



COVID-19 Operational Updates

March 16, 2020

Investigators conducting human subject research

March 13, 2020

ESSENTIAL SERVICES

**Department of Laboratory Animal Resources (DLAR)
Human and Animal Research Administration**

Planning Information for Research Laboratories

Institutional Core Labs



March 16, 2020

Investigators conducting human subject research:

We anticipate that human subjects research will be impacted by the COVID-19 pandemic. As part of your due diligence, please prepare for impact on normal operations. We will continue to provide updates/policy modifications specific to human subjects research as they become available.

In order to: i) mitigate the risk for both employees and research participants, ii) ensure that providers are available to perform clinical duties, and iii) preserve personal protective equipment for clinical care, we request that you consider the following with regard to your current research projects involving direct contact with research participants.

While human subjects research is not being restricted unilaterally, all PIs must review their protocols to determine whether a pause in research activity may be warranted. We will evaluate the need for further restrictions in the coming days based on the evolving conditions.

Continuation of the following types of studies is deemed appropriate:

- therapeutic research wherein there are limited/no treatment alternatives,
- FDA "Treatment" or "Emergency Use" studies,
- studies in which interruption/delay of research could cause significant harm to current research subjects.

For the continuation of all other types of human subject research, the PI must obtain permission from the appropriate departmental chair or center/institute director. Determinations to continue studies must be in alignment with both the ethical principles of human subject research and the safety of employees. We strongly recommend documenting these decisions.

In making a decision to proceed with human subjects research, we recommend the following considerations.

- Is the risk/benefit ratio for in-person contact acceptable?
- Does the study provide direct drug or device therapeutic benefit?
- Is any travel required of participants or employees appropriate, given current travel restrictions?
- Can study procedures be modified to minimize in-person contact (e.g., remote data collection)?
- If the study proceeds, what modifications are necessary to mitigate risk to human subjects and employees (note, there are currently restrictions on PPE for research).
- Is it necessary to pursue new enrollments? Follow-up visits?



- Note, please review the posted IRB guidance to determine how and when changes should be reported to IRB. (Please review the COVID-19 guidance on IRB review at: <http://research.uthscsa.edu/irb/COVID.pdf>)
- If you have questions or would like additional consultation in making a determination as it relates to protecting human subjects or IRB responsibilities, please contact Dr. Joseph Schmelz (schmelz@uthscsa.edu) or Dr. Kimberly Summers (summers@uthscsa.edu) 210-854-5671.

For questions or information related to departmental chair or center/institute director approval for research continuation please contact your respective Dean for Research.

SOM- Dr. Jennifer Potter (potterjs@uthscsa.edu)

SOD- Dr. Brigh Singh (singhbb@uthscsa.edu)

SON- Dr. Jing Wang (wangj1@uthscsa.edu)

SHP - Dr. Timothy Reistetter (reistetter@uthscsa.edu)

March 13, 2020

MESSAGE FOR RESEARCH COMMUNITY

Andrea Giuffrida, Vice President for Research
(210) 567-3720 | Giuffrida@uthscsa.edu

Below is a list of important information about the impact that the COVID-19 pandemic might have on university research operations. We ask the research community to maintain awareness of the dynamic nature of the events through regular monitoring of official communications from the Centers for Disease Control, the World Health Organization and the university for **Coronavirus Updates** at <https://www.uthscsa.edu/notices/coronavirus-update>

Although we might experience some temporary change for workforce support to include remote work options, the Office of the Vice President for Research and all the essential services provided by the Department of Laboratory Animal Resources (DLAR), Research Protection Programs (IRB, IACUC, OCR), and Clinical Trials Office (CTO) will continue to operate and maintain compliance with federal and state regulations.

We do not anticipate significant disruption of the services provided by the Office of Technology Commercialization (OTC), Research IT, Office of Postdoctoral Affairs, Research Partnerships, Conflict of Interest and Research Integrity, as those operations can continue remotely.

ESSENTIAL SERVICES

Department of Laboratory Animal Resources (DLAR)

DLAR has the flexibility to adjust to possible increases in employee absenteeism to ensure continued support of research animal health and husbandry.

- Current services will continue.
- There are no plans to specifically limit access to research animals. Vivarium access will be dependent on the same conditions governing campus access.
- Should there be a decrease in DLAR personnel, animal care practices will be adjusted such that animal health remains the priority.
- Current investigator or protocol specific services (e.g. training, protocol support, surgical support) may be curtailed or discontinued depending on DLAR personnel availability.
- Investigators and their staff conducting animal research are reminded to contact the DLAR administration (Director and Associate Directors) for questions or concerns related to the availability of DLAR services as the need arises.

Human and Animal Research Administration

We understand that some changes to ongoing human and animal research may be expected in response to the current COVID-19 pandemic. Our priority is to ensure the safety and welfare of our research subjects.

All business operations of the Research Administration offices (IRB, IACUC, OCR & CTO), including submission, review and approval can be performed remotely should the need arise.

- Staffing across our offices can be adjusted as our staff are cross-trained, and our business processes are standardized.
- IRB & IACUC convened meetings can be conducted using web-based approaches or conference calls.
- We have the capacity to convene unscheduled meetings if the need arises.

Investigators should keep in mind that multicenter clinical research may be affected by the conditions at the individual performance sites. Please stay in touch with the sites and their institutional offices. In addition, site investigators should check with the lead investigator or regulatory sponsor for any changes in the study.

Planning Information for Research Laboratories

While the Health Science Center has robust emergency response plans in place to maintain general activities, we encourage all research labs across the schools to prepare their own emergency plans detailing how they intend to continue their research activities should there be a workforce reduction due to illness or inability to come to work. PIs are the persons best positioned to develop a continuity plan for their labs.

Practical actions to consider include:

- Identify all critical research activities that require regular personnel attention and share your work plan with colleagues who might help you (e.g. maintenance of cell cultures).



- Cross train lab members to perform critical functions. If possible, reduce or delay large scale experiments.
 - Consider to pre-order critical supplies as they may be out of stock or affected by shipping delays
 - Plan for one individual to carry on activities generally conducted by multiple lab staff to minimize the number of entry and exits and changes of PPE
 - Update the emergency contact list, identify the lab point of contact and share his/her email and phone number with your lab personnel
 - Add on-line meeting options to all your scheduled meetings.
 - Check IT equipment for working from home and remote conferencing
 - Contact DLAR personnel for specific requests
 - Secure all high-risk materials (chemicals, biohazard and radioactive)
- Please start planning NOW and reach out to our office (VPR@uthscsa.edu) for any questions.

Institutional Core Labs

In case of reduced workforce, you may experience delays in the analysis/processing of your samples. Please contact Dr. Ramiro Ramirez-Solis with any questions (210) 567-2059.