitive testing or even the delivery of interventions much of which can be conducted without physical proximity using mailed surveys, and telephone or videoconferencing technology. Such studies can resume immediately.

Clinical Phase 2: In person research in which risk can be mitigated through physical distancing or the use of appropriate PPE.

In person clinical research must be conducted if remote assessment has not been developed or the nature of research protocol requires face-to-face interaction to be valid and interpretable. To reduce risk, the following precautions should be taken:

- maintaining 6 feet between assessors and participants or
- the use of PPE (surgical masks and gloves for both participants and assessors, and
- rigorous hygiene for testing materials, equipment, and waiting and testing rooms.

In some types of clinical research, physical distancing may not be possible, such as some types of behavioral assessments, some forms of imaging, EEG, or blood sampling or restraint of animal subjects. Such procedures will require appropriate mitigation procedures by participants and staff who will be required to

- complete questionnaires about their travel and health,
- have their temperatures taken upon entering the research site.
- in addition, we suggest that the investigator submit a plan for risk mitigation to a SOM research oversight committee for approval in advance.

Clinical Phase 3: In person research in which risk cannot be mitigated to a manageable level.

In some cases, the clinical research may require face-to-face visit and it is not possible or practical to use physical distancing or PPE in ways that ensure valid and interpretable data.

- In general, these studies will not be permitted until risk is naturally reduced to minimal levels, later in the post-pandemic process.
- However, permission for such studies may be considered on a case-by-case basis in consultation with the investigator as study circumstances maybe be idiosyncratic and not applicable to generalized categories of research.

- Such circumstances must undergo IRB review and approval for the research to be conducted.

In summary, restoration of the clinical research involving human subjects will occur in a step wise fashion in accordance with the overarching principles and phases as provided in the overall guidance provided by the Office of the Vice Chancellor for Research (OVCR). The following provides more specific guidance on the categories of human research that are allowable during OVCR defined Phases of ramp-up. The guidance is unlikely to be all-inclusive of particular situations and questions should be directed to the UC Davis Institutional Review Board (https://research.ucdavis.edu/contact-us/irb/) or through the CTSC Medical Director Daniel Nishijima, MD, MAS (dnishijima@ucdavis.edu) or the CTSC PI Ted Wun, MD (twun@ucdavis.edu)

For these study designs:	**Research Phase**			
	Phase 1 Shelter-in-Place	**Phase 2** Time-sensitive research activities	**Phase 3** Gradual restart of research	**Phase 4** return to full research operations
Therapeutic clinical trial (drug, device, or behavioral) where there is **potential for direct benefit** to the participant and risk of viral exposure can be minimized	Allowed	Allowed	Allowed	Allowed
Observational and clinical research that can be conducted remotely **regardless of potential for direct benefit**	Allowed*	Allowed	Allowed	Allowed
In person research where physical distancing may be maintained and risk mitigated to a minimal risk level **regardless of potential for direct benefit**	Not allowed	Allowed	Allowed	Allowed
In person research in which risk cannot be mitigated to minimal risk levels and **no potential for direct benefit**	Not Allowed	Not Allowed	Not Allowed	Allowed

*Only if research personnel safety can be maintained with adherence to shelter-in-place

Research Ramp-Up/Down Taskforce

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Addendum: Phase 1x

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Goal for Phase 1x: Facilitate an incremental and gradual ramp up of a few research activities selected from those categorized for Phase 2, while maintaining adherence to public health guidance and maintaining appropriate hazard mitigation strategies.

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Notes:

- This addendum recognizes persons who self-identify as within one of the high risk groups. Students, staff, and researchers having need for accommodations should first consult with their supervisor or professor for consideration. Human Resources and the Student Disability center may also serve as a resource to help find mutually agreeable solutions.
- Activities that do not require on-campus presence or are categorized in later phases will continue through the current work-from-home efforts.
- No new research should be initiated that cannot be shut down on a very short notice.

