#### NIH COVID-19 FAQs as of 6/18/20 (Prior to implementation of OMB Memo <u>M-20-</u> <u>26</u>)

#### I. <u>General</u>

<u>1. Does this COVID-19 declared public health emergency fall under the "other emergencies" category as it relates to the NIH extramural response to natural disasters and other emergencies?</u>

Yes, this declared public health emergency is considered an emergency situation under NIH standing policy.

2. NOT-OD-20-086 indicates that flexibilities are applicable to NIH applicants and recipients where the entity is conducting research activities related to or affected by COVID-19. What does it mean for my institution to be affected?

Affected entities are those that have been closed, or business activities have been hindered due to COVID-19 precautionary measures and/or illnesses.

Examples of situations in which applicants or recipients are affected by COVID-19 include, but are not limited to:

- Staff supported by an NIH grant are in country covered by a CDC Travel Health Notice or have been quarantined due to travel to a country covered by a CDC Travel Health Notice;
- Involuntary absences from the workplace affecting the organization's ability to perform research and support for NIH-funded grants and cooperative agreements;
- The recipient institution or performance site has closed due to COVID-19;
- The recipient's grant-related travel, meetings or conferences are affected by COVID-19.

#### 3. Where can I find policy guidance specific to COVID-19?

NIH continues to monitor the emergency and will continue to issue guide notices and update FAQs and additional resources. All information can be found on the Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding page.

4. Who should I contact if I have questions about the NIH Policy for Disasters and Other Emergencies? What about questions related to receipt and referral of NIH applications that may be affected by this emergency?

For information related to the specific circumstances of a grant award that is affected by COVID-19, recipients should contact the funding Institute of Center (IC) grants management official and program official named in their Notice of Award.

Please direct broader emergency policy related inquiries to:

Division of Grants Policy
 Office of Policy for Extramural Research Administration
 Office of Extramural Research
 Email: GrantsPolicy@nih.gov

Please direct receipt and referral related inquiries to:

 Division of Receipt and Referral Center for Scientific Review Telephone: 301-435-0715 Email: csrdrr@mail.nih.gov

# 5. How will COVID-19 affect the program and grants management review of grant applications that have undergone peer review and received a score?

NIH staff across the organization continue to conduct their work and have access to the NIH systems required to review and issue awards.

6. Is there a place to find the Emergency Notices of Special Interest (NOSI) for each participating IC?

NIH continues to develop and issue Funding Opportunity Announcements and NOSIs related to COVID-19 for both supplements and new awards for applicants not already receiving NIH funds. In addition to publication in the NIH Guide to Grants and Contracts, the NIH Office of Extramural Research will update its COVID-19 page regularly to show active announcements available related to COVID-19 research.

7. Will NIH defer issuing new FOAs for non-COVID-19 activities? There is a concern in the community for how NIH will address new opportunities and the inability for some research institutions/entities to competitively apply for these FOAs?

NIH ICs will consider delaying new funding opportunities for the remainder of FY 2020 to FY2021, as appropriate.

#### 8. Will NIH allow no-cost extensions for awards that were multiyear funded?

Extensions may be limited for grants that were multiyear funded (i.e. all funds awarded in the first year of the award). Therefore, for grants that were multiyear funded contact the funding IC to discuss the terms and conditions of the award.

# <u>9. Do the flexibilities outlined in the recent guide notices and these FAQs apply to contracts, in addition to grants and cooperative agreements?</u>

No, the guidance provided by the Office of Extramural Research in Guide Notices and these FAQs are specific to NIH grants and cooperative agreements. Contracts must be handled on a case by case basis. Details regarding any contract must be directed to the cognizant Contracting Officer, including questions regarding salary charges.

#### <u>10. Is NIH providing flexibility on the requirements related to the use of Human Fetal Tissue (HFT) in</u> NIH-funded research, in response to the public health emergency?

No. All applications proposing the use of HFT as defined in NOT-OD-19-128 must comply with the requirements in the notice and undergo review by the HHS Ethics Advisory Board.

<u>11. Where can I find information on NIH-funded trials and studies involving COVID-19?</u> Information can be found in ClinicalTrials.gov, COVID-19 Studies Funded by NIH, and in the NIH Reporter. As time continues, additional studies will be added, and these sites will be updated.

