# **MEMORANDUM**

Office of the Vice President for Research and Economic Development

DATE:

March 16, 2020

TO:

University of South Alabama Research Community

FROM:

Lynne Chronister/

Vice President, Research and Economic Development

SUBJECT:

Research Continuity Policy and Guidance During Pandemic Event

As of March 12<sup>th</sup>, 2020 the leadership of the University has reviewed the threat to public health posed by the COVID 19 Corona Virus and responded with requirements and guidance for campus. The Office of Research and Economic Development (ORED) fully appreciates and supports the need to ensure the continuity of research and scholarship even during a pandemic event. However, if, by carrying out research we have a greater than moderate risk of endangering our colleagues or the public through personal contact, we should consider pausing the research and revising the timetable and scope.

If the research can be conducted with little or no risk to the public and our colleagues, the attached document provides policy and guidance to assist in carrying out research but perhaps with modifications and greater attention to safety and security. A complete Pandemic Plan is included in the University Pandemic Plan. However, attached is a COVID 19 Research Continuity policy and guidance covering the following:

- 1. To Whom the Plan Applies
- 2. Research Courses and Meetings
- 3. Sponsor guidance
- 4. Submission of proposals
- 5. Access to Laboratories
- 6. Core Facilities
- 7. Graduate and Undergraduate involvement in research
- 8. Laboratory Safety
- 9. Human subjects research
- 10. Animal research
- 11. Clinical trials

Currently, majority of students are not residing on campus and classes are being moved to on-line delivery. Administrative offices are still open. Grant proposals will continue to be submitted through normal Cayuse approval channels unless further guidance from our sponsors, especially federal agencies.

In the event that this situation changes, I will provide immediate guidance and information to campus. Please take all safety precautions and stay healthy!

attachment

# RESEARCH CONTINUITY PLAN DURING PANDEMIC EVENT

# **Included in this Plan are:**

- To Whom the Plan Applies
- Research Courses and Meetings
- Sponsor guidance
- Submission of proposals
- Access to Laboratories
- Core Facilities
- Graduate and Undergraduate involvement in research
- Laboratory Safety
- Human subjects research
- Animal research
- Clinical trials

# **Key Points**

- 1. Most research can continue during the pandemic event.
- 2. A written plan is required for all laboratories or other in-person research. This plan must be sent to the Dean and then to the Vice President for Research or the Senior Associate Dean for the College of Medicine. A form to complete for this plan will be sent separately.
- 3. Graduate student research can continue unless it poses a health risk.
- **4.** Undergraduate student research can continue with approval from the Vice President for Research.
- **5.** Social distancing should be practiced at all times.
- **6.** Laboratories must limit the number of individuals in the space at a given time. At no time should more than 10 individuals be in a laboratory space at one time. Individual laboratories may set lower limits.
- **7.** Office of Research and Economic Development units will all continue to operate including answering phone call and emails.
- **8.** Graduate and undergraduate students will continue to be paid from federal grants and contracts for the next few weeks. We do not have guidance from OMB on how long this will continue.

# **NOTE:** Guidance on Conducting Clinical Trials will be distributed separately

**Applies to:** All faculty, technical and support staff, postdoctoral fellows, and graduate and undergraduate engaged in research at the University of South Alabama including the College of Medicine, and off-main campus sites such as the Mitchell Cancer Institute.

Hospital and Clinic employees will abide by the University Health System Plan.

**NOTE:** Some buildings on campus may be locked 24/7.

# **Research Courses and Meetings**

Please see Guidance from each College Dean. However, unless specifically approved for inperson meetings, all meeting and courses will be online or cancelled.

- Research/dissertation and directed studies these courses should transition to online, independent study if possible, using email/phone communication or Zoom.
- Routine laboratory team meetings transition to **Zoom**.
- Seminars/workshops/dissertation committee meetings cancel or transition to **Zoom**.
- **IMPORTANT NOTE:** You should use the University's single sign-on to access the **Zoom** platform. This will allow you to access all Zoom features.

#### **Sponsor Guidance**

For NIH proposers and awardees, please see the NIH COVID-19 Guidance at www.grants.nih.gov.

