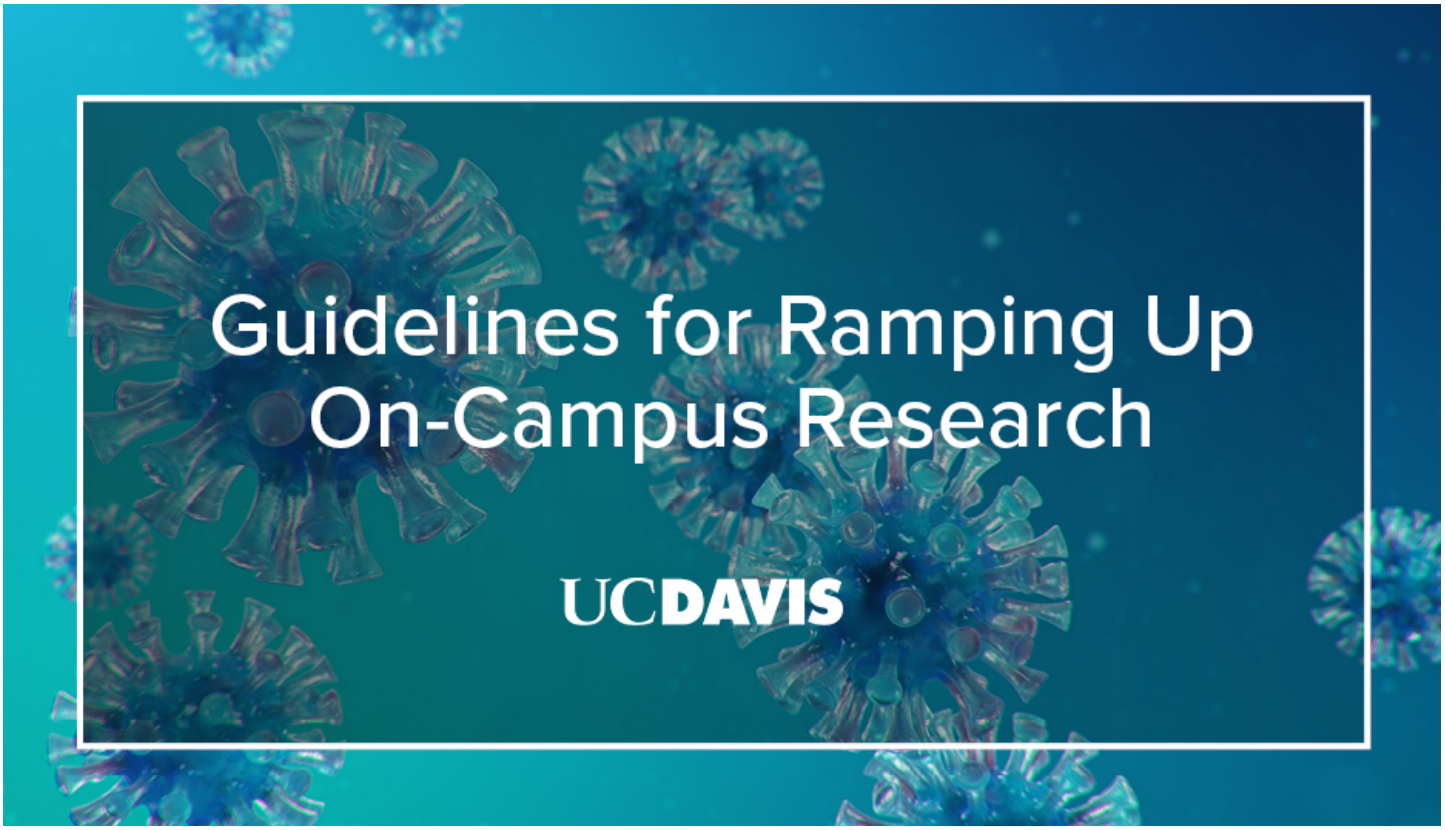
Guidelines for UC Davis Research Ramp-Up/Ramp-Down (April 23, 2020)



April 23, 2020

IMPORTANT: The following outlines a plan for ramping up on-campus research. At this time, it is to only be used for planning purposes until a decision is made to activate it. A start date has not been announced.

Goal: To enable all UC Davis research to resume as soon as possible while ensuring safety and while maintaining public health requirements.

We are not specifying a start date or the basis of transition from one phase to another. Timings and transitions of events will be decided on the basis of guidelines we will receive from the County and State Health Officials.

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.

Notes:

- The following guidelines may not apply to persons currently identified as high risk groups.
- 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.
- Issues related to human resource policies and funding of research are not included in this document.
- It is important to recognize that health care systems, including UCDH, have developed procedures for mitigating risk to minimal levels 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:

- **Principle #1:** *Follow local, State, and National Public Health Authority directives to shelter-at-home and maintain physical distancing.*
  - Decisions on when UC Davis 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 Governor 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.*
  - No researcher should feel they are being compelled to work on campus or in the field during periods of shelter-at-home directives.
  - 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 ensures safety of all employees and compliance with public health guidelines, we highlight the following strategies.*

1. 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.
2. 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.
3. 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.

Phases of Ramp Up (or Ramp Down):

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 2: 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.

REQUIREMENTS FOR PHASES 1 – 3: 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:
    1. How many individuals can be in a space at any given time
    2. A clear process to ensure work shifts do not accidentally overlap
    3. A listing of supplies provided to maintain safety and their storage location: face coverings, soap, hand sanitizers, cleaning materials, first aid kits.
    4. Procedures to clean/wipe down shared items, equipment, cars, and work surfaces prior to usage by others
    5. 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.
    1. 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.
    2. 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 (keyboards, door handles, multi-user equipment, etc.).

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.

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.

Phase 2: In person research in which risk can be mitigated to a minimal risk level 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 to minimal risk levels, 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.

Phase 3: In person research in which risk cannot be mitigated to minimal risk levels.

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	**Phase 2**	**Phase 3**	**Phase 4**
	Shelter-in-Place	Time-sensitive research activities	Gradual restart of research	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

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