12. What controls, if any, has NIH established for managing funding and activities related to the COVID-19 response? How will NIH management balance the need to implement the program quickly and maintain strong internal controls and manage the associated risks? NIH has developed an internal control plan as required by OMB *Circular A-123, Management's Responsibility for Internal Controls*, as well additional internal controls implemented or being implemented as the strategy for identifying and mitigating the risks associated with the administration and monitoring of COVID-19 Funds. (See OMB Memos M-20-11, M-20-17 and M-20-20).

#### **II. Application Submission**

#### 1. How does this public health emergency declaration affect my application's review?

NIH assures the applicant community that peer review will continue to take place. NIH will be flexible about accommodating virtual participation for aspects of peer review that would otherwise require inperson meetings.

# 2. Is NIH providing flexibility for the required registrations for organizations to submit an application to <u>NIH?</u>

The Office of Management and Budget (OMB), in memo M-20-17, provides flexibility to relax the requirement for active System for Award Management (SAM) registration at time of application. This effort is coordinated at the Department of Health and Human Services (HHS) level through Grants.gov.

- Applicant organizations not registered in SAM must contact gov Applicant Support and register in Grants.gov in order to submit a grant application. Organizations are still expected to obtain active SAM registrations as soon as possible.
- Applicant organizations are still required to complete registration in the eRA Commons prior to application submission. See Organization Registrations.

#### 3. Will NIH accept late applications for new awards from applicants affected by COVID-19?

NIH has announced an updated late policy for the parent institutional training grants which have just a single due date each year. In addition, some NIH ICs have issued late notices for specific funding opportunities, which are posted on the Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding website. For all other Funding Opportunity Announcements NIH is taking a very flexible stance for applications submitted within the standard two week late policy. Applicants should include a cover letter with an explanation for the late submission.

### <u>4. What happens if an institution has already submitted an application, and due to effects of COVID-19, some of the information needs to be revised?</u>

Institutions affected by COVID-19 will be allowed to submit post-submission grant application materials up to fourteen days before the start of the review meeting. Only the materials allowed under NOT-OD-18-083 will be allowed and must demonstrate concurrence of the Authorized Organization Representative (AOR).

#### 5. Can an institution affected by COVID-19 still apply to an FOA that has expired?

Yes. The applicant institution should contact the eRA service desk at least 2 business days prior to your anticipated submission so they can coordinate any changes needed to allow systems to process your application.

### <u>6. PA-18-591, the parent FOA for admin supplements, requires a paper submission for certain activity</u> codes. Will paper applications be accepted for supplements related to COVID-19?

Due to the need for better tracking and reporting as it relates to COVID-19, all applications should be submitted electronically via one of our electronic solutions (i.e. NIH ASSIST, grants.gov workspace, or institutional system-to-system (S2S) solution), rather than paper applications. Supplements submitted for multi-project parents must be submitted as single project applications. Depending on the needs of a multi-project application, more than one supplement may be submitted. Please refer to the instructions provided in the specific NOSI and/or FOA for further guidance.

# 7. Will NIH extend Funding Opportunity Announcements that are nearing expiration to accommodate delays due to COVID-19?

For FOAs expiring on or before June 30, 2020, NIH will extend the FOA expiration date by 90 days.

#### 8. Will NIH accept late submissions of reference letters?

Reference letters, including corrected or revised letters, for due dates between March 9, 2020 and May 1, 2020 must be submitted by May 1.

# 9. What guidance are reviewers being given as they consider applications during the COVID-19 pandemic?

Reviewers are being told to assume that issues resulting from the coronavirus pandemic will be resolved prior to award, and not allow concerns about temporary, emergency situations to affect their scores. See Coronavirus Update: Reviewer Guidance.

#### 10. What should I do if I don't have enough preliminary data for my application?

Applicants should always submit the best application possible. If preliminary data is lacking, the applicant should consider waiting to submit a stronger application for a later due date.

#### 11. Do applicants have to apply for supplemental funds from the same IC that funded the parent grant?

At their discretion, NIH ICs may fund competitive revisions to parent awards funded by another IC. Applicants should apply to a NOSI from an IC that is within the scientific mission of the application proposal even if the parent award is not funded by that IC.