The Federal Office of Management and Budget (OMB) have provided this guidance:

- Awarding agencies may allow necessary pre-award costs that are incurred (i) from January 20, 2020 through the Public Health Emergency Period and (ii) prior to the effective date of a Federal award.
- Awarding agencies will be more flexible on no-cost extensions on expiring awards.
- Awarding agencies may extend awards which are active as of March 31, 2020, and scheduled to expire prior to or on December 31, 2020, automatically, at no cost for a period up to twelve (12) months.
- Abbreviated non-competitive continuation requests for non-competitive continuation requests scheduled to come in from April 1, 2020, to December 31, 2020, from projects with planned future support. Awarding agencies may accept a brief statement from grantee organizations to verify that they are in a position to: (i) resume or restore their project activities and (ii) accept a planned continuation award.
- Expenditure of award funds for salaries and other project activities. Awarding agencies
  may allow recipients to continue to charge salaries and benefits to currently active
  Federal awards consistent with the recipient organization's policy of paying salaries
  (under unexpected or extraordinary circumstances) from all funding sources, Federal and
  non-Federal.
- Waivers from prior approval requirements. Awarding agencies are authorized to waive prior approval requirements as necessary to effectively address the response. All costs charged to Federal awards must be consistent with Federal cost policy guidelines and the terms of the award, except where specified in M-20-11, the OMB memorandum dated March 9, 2020.

# Submission of Proposals During a University Full or Partial Closure

The Sponsored Project Office will be submitting proposals during a full or partial campus shutdown.

- The Sponsored Projects Administration (SPA) Office will inform campus if sponsors have sent notices that they are NOT receiving proposals during a pandemic event.
- When administrative offices are open, i.e. a partial shutdown, all proposals will be submitted through normal channels using Cayuse.
- During a full campus shutdown, i.e. administrative offices are closed, proposals may still be submitted through Cayuse. One of the benefits of this platform is the ability to remotely submit proposals. Proposals that are submitted via Cayuse's 424 will continue to be submitted consistent with federal sponsor processes. The Executive Director of SPA will notify campus if any adjustments in the normal Cayuse process will be needed.
- All faculty are strongly encouraged to submit well in advance of posted sponsor deadlines. With uncertainty about network strength with a massive uptick in use, submission near the deadline is anticipated to be highly risky.
- At the time the University implements its pandemic plan, please allow issues which are
  not time sensitive to be addressed at a later date when SPA staff has resumed to full
  capacity.

## **Access to Laboratories**

When the University is in full or partial closure in the event of a pandemic, access to laboratories may be limited. Research should be limited to work needed to manage critical needs and not to normal open access .(i.e. not business as usual). It is recommended transitioning when possible to remote work for tasks such as writing, data analysis etc. with Zoom lab meetings.

- Access to laboratories is permitted for faculty and post-doctoral fellows. However, if
  faculty intend to carry out research in the laboratory, for information purposes, they
  should send an email to the Vice President for Research and Economic Development, or
  to the Senior Associate Dean, College of Medicine. A written research plan is required
  and must be included in the email.
  - o If graduate students are to carry out research for faculty or conduct thesis or dissertation work in a laboratory they should have access.
  - Undergraduate students should be granted access only under exceptional circumstances, and must be approved by the Vice President for Research and Economic Development.
  - O To gain approval for students in the laboratory, the lead faculty/researcher must send an email to the Vice President for Research or Vice President for Medical Affairs and include the Laboratory Room/Bldg. number and the names of the individuals who will be working in the Lab. Include in the

- email a short justification for student access. The Vice President for Research or Medical Affairs, as appropriate, will review and confer with the College/School Dean and respond ASAP.
- O Social Distancing practices should be followed in all instances. In small laboratories it is prudent for only one individual to be present in a laboratory at the same time. This will require scheduling of access.
- If best practices or information indicate that it is likely the virus survives on surfaces, the laboratory must include guidance for disinfecting all work spaces.
- o Remind each individual to follow strict laboratory safety protocols.

**NOTE**: Access to the Laboratory for Infectious Disease (LID), Shelby Hall (SH) and the Mitchell Cancer Institute Research Section (MCI) are always restricted to those with appropriate clearance and FOB or keycard entry.

