

Considerations Related to COVID-19 for MaineHealth Clinical Researchers

As we continue to address the impact of COVID-19 on our clinical research at MaineHealth, we have prepared some guidance to assist researchers in determining whether or how to modify their studies. It is especially important to maximize the safety of our patients enrolled on studies; do our best to maintain the fidelity of the study; and to embrace a collective and inter-professional dialogue among the patient, study team and treating physician to reconcile the challenges posed in this public health crisis. *Importantly, the ultimate decision regarding how to proceed is up to the Principal Investigator using their knowledge of the specifics of the trial and their patient population.* A

The following broad prioritization list has been created to assist you in developing your plan to protect human subjects and others amidst this outbreak.

1. Studies related to potential treatment for COVID-19.
2. In-patient treatment trials in which patients are receiving investigational products or procedures
 - a. Potential benefit to patients
 - b. Treatment trials in which discontinuation could have negative impacts to patients if withdraw
 - c. All other treatment trials
3. Out-patient treatment trials in which patients are receiving investigational products or procedures. (These studies may be amenable to changes that allow the study to stay open; for example, shipping drug to participants, remote study visits, etc.)
 - a. Potential benefit to patients
 - b. Treatment trials in which discontinuation could have negative impacts to patients if withdraw
 - c. All other treatment trials
4. Non-treatment research
 - a. Potential direct benefit to patients
 - b. No direct benefit to patients

Considerations for Human Subjects Research

- Is the location of the study remaining open and available for participants to be present? Has the location implemented any procedures to slow the spread of the coronavirus that will affect participation in your study or the ability of your study to proceed?
- Does your protocol require in-person participation or treatment? Can it be modified for remote participation?

- Does your protocol require in-person monitoring? Can it be modified for remote monitoring?
- Should your participants be screened for coronavirus as part of your inclusion/exclusion criteria?
- Would your data or results be affected if your participants had to self-quarantine or if they contracted coronavirus?
- Do any modifications made to your protocol and approved by the IRB due to the coronavirus also need to be reflected in ClinicalTrials.gov?

Both the Common Rule and FDA regulations require that prospective IRB approval be granted for changes in research ***except where necessary to eliminate apparent immediate hazards to the human subjects.***

Due to the potential exceptional impact of the declared public health emergency, we want to assure our community that we will be doing our part to help you continue your research.

The ultimate decision regarding how to proceed is up to the Principal Investigator using their knowledge of the specifics of the trial and their patient population.

Please contact us with questions:

Human Research Studies – Emily Berg (207-661-4471 or berge@mmc.org)

Clinical Trials – Krista Garrison (207-396-8074 or GARRIK@mmc.org)

Sponsored Programs – Michele Locker (207-396-8144 or LOCKEM@MMC.ORG)

Considerations Related to COVID-19 for Researchers

As we continue to address the impact of COVID-19 on our research at MaineHealth, we have prepared some guidance to assist researchers in determining whether or how to modify their studies.

Please consider the points below for your research.

- What would the impact be to my research and sponsored programs if I had to self-isolate for two weeks?
- What would the impact be to my research and sponsored programs if more than one of my research staff had to self-isolate for two weeks?
- What would the impact be to my research and sponsored programs at MaineHealth if all research staff had to work remotely?
- What would the impact be to my research and sponsored programs if the event duration were two, four, or six weeks?

Here are some additional ways to begin assessing the potential impact of the coronavirus on your research:

- Are there any studies involving participants, animals, ingredients, or experiments that would be adversely affected? If so, what plans should be put in place to allow for them to continue or allow for them to be stopped and later resumed in the least impactful way?
- What standing purchasing orders or human resource issues might be impacted?
- Would data collection/analysis/storage be impacted?
- What costs would be associated with these impacts?
- What regulatory approvals will expire soon and might be impacted if they are not renewed? Can they be renewed early?
- Are there any collaborators that need to be notified?
- What sponsor reports or deadlines might be due during this time period?
- Would the impact of these actions warrant a for-cost or no-cost extension request for any of my sponsored projects?

- What notice might I need to give sponsors or regulators if the research is going to be paused or significantly delayed beyond a couple of weeks?

Considerations for Environmental Health and Safety

Most considerations for environmental health and safety would only come into play should critical lab staff with unique knowledge be unavailable.

- Do you have a limited number of critical lab staff with unique knowledge? Are there others in your lab who can be cross-trained?
- Does your lab operate machines that use active cooling through liquid gasses, dry boxes, or inert boxes using gas blankets? What would happen if materials like liquid gasses, CO₂, nitrogen, or dry ice become unavailable?
- How frequently are you saving or freezing samples of your cell cultures?
- Do you have long-term experiments that might benefit from more frequent preservation?
- Do you have the requisite local knowledge to do controlled shutdowns of complex machines or devices such as NMRs without on-site help from the company?
- Have you shared with MMCRI the locations and amounts of materials that are air, water, or otherwise unstable for observation in case of lab closure?

Once you have considered the potential impact, please take appropriate steps to implement any necessary actions.

Due to the potential exceptional impact of the declared public health emergency, we want to assure our community that we will be doing our part to help you continue your research.