Before submitting, applicants should first contact the relevant PO of the IC that would support the supplement (see Matchmaker to find a PO) to ensure the scientific scope is appropriate.

ICs that choose not to fund competitive revisions to parent awards funded by another IC will include a statement in the NOSI that applications will only be accepted when the parent award is funded by the IC issuing the NOSI.

#### III. Delays in Research Progress

<u>1. Delays due to COVID-19 have caused low subject enrollment that could affect research project progress. What should recipients do and who, at NIH, should be informed?</u>

First and foremost, NIH is concerned about the safety and welfare of research staff and human subject participants. Therefore, institutions should take all steps necessary to ensure safety of all human subject's participants involved in NIH awards, recognizing that the effects of COVID-19 may affect patients' ability to participate in NIH research, which may delay the recipient's ability to achieve project milestones. If the recipient anticipates delays, please discuss this with the funding IC.

#### <u>2. Will NIH allow project extensions due to delays related to COVID-19?</u> Recipients can request funded extensions by contacting the funding IC.

#### <u>3. Travel to a research site is hindered due to travel restrictions that are in place related to COVID-19.</u> What should the recipient do?

NIH understands that travel restrictions may continue to occur through the remainder of the public health emergency and will likely affect the progress of NIH-funded research. Recipients must contact the funding IC to alert them of the delays. NIH is committed to working with its applicants and recipients during this public health emergency.

# <u>4. If a recipient closes facilities due to COVID-19 and research labs and results cannot be maintained due to the closure, will NIH provide funding to cover such losses?</u>

Recipients should determine whether their insurance will cover such losses. Once determined, if costs are not covered by insurance, recipients may request supplemental support to recover NIH-funded resources by contacting the funding IC.

# 5. My institution is conducting a clinical trial or human subject study and has experienced delays in IRB approvals due to COVID-19. Who should we contact?

The recipient institution should notify the funding IC of any delays to clinical trials and human subjects studies, and NIH will work with the recipient to provide support and address any impact on the NIH-funded research. NIH is committed to working with recipients during this public health emergency, and our top concern is for the safety and welfare of human subject participants and research staff.

#### 6. My institution is conducting a clinical trial and had to arrange alternative strategies to conduct participant study visits. Will NIH support unanticipated costs associated with alternative study visit strategies necessary to maintain health and safety of study participants and the continuity of the trial? Institutions should take all steps necessary to ensure safety of all human subject's participants involved in NIH awards, recognizing that the effects of COVID-19 may affect patients' ability to participate in NIH research. The recipient institution should notify the funding IC of any changes necessary to maintain the health and safety of study participants and may request an administrative supplement to cover unanticipated costs.

# 7. Can I request an extension for a Ruth L. Kirschstein National Research Service Award (NRSA) fellowship award?

Yes. Recipients may submit extension requests to the funding IC for consideration when the effects of COVID-19 have altered the planned course of the research training. Extension requests must include a description of how COVID-19 affected the fellowship award, and clearly outline how much additional time is needed. All such requests must be signed by the fellow, the Authorized Organization Representative, and the fellowship sponsor.

#### 8. Under which circumstances will NIH provide administrative supplements?

NIH funding ICs will consider administrative supplements to support existing resources that were diverted due to COVID-19, where the faculty member may have donated personal protective equipment, lab equipment, lab supplies, or travel costs to support COVID-patient care, etc.

#### IV. Financial and Performance Reporting (RPPR)

### <u>1. How should recipients submit details on how COVID-19 has delayed or affected the progress of research activities on NIH-funded grant projects?</u>

NIH understands the potential effects of COVID-19 on the progress of NIH supported research. Recipients must report on any effects on the NIH funded research in their next RPPR submission. Recipients are not to submit standard letters, but rather report on these details within the RPPR. The funding IC will consider the effects that are reported by the recipient when reviewing and approving the RPPR. NIH remains committed to working with its applicants and recipients during this public health emergency. In addition, NIH recognizes that there may be delays in submission of RPPRs and other reports. See NOT-OD-20-086 for details on late submission.

#### 2. My institution has received an award for COVID-19 research funded by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. Are there any specific reporting requirements for these awards?