# **Graduate and Undergraduate involvement in Research**

Under the Research Continuity Guidance graduate students may continue their research with approval from the College/School. Continuation of all undergraduate student involvement in research, including travel and work related to the research (collectively "Research"), requires approval. Research includes, but is not limited to, laboratory, digital and field work.

The following guidance applies when: (a) campus access is limited to administration, staff and faculty; (b) students are not allowed on campus, and (c) classes are only provided online (collectively "Limited Access"). Research may continue subject to approval and the restrictions below.

- Under limited access due to full or partial closure, all graduate students under stipend (and undergraduates as explained below) doing research can access campus and the relevant academic building(s) to continue research under the supervision of a faculty advisor. Research can continue by respecting social distancing, limiting personal interactions only as necessary, communicating remotely whenever possible and observing appropriate personal hygiene and equipment sanitation protocols. If portions of Research can be done remotely, in full compliance with all security and confidentiality protocols (e.g., VPN, etc.), then this work should be done initially to avoid the need for campus access (collectively "Restrictions").
- If necessary, with specific approval, undergraduates can access campus to complete
  research necessary for graduation or as part of a directed study, departmental thesis or
  Honors thesis, subject to Restrictions. Faculty are encouraged to work with students to
  make modifications, when possible, to facilitate completion of Research on schedule by
  remote access.

It is the general intent of the Research Continuity Plan during limited access to laboratories: (1) to approve the continuation of Research, or any portions, subject to Restrictions; and (2) to require a written request to continue the Research subject to Restrictions.

# **Laboratory Safety**

#### 1. BIO/LIFE/PHYSICAL SCIENCES LABORATORIES

# Research Preparation and Implementation:

- Have up-to-date contact information for your team, including staff, postdoctoral fellows and students (phone numbers, addresses, emails).
   Practice social distancing at all times.
- Create a plan for your laboratory for closure or reduced level of activity. The plan must be submitted to the Chair and Dean in writing. The plan should prioritize safety of all personnel engaged in research, and ensure laboratories and research areas are placed in a safe configuration that is maintainable for an extended period with available custodial/maintenance personnel.
- Insist your team use good hand hygiene and preventative measures.
- Document critical equipment on emergency power and ensure backup.
- If you are carrying out a long-term experiment and if it is feasible to freeze, preserve or otherwise capture samples or data at specific steps, you might consider doing this more often.
- Ensure that those involved in research projects have access to information they need to carry out work remotely (e.g., access to literature, existing datasets and research-related files, etc.)
- Identify emergency personnel and ensure they know what to do in the event of suspended operations.
- Identify critical job functions and positions, and plan for alternative coverage by cross-training staff and faculty.
- Remind lab personnel of your communication plan or create one if not in place.

**Discuss with your team a plan to rapidly switch to remote work:** Researchers and staff should check ahead of time that they have adequate resources and access to information to work remotely:

- Discuss with your team a list of projects that could be completed while working remotely, and formulate a plan for managers and staff to maintain communication and manage workflows during such a scenario.
- Ensure remote access to files, data, servers, etc.
- Identify priorities in case of restricted access, prioritize experiments:
- Consider prioritizing work that can only be carried out in your research lab, and save tasks such as data analysis or administrative work that can be completed remotely for a later time.
- Consider the management of your samples, and whether or not samples can be frozen or otherwise saved on a more frequent basis to prepare for the scenario that you could not return to the lab the following day.

- Identify backup sources for liquid N2 and dry ice if primary vendors are unavailable, or identify strategies to have sufficient supplies on hand for a 2-3 week closure.
- Identify non-critical equipment that could be shut down in the event of closure.
- Backup electronic research data and ensure remote access.
- Identify critical research tasks that must be completed to sustain continuity.
- Determine whether your team is sufficiently cross-trained on critical tasks.
- If cross training is needed to support animal research, make sure crosstrained individuals are included in IACUC protocols and have appropriate vivarium access.
- Inventory supplies to ensure stocks of critical materials if ordering is suspended, including special supplies that might be needed for research animals.
- Submit revised protocols for any change in approvals from IACUC, IRB, Bio-Safety, and other assurances and approvals.
- The Office of Research Compliance and Assurance provides additional detail
  regarding proactive measures researchers can take to help mitigate the impact of
  a pandemic on their research programs and a checklist to follow to ensure
  preparedness in the event of shut-down/closure for unoccupied research labs.
  For additional details, see Office of Research Compliance and Assurance
  website.

