



# Office of Research Compliance

Home Contact Us News & Events

## COVID-19 Guidance for Researchers

Updated 11/9/2020 (Human Subjects Research Effective 2/10/2021, updated 2/17/2021)

An update regarding the University's [Plan for Phased Continuity of the Research Enterprise \(PDF\)](#) due to the recent [announcements](#) by the State of Maine in response to the surging cases of COVID-19 in Maine and the nation:

We have been in Phase 3 of the Phased Research Continuity Plan since August 1st and are continuing in that Phase for the time being. We appreciate all the good work that everyone has done in conducting research while keeping the community safe, and urge everyone to please remain diligent and continue with the work in keeping our community safe. Please continue to submit your new research activities through the [request form](#) and utilize [UMSpaceSafe](#). This continuing process is necessary to monitor activity and to allow for planning in case circumstances change.

If it becomes necessary to move back to Phase 2, which is more restrictive, some previously approved projects will need to be halted until conditions improve. Researchers with active approvals will be notified via email regarding their phase designation. Questions may be directed to Tammy Crosby at [tammy.crosby@maine.edu](mailto:tammy.crosby@maine.edu).

As a reminder, additional COVID-19 Research Guidelines are available at the links below:

- [Guidance for Research](#)
- [Graduate School Community Guidelines](#)
- [Office of Research Development Guidelines](#)
- [Office of Research Administration Guidelines](#)

The response to COVID-19 continues to be a rapidly evolving situation even at this stage of the pandemic and this guidance is subject to change. Please continue to regularly check the UMS Information page (<https://www.maine.edu/health-advisory/>) and the UMaine Information page (<https://umaine.edu/coronavirus/>).

### Field Research

Faculty and staff are encouraged to discuss proposed field work plans with their college or center prior to submitting a request. [Specific guidance for field research \(PDF\)](#) has been developed to provide an overview of key review criteria and safety considerations for fieldwork activity during the COVID-19 pandemic.

### Human Subjects Research – IMPORTANT UPDATE Effective 2/10/2021

The Chancellor has decreed that all members of the University community who have a regular presence on campus must participate in weekly COVID testing. In addition to increased COVID testing, the University has reduced public access to certain areas to strengthen the 'bubble' around our campuses to slow the transmission of COVID-19.

Researchers conducting research with human subjects are encouraged to design their studies to be conducted remotely if at all possible as this is the safest approach for our research participants, researchers and the university community. For those studies which cannot be conducted remotely, face-to-face human subjects research may be allowed on a case-by-case basis if it is determined that it can be conducted safely, and all participants either participate in the University's COVID testing program or provide documentation that they've had a negative PCR or antigen test no more than 72 hours prior to being on campus. It is recommended that researchers limit research participants to those individuals who are already on campus and participating in the University's COVID-testing program. Limited approvals for participants outside of the university COVID-testing program may be given under other circumstances (outside PCR or antigen test within 72 hours prior to campus visit). The guidance below has been updated to include this new requirement.

To determine if your human subjects research may be eligible to submit a request for Face-to-Face interaction, please review the table in the [Human Subject Research Ramp Up Guidance \(PDF\)](#). The University is still in Research Activity Category 'Medium Level (Early Phase 3)' for HSR.

Key steps for engaging in Face-to-Face HSR include:

- HSR studies that require modifications to an IRB approved protocol need to submit an amendment package to the UMaine IRB for review and approval.
- Along with any application modifications, research teams will need to develop plans for safety [[Hierarchy of Controls \(HOC\) Task Assessment \(Excel\)](#)] and a signed [Hierarchy of Controls Checklist \(Word\)](#)] and submit a [Research & Scholarly Activity Request](#) for review and approval.
- Key safety requirements which must be addressed in the HOC:
  - Social distancing plans (both throughout the in-person session and between appointments)
  - Mandatory face covering for research team and participants
  - Increased disinfecting procedures
  - Documented COVID testing requirement for research team & participants who will be on campus

Additional COVID Requirements for Face-to-Face HSR in Research Activity Category 'Medium Level':

1. All research personnel must complete [UMS Return to Campus: UMS Plan to Reopen for Fall 2020](#) (in UMS Academy; requires @maine.edu log in) which includes COVID-19 safety precautions (PI is responsible for ensuring all project personnel complete the appropriate training).
2. COVID-testing: Research team must participate in the University's weekly COVID testing program and participants must participate in the University's COVID testing program or show documentation that they've had a negative PCR or antigen test no more than 72 hours prior to being on campus.
3. Research team and participant screening must be completed prior to any in-person interaction. The screening information should be collected from any new or returning participants via phone, email, or other virtual method within 24 hours of the participant's planned study-related visit or interaction **and** immediately before in-person interaction. The screening questions to be utilized can be found in the [COVID-19 Participant Screening \(Word\)](#).
4. Research team must track activity that can be used for contact tracing in the event of a report of illness or exposure (In the study's informed consent, ensure that you tell participants that information collected for contact tracing may need to be shared with UMaine/UMS Administration and/or Maine CDC).
5. Supply all potential participants with the handout [COVID-19 Information for Participants \(PDF\)](#) which includes information about COVID-19, additional measures implemented to reduce risk of COVID-19 exposure, and their responsibilities if they choose to participate.

Need help preparing a Hierarchy of Control (HOC) for your project?

1. Watch UMS Safety Management's [video on the hierarchy of controls](#) (requires @maine.edu log in)
2. Download the [task assessment](#) and edit the document to include your tasks involving human subjects. (The task assessment includes examples to assist in evaluation of your research tasks).
3. Contact UMS Safety Management ([SEM@maine.edu](mailto:SEM@maine.edu)) to schedule a 1 hour HOC session and walk through your project's tasks.

Please contact the IRB office at [umric@maine.edu](mailto:umric@maine.edu) if you have any questions about this guidance or need more information.

### Animal Research

In addition to requiring IACUC approval, all not-previously approved research and scholarly activity requires approval using the [request form](#) which has been in place since March 24th.

Before initiating an approved research & scholarly activity which involves animals, please note that permission by the applicable lab manager must be obtained prior to performing any experiments in close quarters. Please email your request to the appropriate lab manager with copy to ORC ([umric@maine.edu](mailto:umric@maine.edu)). Your request should include applicable IACUC protocol number(s), a description of the experiment, and date of approval by the OVPRDGS.

**We ask that you remain flexible as Animal Facility ramp-up is also dependent on all of the following:**

- Appropriate animal care staffing levels
- Personal Protective Equipment (PPE) required for entry to the facility as well as any additional protocol-specific PPE (i.e. for handling hazardous agents)
- Disinfectants required for use on surfaces within the facilities

Please contact the Office of Research Compliance for assistance ([umric@maine.edu](mailto:umric@maine.edu)).

### Be prepared: Plan for Contingencies

If and when UMS and/or State health officials provide limiting/restrictive guidance that are out of alignment with current research activities, research efforts will drop back to lower phases as appropriate and will be ramped up when the guidance changes. Thus, researchers must maintain contingency plans and be prepared to halt all activities on short notice in case this becomes necessary. ORC's [Guidance for Research Ramp-Down \(PDF\)](#) includes information to help you prepare, or update, your contingency plans.