Phase 1x:

- Only selective on-campus research facilities will be considered for a slow-start based on a process that will involve justification by the PIs.
- Guidelines stated here must be adopted as the minimum level of compliance by the research units. Various units may elect to introduce and enforce stricter guidelines as needed. Not all units should initiate their ramp-up to Phase 1x.
- At the minimum, the following restriction should be agreed upon before you consider Phase 1x.
    - The proposed restart of activities must belong to the categories identified in Phase 2. Ongoing efforts from Phase 1 are not impacted by this addendum.
    - PIs would restrict one person per ~250 square feet of lab space per day. Smaller enclosed labs may allow only a single researcher per day. The goal is to allow some research to be conducted to collect additional data that can be analyzed at home or to promote projects that are of significant importance while maintaining a low density of people in a space, minimal person-to-person contacts and a minimal number of individuals in a space during a 24-hour period. These goals are in place to reduce the probability of contamination and to facilitate contact traces if someone were to be tested positive for COVID-19. Under certain circumstances, chairs/directors could use other parameters or devise other constraints and request for approval with the goal of mitigating hazards and facilitating research needs of specific units.

    - PIs need to have a process in place to log access to their facilities for contact tracing if needed.
    - PIs must acknowledge that activities initiated during Phase 1x could be terminated if concerns about safety and public health arise.
    - Standard Operating Procedures (SOP) that are approved by the PI and their department must be practiced in the research facilities. The VCR committee may request the SOP prior to the approval for Phase 1x.
- CONTINGENCIES: As we learn more, the ramping process may be tuned in either direction. If and when proper guidance is not followed, the approval for Phase 1x may be rescinded. In general, this incremental phase should be considered as a pilot process to iron-out the logistics of future ramp-ups.

Additional guidance for restoration of clinical and human subject research during Phase 1x

- Clinical or behavioral assessment that can be done remotely or with full social distancing could resume at normal levels.
- Research can resume for: In-person clinical and human subject research in which risk can be mitigated through physical distancing or the use of appropriate PPE. Ongoing studies involving time sensitive cohorts where stage of illness, treatment or developmental timing are critical aspects of the study. Where subjects have completed partial data collection prior to the pause in human subjects research, and subjects' data will be unusable without completion of procedures.

Phase 1x for Core Facilities

Core Facilities are ideally positioned to expand low-contact, high-impact support to the research community while adhering to the Phase 1 guidelines of suspended research operations. Cores are also ideally suited to serve as pilot locations for health surveillance programs as they are developed in the coming weeks.

Eligible cores

- the core location must be a discrete physical space that is separated from other labs or common areas
- access to the physical site or instruments must be under core control (either physically or electronically)
- core must be able to track access if contact tracing becomes necessary.

Scope of permitted work

- samples that already exist at the core and/or are generated under approved critical projects
- time-sensitive samples that can be transferred to core with no contact (per SOP)

Staffing to ensure physical distancing

- only core staff or approved trained users are permitted in the core laboratory. Scheduling software should be used, where possible, to enforce physical distancing.
- participation will be voluntary: no staff member will be compelled or coerced to work onsite during Phase 1x

- staffing levels will be low density and appropriate for core physical dimensions and layout (> 250 ft^2 per person)
- time onsite will be minimized to essential tasks
- staff working alone will be guided by an approved SOP (per Work Alone SOP template)
- use of common areas, outside the laboratory, will be limited and guided by the lab SOP (congregation for breaks, lunch, etc. should be avoided)

Core facility access review and oversight process:

- CRCF will develop Phase 1x SOPs that provide for physical distancing, disinfection, and safe-working-alone processes (if applicable) in adherence with campus guidelines
- CRCF Phase 1x SOPs will be reviewed by local governance (facility advisory board and unit (dept/Dean) authority)
- researchers will submit a research request form for access to Phase 1x core work and will be confirmed to be compliant with chair/dean authorization.
- availability of services does not imply or confer authorization for researchers to resume lab-based activities
- core services will be denied to those researchers who abuse access privileges

Phase 1x Requests and Approval Process:

PIs interested in the Phase 1x ramp-up, should email the following information in any format (text, doc, pdf) to their Chair/Dean/Director. Multiple PIs in single facility/department/laboratory/studio may elect to submit a single proposal. The Chair/Dean/Director would either deny (based on local constraints/guidance) or forward the request via email to the VCR (send to pking@ucdavis.edu). The Ramp-Up/Down Taskforce will make quick decisions and respond back to the PI and the Chair/Dean/Director.

The request should include:

1. PIs name, Department/School/College, and contact information
2. Project Title
3. Justification that the project meets the categorization for Phase 2.
4. Lab/Facility/Studio address
5. A plan outlining the approach used for maintaining low density of personnel on site.
6. A statement agreeing to adopt the facility SOP, use proper PPE as needed, and adhere to the constraints specified in this addendum and the previous guidance.