# 2. COMPUTING/ TECHNOLOGY LABORATORIES

Please see STEM Lab Policy. In addition, it is critical to assess security requirement and to determine off-campus access issues e.g. use of VPN. Please be aware that malicious cyber actors may be targeting employees working from home, so review the University VPN announcement carefully.

#### **Core Facilities**

- Identify contingency plans to continue critical research support.
- Identify what core resources would not be available if core staff is ill.
- Communicate to existing users the availability of the core facility.
- If it is critical to use the facility, post the process for access keeping in mind social distancing.

#### Faculty/Laboratory Manager

- Monitor wellness of all individuals in your team.
- Consider regular Zoom lab meetings as a means to not only keep up-to-date on remote research progress. but also to check on team wellness.
- Limit building access to those who remain well and are needed to complete critical research tasks.
- Insist team members maintain social distance if physically present consider that students may be asked to limit social distance before campus closure (i.e., if classes are cancelled but faculty/staff are expected to work).
- Consider rotating team members assigned to complete on-site tasks to maintain critical research continuity.

# **Research Compliance**

The University Office of Research Compliance and Assurance is positioned to continue to function across its areas. The preparation, review and submission of applications to the IRB, IACUC and IBC can happen entirely electronically. The IRB, IACUC, and IBC have the capability to meet by teleconference. Researcher guidance documents on the impact of pandemic and operational continuity associated with these research activities are posted on the Office of Research Compliance and Assurance website.

# **Animal Research**

The disaster plan for the vivarium is robust, with contingency plans for staffing, power and HVAC, temporary housing for animals, food and water, sanitation, security and veterinary care. In the event of a pandemic, where staffing is affected, the veterinarian or vivarium staff may make modifications to the regular cage change schedule (lengthening time between complete cage changes) or enlist the assistance of investigators or research staff who use animals on IACUC-approved protocols to help with routine husbandry in their respective colonies.

- Discuss strategies for maintaining breeding colonies in the event of closure with DCM personnel.
- Document plans to identify and safeguard critical animal strains in the event of closure.
- If cross training is needed to support animal research, make sure crosstrained individuals are included in IACUC protocols and have appropriate vivarium access.
- Inventory supplies to ensure stocks of critical materials if ordering is suspended, including special supplies that might be needed for research animals.
- There will NOT be any disruption to the Institutional Animal Care and Use Committee, and the review of protocols? The IACUC will continue to review submissions. Researchers can submit submissions to the IACUC using IRBNet. The Office of Research Compliance and Assurance will continue to provide service to the research community.

# **Human Subjects Research**

As you proceed with Human Subject research, you should consider the following questions and address them for your particular research protocol.

- Do you have cross-training among your staff that can mitigate any impact on your clinical trial activity?
- Do you have an alternative study site (within USA Health or outside) if your primary site is closed in a pandemic, to enable completion of critical study visits

in therapeutic trials?

- Can you reduce or suspend recruitment in the event of a pandemic?
- Do you maintain up-to-date contact information for subjects/patients?
- Is this information backed up and remotely accessible to authorized personnel?
- Must the IRB approve amendments to the study protocol prior to implementing changes?
  - i. If changes are needed for the immediate health and safety of participants that require modifications from protocols submit an amendment within 5 days.
- Does the IRB require approval for communications to study subjects to explain any pause in activity?
  - i. No, it is not necessary to submit a modification.
- Will there be any disruption to the Institutional Review Board, and the review of protocols?
  - No. The IRB will continue to review submissions. Researchers can submit submissions to the IRB using IRBNet. The Office of Research Compliance and Assurance will continue to provide service to the research community.

# **Bio-Safety**

In the event of an emergency, the USA IBC will continue to conduct official business. The Office of Research Compliance and Assurance will be available to answer questions, assist in protocol preparation and provide training and consultation as needed. If campus operations are interrupted, the Office of Research Compliance and Assurance will arrange for alternatives to face-to-face meetings such as teleconference, if required.

#### **Clinical Trials**

**NOTE:** This section will be distributed separately