NIH awards issued using the supplemental funding provided in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (PL 116-123), will be issued in separate subaccounts in the HHS Payment Management System, with a 'CV' suffix. In order to track these special appropriations, recipients will be required to submit separate Federal Financial Reports (FFRs) for these subaccounts. NIH will not require separate Research Performance Progress Reports (RPPR) for these activities. Specific reporting requirements will be included in the terms and conditions of award for all awards issued using these COVID-19 funds.

### <u>3. As a recipient, what information should be included in RPPRs due in the next 90 days related to COVID-19?</u>

Recipients should document COVID-19 effects and state that research outcomes are not available at this time. Recipients should outline when they believe they will be able to include details related to the disruptions to the research efforts.

#### 4. How should recipients notify NIH that closeout reports will be late?

Institutions that experience delays related to COVID-19 impacting their ability to submit closeout reports should contact the NIH Closeout Center at NIHCloseoutCenter@mail.nih.gov, and provide a detailed justification on the effects of COVID-19 on the institution, and the grants where reporting will delayed. Delays in submission of closeout reports may not exceed one year.

### 5. Is NIH providing flexibility to S10 recipients, who may be unable to submit on-time Annual Usage Reports, or unable to fulfill institutional usage commitments?

As with other financial and performance reports, NIH will allow delayed submission of Annual Usage Reports for S10 recipients. When equipment usage is affected by COVID-19, recipients should report those effects in their reports, when discussing machine downtime and any changes in operation. NIH will consider the effects of COVID-19 on these activities in its review of reports received. Recipients should contact the funding IC to notify them of anticipated delays.

#### V. Foreign Components

### <u>1. If a post-doc on an active NIH grant must return home, to a foreign country, and work remotely due to COVID-19, must this be reported to NIH as a foreign component?</u>

For post-docs that are required to work on their originally approved work remotely from a foreign country due to COVID-19 travel restrictions, where no grant funds are going to a foreign entity, NIH has determined that this scenario does **not** constitute the performance of a significant scientific element or segment of the project outside the US, as outlined in the NIH Grants Policy Statement definition of a foreign component.

#### VI. Costs

#### A. Travel Costs

1. Conferences/meetings have been cancelled due to COVID-19. Can the airline ticket and conference registration fee be charged to the NIH grant? What if airline gives us traveler a one-year voucher? Non-refundable costs associated with grant-related travel that has been cancelled due to COVID-19 may be charged to the NIH award if they would have otherwise been allowable. See NIH GPS 7.9.1 for detailed information on the allowability of travel expenses.

If vouchers have been granted for any of the travel expenses affected by COVID-19, recipients are required to use the vouchers and may not request additional support.

Institutions must document that costs charged to a grant are non-refundable and maintain documentation, in accordance with record retention requirements, and make them available to NIH upon request.

2. Can recipients charge travel costs to an NIH grant for travel booked and paid, but not taken, because a researcher chooses not to travel, or the recipient institution limits employee travel due to coronavirus? First and foremost, NIH is concerned about the safety and welfare of research staff and human subject participants and recognizes that many recipient institutions are instituting temporary limits on travel due to COVID-19, and staff at these institutions should comply with these institutional policies.

3. Can recipients charge travel costs at a higher rate than usual because of inflated market costs? As outlined in the NIH GPS 7.9.1 travel costs are limited to those allowed by formally established organizational policy, and, in the case of air travel, the lowest reasonable commercial airfares must be used. Recipients should continue to comply with their institutional travel policies to determine the allowability of these costs in cases of unforeseen or emergency circumstances.

#### B. Conference Costs

<u>1. My institution has a conference grant. Money has been paid to the conference center but now many universities are cancelling due to the institutional travel policies that do not allow non-essential travel. Are any conference center charges allowable?</u>

NIH understands that scientific meetings, conferences and workshops supported by NIH funding may be delayed or cancelled due to COVID-19. Non-refundable costs associated with NIH supported meetings and conferences affected by COVID-19 are allowable and may be requested as an administrative supplement to the appropriate funding IC. Recipients should contact their assigned grants management

specialist and program official to provide documentation demonstrating the effect of COVID-19. The funding institute or center will work with the recipient to address the effects on the NIH grant.

