From: Michelle Christy <<u>MChristy@cogr.edu</u>> Date: Thursday, March 19, 2020 at 12:18 PM To: "REC (Formerly Research & Regulatory Reform)" <<u>REC@COGR.edu</u>>, "RSIP (Formerly CIP)" <<u>RSIP@COGR.edu</u>>, "CGA (Formerly RCA)" <<u>CGA@COGR.edu</u>>, "CFC (Formerly Costing Policies)" <<u>CFC@COGR.edu</u>>, Board Alumni <<u>boardalumni@COGR.edu</u>> Subject: USAMRAA's COVID-19 FAQs

per discussion on the call

USAMRAA's COVID-19 FAQs

This Notice addresses general questions associated with proposal submission and award management that may arise in relation to COVID-19. The United States Army Medical Research Acquisition Activity (USAMRAA) is providing this information as a service to our applicant and recipient communities to address immediate, high-level questions that have been posed to federal research assistance agencies. Please note that given the fact that COVID-19 and associated impacts continue to evolve, applicants and recipients are strongly encouraged to monitor the resources noted below for updates. USAMRAA is publishing information on flexibilities for organizations funded by USAMRAA to conduct research on COVID-19 along with Frequently Asked Questions (FAQs) on other administrative flexibilities whose operations have been adversely impacted in the emergency response related to COVID-19. *These FAQs will be updated as more information becomes available.*

1. What will be done for recipients whose awards support the continued research and services necessary to carry out the emergency response related to COVID-19 during the period formally declared by the Department of Health and Human Services through the 90 Day Public Health Emergency Declaration (Public Health Emergency Period)?

The Office of Management and Budget (OMB) has identified the following actions to relieve short-term administrative, financial management and audit requirements under the Uniform Guidance at <u>2 CFR Part 200</u> – "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards"-without compromise to accountability requirements (<u>M-20-11</u>). USAMRAA will extend flexibilities to awards that support efforts related to COVID-19 on a case-by-case basis. Please contact the Grants Management Specialist or Grants Officer's Representative listed in the award document for information concerning individual grants.

2. I have a question related to COVID-19's potential impact on my research project, project- related travel, or field work. Where are some of the places I can find helpful information?

Your employing organization is an ideal starting point. In many cases, colleges and universities have created websites offering information.

Beyond that, we encourage you to consult the following resources:

• COVID-19 in general:

- <u>Centers for Disease Control (CDC)</u> including its guidance for <u>Institutes of Higher</u> <u>Education</u>
- World Health Organization (WHO)
- Local and state public health department
- Travel to/from and quarantine in foreign countries: See the <u>State Department Travel</u> <u>Advisories website</u>
- The Department of Defense's Coronavirus Update

3. The <u>DoD Research & Development (R&D) General Terms and Conditions</u> provide the recipient the authority to extend the period of performance one time for up to 12 months beyond the original completion date down stated in the award document. Any additional project period extension beyond the initial extension of up to 12 months requires prior approval from the DoD awarding component.

Part 2, Article V., Section C (Financial and Program Management) of the R&D General Terms and Conditions addresses pre-award costs, carry forward of unobligated balances, and one-time no cost-extensions. Item 3 indicates that one-time no-cost extension provisions are reserved for the discretion of the DoD awarding component. See the agency-specific or award specific section of your award to see whether the awarding agency has already authorized a one-time no-cost extension without the need for prior approval. If it has not done so, once you have assessed how much additional time will be needed to complete performance, contact the POC on the award to request an extension. Grants officials have been advised to be flexible in considering requests related to this public health emergency.

4. I am an investigator on a USAMRAA-funded award that includes travel to a meeting/conference, but the meeting/conference has been canceled. Who do I contact regarding the impact to the USAMRAA award?

You should contact the cognizant USAMRAA grants official named in the award document to alert them to the situation. Also, copy the program official to ensure all appropriate federal staff are aware of the circumstances. In light of the public health threat, you may wish to consider alternate plans, such as providing or using options for virtual participation. Additionally, it may be possible to attend if the meeting/conference is rescheduled within a year. See the question above regarding one-time no-cost extensions.

For meetings that are specified directly in the application or award notice, or that have been required by the Congressionally Directed Medical Research Program (CDMRP) (e.g. Milestone Meetings, In-Progress Reviews, etc.), we will be open to rescheduling the meeting or setting up a virtual presentation.

5. A conference has been canceled, but I have nonrefundable travel, registration, and/or hotel costs. Can these be charged to a USAMRAA grant?

USAMRAA is currently working within DoD as well as with our federal partners on a number of proposal and award-related issues pertaining to COVID-19. We will communicate with the about these issues through updated FAQs as further information becomes available. In the meantime, please continue to follow your organization's relevant travel policies and procedures.

6. I am involved with a USAMRAA award with a meeting/conference scheduled to take place in the coming weeks. Should I continue with plans for the meeting?