Please contact us with questions:

Animal Research Studies – Kelly Crowe (207-396-8195 or KCrowe@mmc.org)

Human Research Studies – Emily Berg (207-661-4471 or berge@mmc.org)

Clinical Trials – Krista Garrison (207-396-8074 or GARRIK@mmc.org)

Sponsored Programs – Michele Locker (207-396-8144 or LOCKEM@MMC.ORG)

Environmental Health and Safety – Bill Meggison (207-396-8786 or WMeggison@mmc.org)

Additional Resources related to COVID-19 Research

Additional Resources:

American College Health

Association: https://www.acha.org/documents/resources/guidelines/ACHA_Preparing_for_COVID-19_March-3-2020.pdf

Association of American Medical Colleges: <https://www.aamc.org/coronavirus-resources>

Association of Public and Land-grant Universities Responses to

Coronavirus: <https://www.aplu.org/news-and-media/communications-resources/coronavirus/>

Centers for Disease Control: <https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/index.html>

Coronavirus COVID-19 Global Cases by Johns Hopkins CSSE:

<https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

Council on Governmental Relations: FAQs Regarding COVID-19's Impact to Federal Awards: <https://www.cogr.edu/faqs-regarding-covid-19s-impact-federal-awards>

COVID-19 ("Coronavirus") Information and Resources for Schools and

School Personnel (Department of Education) <https://www.ed.gov/coronavirus>

Department of State Travel

Advisories: <https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories.html/>

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic:

<https://www.fda.gov/media/136238/download>

Guide for Developing High-Quality Emergency Operations Plans for Institutions of Higher

Education (2013): https://rems.ed.gov/docs/REMS_IHE_Guide_508.pdf

Guidance for Interruptions of study related to Coronavirus (Department of

Education): [https://www.cdc.gov/coronavirus/2019-](https://www.cdc.gov/coronavirus/2019-ncov/communhttps://ifap.ed.gov/electronic-announcements/030520Guidance4interruptionsrelated2CoronavirusCOVID19ity/guidance-ihe-response.html)

[ncov/communhttps://ifap.ed.gov/electronic-](https://ifap.ed.gov/electronic-announcements/030520Guidance4interruptionsrelated2CoronavirusCOVID19ity/guidance-ihe-response.html)

[announcements/030520Guidance4interruptionsrelated2CoronavirusCOVID19ity/guidance-ihe-response.html](https://ifap.ed.gov/electronic-announcements/030520Guidance4interruptionsrelated2CoronavirusCOVID19ity/guidance-ihe-response.html)

Interim Guidance for Administrators of US Institutions of Higher Education (IHE) to Plan, Prepare, and Respond to Coronavirus Disease 2019 (COVID-19): <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-ihe-response.html>

NAFSA: Association of International Educators COVID -19 Information and Resources: <https://www.nafsa.org/regulatory-information/coronavirus-critical-resources>

NASA Administrator Statement on Agency Coronavirus Status: <https://www.nasa.gov/press-release/nasa-administrator-statement-on-agenc...><https://www.nasa.gov/press-release/nasa-administrator-statement-on-agency-coronavirus-status>

NCI:
https://www.ncicirb.org/system/files/Interim_Guidance_Clinical_Trial_Activities_Affected_%20by_Novel_Coronavirus_3-13-2020_0.pdf

COVID-19 Resources for Applicants and Recipients of NIH Funding
<https://nexus.od.nih.gov/all/2020/03/13/covid-19-resources-for-applicants-and-recipients-of-nih-funding/>

NIH Extramural Response to Natural Disasters and Other Emergencies:
https://grants.nih.gov/grants/natural_disasters.htm

NIH-Funded Clinical Trials and Human Subjects Studies Affected by COVID-19:
<https://nexus.od.nih.gov/all/2020/03/17/guidance-for-nih-funded-clinical-trials-and-human-subjects-studies-affected-by-covid-19/>

NIH NIAID: Coronavirus Resources for Researchers: <https://www.niaid.nih.gov/diseases-conditions/coronavirus-resources>

Office of Laboratory Animal Welfare (OLAW) Disaster Planning and Response
Resources: <https://olaw.nih.gov/resources/disaster-planning.htm>

PRIM&R:COVID-19 and Coronavirus: Updates for the Oversight
Community: <https://blog.primr.org/covid-19-and-coronavirus-updates-for-the-oversight-community/>

Resources of Institutes of Higher Education (CDC): <https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/index.html>

Smart Traveler Enrollment Program (Department of State) <https://step.state.gov/step/>

State and Territorial Health Department
Websites: <https://www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.htm>

|

Student and Exchange Visitor Program (ICE): <https://www.ice.gov/doclib/sevis/pdf/bcm2003-01.pdf>

United States Senate Letter to OPM on Protections for Federal Employees and Contractors:

https://www.warner.senate.gov/public/_cache/files/5/c/5c6cf147-46de-4d25-a9f1-089c74a7dcb4/A1EF0326647F6B21227B5F702169F9E4.3.6-final-opm-coronavirus-letter.pdf

World Health Organization: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public>