#### C. Salary/Stipend Costs

#### 1. Can a recipient continue to pay personnel costs under awards in the event of an emergency?

Charging salaries, **regardless of whether it is for academic or summer appointments**, to NIH grants when no work is being performed is allowable if your organization's policy allows for the charging of salaries and benefits to currently active awards (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal. Recipient institutions should consult with their Human Resources Department to determine whether there are internal policies in place allowing employees to take paid leave, and to charge the grant, regardless of the source of funds, e.g. emergency or disruptive event policies. If the institution has a policy in place, and anticipates a need to charge personnel costs, notify the funding IC. NIH will request documentation to confirm the requirements of the institutional policy, and the effects of COVID-19 on the grant.

### 2. Does the ability to charge personnel costs to NIH awards when no work is being performed also apply to summer salaries?

Charging salaries, regardless of whether it is for academic or summer appointments, to NIH grants when no work is being performed is allowable if your organization's current policy allows for the charging of salaries and benefits to currently active awards (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal. Recipient institutions should consult with their Human Resources Department to determine whether there are internal policies in place allowing employees to take paid leave, and to charge the grant, regardless of the source of funds, e.g. emergency or disruptive event policies.

If the institution has a policy in place, and anticipates a need to charge personnel costs, notify the funding IC. NIH will request documentation to confirm the requirements of the institutional policy, and the effects of COVID-19 on the grant.

3. May National Research Service Award (NRSA) trainees and fellows, who receive stipends rather than salaries, continue to receive stipend payments if they are unable to work as a result of COVID-19? Yes, stipend payments may continue to be charged to NIH NRSA grants affected by COVID-19. Recipients should notify the Grants Management Specialist named in the notice of award and provide documentation demonstrating the effect of COVID-19, and how long the institution will be affected.

### <u>4. If faculty at my institution are diverted from research to clinical work to care for COVID-19 patients, can the institution continue to charge their salary to an NIH grant?</u>

Charging salaries to NIH grants when no work is being performed is allowable if your organization's policy allows for the charging of salaries and benefits to currently active awards (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal. Recipient institutions should consult with their Human Resources Department to determine whether there are internal policies in place allowing employees to take paid leave, and to charge the grant, regardless of the source of funds, e.g. emergency or disruptive event policies. If the institution has a policy in place, and anticipates a need to charge personnel costs, notify the funding IC. NIH will request documentation to confirm the requirements of the institutional policy, and the effects of COVID-19 on the grant.

5. For recipients affected by COVID-19, is it appropriate to activate new awards at this time and charge salaries and benefits to them, when work cannot be performed due to COVID-19? As these are new awards, we would not be continuing to charge salaries and benefits, but to initiate these charges. Recipients may not initiate charges for salaries and benefits on new awards where the work has not yet started. Recipients may only charge salaries and benefits when no work is performed on currently active awards, when your organization's current policy allows for the charging of salaries and benefits to currently active awards (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal.

If the recipient's performance site/facilities are open and/or telework options are available for work to begin, recipients may charge salaries and benefits to NIH grant awards.

# <u>6. If institutional funds are not available, can recipients affected by COVID-19 supplement NRSA stipends</u> with funds from other federal awards?

OMB Memo M-20-17 allows recipients to charge NIH awards for costs directly related to the affected grant project. Salary supplementation for NRSA stipends is not a cost supported by an NIH project, and is not allowable. NIH remains committed to supporting and providing maximum flexibilities to our recipients; however, in doing so, we want to remove options that would pose an audit risks for unallowable charges.

#### D. Prior Approvals

#### 1. Can a recipient back-date pre-award costs associated with COVID-19?

Recipients may charge pre-award costs to NIH supported grants dating back to January 20, 2020 through April 30, 2020 as outlined in the declaration of the public health emergency.

### <u>2. How will NIH support a recipient's need to limit in-person meetings for the sole purpose of instruction/training due to COVID-19?</u>

NIH will allow for special circumstances for trainings and instruction that typically require in-person attendance, such as training in the responsible conduct of research (NIH GPS 11.3.3.5). Training can be completed online during this declared public health emergency. Prior approval is not required in these specific cases.

#### <u>3. Can recipients that are not covered under Streamlined Non-competing Application Process (SNAP)</u> carry forward unobligated balances on their active awards that are affected by COVID-19?