USAMRAA recommends reaching out to the conference organizer or host. They are best positioned to know the guidance at the event location. They may recommend having contingency plans if the event is ultimately cancelled or re-located, or might be planning to provide options

for virtual participation. If you are the organizer, you should consider developing contingency plans.

We also suggest checking the <u>State Department Travel Advisories</u> website if the conference involves foreign travel.

7. My USAMRAA grant involves an exchange of researchers (including students) and/or other foreign travel. Should I continue with plans?

Travel logistics, accessibility, and health and safety considerations of the participants in an active research project should always be a foremost consideration. USAMRAA recommends consulting with your organization about its policies and procedures. You should consider approaching the planned researcher exchanges and/or other foreign travel with flexibility, and/or devising alternate plans including virtual collaboration as appropriate. As noted above, we understand that plans for active research projects may be disrupted, to the point of needing extensions on the original award durations. For foreign travel, you should consult the <u>State Department Travel Advisories</u> website.

8. I have plans to attend a large scientific gathering. Should I continue?

We recommend first consulting with your organization about its policies and practices. In addition, you may consider reaching out to the organizer or host of the scientific gathering. They are best positioned to know the guidance at the event location. They may have contingency plans if the event is ultimately canceled or re-located, or they might be planning to provide options for virtual participation. We also suggest checking the <u>State Department Travel Advisories</u> website if the gathering involves foreign travel.

9. (a) My organization is open, but I am quarantined for a period of time. There is an application submission deadline during my quarantine period and some essential materials are in my office. I am the PI. Can my organization receive an extension to the deadline? (b) My organization has asked staff to stay home for an undetermined period of time. How would I petition for an extension of an application deadline?

There are currently no plans to modify existing application deadline dates but please continue to monitor <u>Grants.gov</u> for any potential change(s) to an application deadline.

Please contact the CDMRP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507 if you need further assistance.

This response may be updated at a later date depending on whether application review panel meeting dates are revised. Please check this page periodically for possible updates.

10. My position is funded through an USAMRAA award. The university will officially close until further notice as a result of the COVID-19 outbreak. Can the USAMRAA award be used to pay my employment costs?

The Department of Defense (DoD) will only allow recipients to charge salaries and benefits to currently active awards for work actually performed to meet the project activities, regardless of the location where those duties are performed (i.e., telework eligible). Some allowable activities may include -- e.g., data analysis, preparation of articles and papers based on the analysis of the research findings, monitoring subrecipients, care of research animals, direct charged administrative costs, etc. Additionally, such charges to the award should only be made when the work is performed within the recipient organization's policies for allowable remote/telework and/or emergency operations.

Applicable indirect costs may be charged to all allowed costs.

11. The COVID-19 pandemic has impacted the conduct of my DoD-supported human subjects research protocol. What do I need to report to the USAMRDC Human Research Protection Office (HRPO)?

In addition to seeking local guidance from your human research protection program officials and reviewing Institutional Review Board (IRB), notify the HRPO in the following circumstances:

a) Amendments: Per the terms of your HRPO approval, substantive amendments require HRPO review and approval prior to implementation. The HRPO will not require pre-approval of amendments intended to minimize risk of COVID-19 exposure for research volunteers or study team members. You must follow your institution's guidance or requirements for IRB review and approval for amendments and must provide documentation to the HRPO of all such actions in a prompt manner via email to the following address: <u>usarmy.detrick.medcom-</u>usamrmc.mbx.COVID-19@mail.mil.

b) Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs): Per the terms of your HRPO approval and the Common Rule, UPIRTSOs must be promptly reported. This includes any UPIRTSOs related to the COVID-19 pandemic, such as inadvertent exposure of research subjects and/or study personnel, missed or delayed safety assessments due to the pandemic, inability to provide study product or conduct key research interventions, etc. UPIRTSOs related to the COVID-19 pandemic must be promptly reported to the reviewing IRB and the following HRPO mailbox: <u>usarmy.detrick.medcom-usamrmc.mbx.COVID-19@mail.mil</u>

c) Halting research: Promptly report any actions taken to halt the conduct of ongoing human subjects research (e.g. pausing new enrollment, canceling follow-up procedures with previously enrolled subjects, etc.) due to the COVID-19 pandemic to the reviewing IRB and the following HRPO mailbox: <u>usarmy.detrick.medcom-usamrmc.mbx.COVID-19@mail.mil</u>

d) Note: You must adhere to all other reporting and submission requirements specified in your HRPO approval memorandum.

If notification by electronic mail is not feasible, notifications can be made telephonically to 301-619-2165. If you have questions, you can contact 301-619-2165 or the HRPO mailbox atusarmy.detrick.medcom-usamrmc.mbx.COVID-19@mail.mil.

USAMRAA is currently working internally with DoD as well as with our federal partners on a number of proposal and award-related issues pertaining to COVID-19. USAMRAA will communicate with the community about this issue and will provide guidance as further information becomes available. Please check the <u>USAMRAA website</u> for updates.