Yes, as outlined in NOT-OD-20-086, recipients of grants that do not fall under SNAP will be allowed to carry forward unobligated balances on their active grants for immediate efforts to support activities related to or affected by COVID-19. In order to track the use of this flexibility and ensure that approval is noted prior to the submission and review of Federal Financial Reports (FFRs), recipients must contact the funding IC for approval. NIH is providing maximum flexibility in the review of these requests. Reminder: the charges must be allowable costs within the scope of the original award.

#### <u>4. Can recipients request a no-cost extension for awards affected by COVID-19? Is prior approval</u> <u>required?</u>

As outlined in NOT-OD-20-086, recipients may extend the final budget period of the approved project period one time for a period of up to 12 months. Recipients who do not have access to the No-Cost Extension feature within eRA commons should contact the funding IC to request their first no-cost extension. NIH will also approve requests for second no-cost extensions related to COVID-19. Recipients

should notify the funding IC via the prior approval module in eRA, including the justification, number of months of the extension and the unobligated balance on the award. A blank document may be uploaded in the Progress Report and Budget Document Fields. These documents are not required for no-cost extension requests related to COVID-19.

Note:

Extensions may be limited for grants that were multiyear funded (i.e. all funds awarded in the first year of the award). Therefore, for grants that were multiyear funded contact the funding IC to discuss the terms and conditions of the award.

# 5. Can grant recipients shift NIH grant money from one ongoing grant project to a different, COVID-19 related grant project?

No, grant funds allocated for a specific NIH grant may not be transferred to another grant project. General cost principles related to allocability of funds still apply to NIH grants.

Grant recipients interested in applying for COVID-19 related research projects can find Funding Opportunity Announcements for competitive supplements and new awards in the NIH Guide and on our COVID-19 page.

6. Can recipients donate Personal Protective Equipment (PPE) and supplies acquired with NIH grant funds to local hospitals and health care facilities in support of COVID-19 efforts?

Yes, recipients may donate PPE and other lab supplies to hospitals, medical centers, and other local entities that are directly serving the public health emergency crisis for COVID-19 response. NIH has aligned its guidance with OMB Memo M-20-20.

In order to proceed with these donations, recipients must maintain documentation that supports the following:

- 1. the donated equipment or supplies are not currently needed due to temporary suspension of project activities or no longer necessary to meet the objectives of the grant;
- 2. if the equipment remains in usable condition, it should be returned to its original purpose upon completion of the public health emergency;
- 3. the donation(s) will be documented for single audits and will be provided to NIH funding ICs upon request.
- 4. As outlined in the NIH GPS (Section 8.3.3.2.1) the title for equipment and supplies acquired under NIH grants vests with the recipient institution.

Recipients should not assume that NIH funding ICs will provide additional funds to replace the donated PPE and supplies.

7. Our institution has closed the lab for all but maintenance activities at this time. While we understand that charges for salaries, animal care, and other expenses may be allowable during this closure, will additional funds (e.g. from administrative supplements) be made available to support the lost time? NIH understands the effect of closures on the progress of NIH-funded research. Recipients affected by COVID-19 should contact the funding IC to discuss the progress on the specific award and identify potential solutions.

While Institutes and Centers plan, based on availability of funding, to issue administrative supplements when absolutely necessary, it is clear that for the vast majority of grantees, supplement requests in the next 2-3 months would be premature. We therefore recommend that institutions *hold off on submitting COVID19-related administrative supplement requests* until such time as (1) the full impacts of the pandemic on your research are clear, and (2) you have had the chance to discuss the various options with the relevant NIH staff and you have agreed that an administrative supplement is the best option for your project.

There are two exceptions. The exceptions to this recommendation are for (1) supplements to existing projects that will allow investigators to immediately address scientific questions of direct relevance to the COVID19 epidemic, and (2) supplements that are needed to address immediate, mission critical needs over the next 3 months. Investigators who believe they meet these exceptions should raise these issues with their program officers or grants management specialists prior to submitting such requests.

8. For grants where funds support a specific in-person activity (e.g. conferences, steering committee meetings, training, etc.), can grant funds be used to support converting the activity to a virtual setting? Yes. Recipients can use their existing authorities to re-budget costs for allowable grant activities within the scope of the award. This includes costs to support virtual meetings and events that support the existing aims of the award.

# <u>9. Is prior approval required if my institution plans to divert staff from research to clinical work to care for COVID-19 patients or to work on COVID-19 research activities?</u>

Prior approval is not required to divert faculty from research to clinical work related to COVID-19 until the end of the public health emergency period. Recipients may use clinical revenue from the work done by faculty as voluntary cost sharing to support salaries under the NIH funded project. The recipient institution may continue to charge salaries to the grant in accordance with their institutional policies.

If the PD/PI is absent from the project for a period of 3 months or more, recipients should notify the funding IC to identify a temporary replacement until the COVID-19 public health emergency/pandemic has passed or the research will, by default, be placed on hold and the delays must be reported in the RPPR.

#### E. Other Costs

# <u>1. Since most investigators are teleworking, can institutions now purchase laptops, desktops and other equipment using grant funds, to aid in telework?</u>

Direct charges for laptops, desktops and other equipment are allowable only when specific to a grant project. Laptop and desktop computers may be procured with grant funds consistent with recipients' institutional policies and treatments of cost. These costs are generally assigned to facilities and administrative (F&A) costs (see NIH GPS 7.2).

#### VII. Human Subjects

### <u>1. If my institution makes changes to an IRB-approved protocol related to COVID-19, does this need to</u> be recorded in clinicaltrials.gov?

Yes, as outlined in 42 CFR 11.64(a)(1)(ii), if a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, the regulations require that updates to any relevant clinical trial information be submitted not later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board. Additional details can be found in the clinicaltrials.gov FAQs.

# 2. What should recipients do if human subjects studies are cancelled, suspended, or need to transition to telemedicine due to COVID-19?

Recipients should contact the funding IC to determine the impact on research progress and the appropriate steps forward. Institutions should involve their Human Research Protections Program and the responsible IRB(s) as these plans are devised and implemented.

# <u>3. Is NIH offering COVID-19-related flexibilities for updating and correcting study information in ClinicalTrials.gov?</u>

It remains important to ensure that accurate and up-to-date clinical trial information is available to the public on ClinicalTrials.gov, particularly for COVID-19 related research. However, due to the potential exceptional impact of this public health emergency on research-related staff availability, NIH acknowledges that delayed updates and corrections may be unavoidable. Refer to the Top Questions from Responsible Parties Related to COVID-19 for information on specific questions.

# <u>4. My study was delayed during the COVID-19 public health emergency and I will not finish my project by the CoC expiration date. Can I get an extension on my CoC?</u>

To decrease the burden for the research community and ensure that research participants continue to have the protections afforded to them through a Certificate during the HHS declared public health emergency for COVID-19, NIH determined to automatically extend the expiration dates for NIH issued but non-NIH funded CoCs that were current (i.e., not expired) as of April 15, 2020. NIH funded COCs automatically extend for as long as the NIH funding continues, including any extensions.

Investigators and/or institutions should have received notification by email of the CoC extension and a new CoC Certificate with the revised CoC expiration date for their records. The expiration date extension applies to your CoCs current (i.e., not expired) as of April 15, 2020 even if you did not receive a copy of the new Certificate. CoC recipients are reminded that they are expected to abide by applicable laws and regulations, including the Certificate protections and disclosure requirements in 42 U.S.C. § 241(d), for data collected up to the new expiration date.

If you have an active CoC and did not receive a new Certificate, but would like to have one for your records, please contact NIH-CoC-Coordinator@mail.nih.gov. If NIH can verify your CoC was current as of April 15, 2020 an updated CoC will be emailed to you. If a current (i.e., not expired) certificate cannot be verified, you will need to apply for a new CoC if you want to provide CoC protections for new data collection.

5. Is NIH providing flexibility to recipients for late results reporting in ClinicalTrails.gov due to COVID-19? Yes. NIH will allow late submission of results reporting for recipients covered by the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information that are unable to submit results reporting information on-time in ClinicalTrials.gov due to COVID-19. Recipients should notify the funding IC of the delay along with documentation of the effects of COVID-19 on the study.

#### VIII. Animal Welfare

#### <u>1. How can institutions and their Institutional Animal Care and Use Committees (IACUCs) best prepare</u> for a pandemic like COVID-19?

- The Office of Laboratory Animal Welfare (OLAW) reminds institutions that the Guide for the Care and Use of Laboratory Animals (Guide) requires institutions to have "a disaster plan that takes into account both personnel and animals." Guidance for preparing for a pandemic can be found on the OLAW website in the Frequently Asked Questions section, under Institutional Responsibilities, FAQ G9.
- See also OLAW's Disaster Planning and Response Resources webpage to find resources for developing plans to prepare for and respond to disasters and public health emergencies that may impact animal care and use programs.
- For specific information about COVID-19 and situation updates, see https://www.cdc.gov/coronavirus/2019-ncov/index.html, https://www.nih.gov/healthinformation/coronavirus and https://grants.nih.gov/grants/natural\_disasters/corona-virus.htm.

# 2. What option is available if institutions cannot adhere to provisions of the PHS Policy due to the impact of COVID-19?

- OLAW may temporarily waive specific IACUC functions in accordance with PHS Policy Section V.D. Authorized institutional representatives may request a waiver of a provision or provisions of the PHS Policy by submitting a request with justification to OLAW at olawdpe@mail.nih.gov.
- The waiver will be reviewed and approved in writing by OLAW.
- OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

# 3. If animals already on study were scheduled for post op analgesia or other required treatment for clinical care, but the institution shuts down before the treatments are given, is this considered protocol noncompliance?

Failure to provide scheduled post-op analgesia or other necessary treatments may be considered a reportable noncompliance because adequate veterinary care was not provided. The circumstances surrounding the incident should be discussed with the OLAW Division of Compliance Oversight before reporting. The *Guide* requires that "procedures must be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours." This includes instances where the institution is not operating under a normal schedule. If appropriate animal care cannot be provided, subsequent procedures requiring post-op analgesia should not be initiated.

# <u>4. If animals already on study need to be euthanized because the institution has shut down, what type of documentation or reporting is expected of the IACUC?</u>

Euthanasia of animals should be a last resort and the circumstances for when it is necessary should be described in the institution's disaster plan. It is an institutional decision involving the veterinarian and the institution's leadership. Careful planning and alternatives to consider include:

- Transferring animals to a holding protocol,
- Postponing unnecessary procedures or manipulations,
- Relocating animals to another facility, and
- Cryopreservation for certain species.

5. If animals are currently in the vivarium but experiments have not started yet - can the animals be kept temporarily on a holding protocol (per diem charges still to the grant) until animals are used at the later postponed date?

Yes. Animals may be placed on an IACUC-approved holding protocol and maintained throughout the duration of the research stoppage. Please see NIH-NOT-OD-20-086 for guidance on re-budgeting authority.

6. If investigators halt animal work due to the pandemic, preventing congruency with the approved protocol timeline, what is required of the investigator or the IACUC? Is it acceptable to issue a blanket statement allowing investigators to alter timelines, rather than requiring each PI to amend their study? Institutions should consider ramping down animal research activities, allowing critical duties (maintaining daily animal care) to take priority. The IACUC may identify the impacted protocols and transfer them en masse to holding protocols with the expectation that the research protocols may require modifications when facilities become operational. As with individual protocols, the transfers must be documented, and capabilities must be in place to provide husbandry and veterinary care to transferred animals. Per diem charges during this time are allowable for animals placed on an IACUC-approved holding protocol and maintained throughout the duration of the research stoppage. Grantees may contact the NIH awarding Institute/Center to request administrative supplements for these unanticipated costs. Please see NOT-OD-20-086 (Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19) for guidance on rebudgeting authority.

7. What options are available for institutions that are "shut down" and their animals must be relocated because their facility is being taken over for other functions related to COVID-19? OLAW offers the following options for consideration:

- Partner with a neighboring institution to place the animals within the neighboring institution's animal program.
- Move animals to another building within the institution being mindful of environmental conditions and the need for continuing care. OLAW does not recommend taking the animals to an individual's residence due to concerns for both human and animal health.
- For critical strains, consider cryopreservation. Several commercial institutions have expertise in cryopreserving and maintaining critical strains.
- Depopulation or euthanasia should be a last resort. The circumstances for when it is necessary should be described in the disaster plan, and the institution's leadership and veterinarian should be involved in the decision to proceed.

# <u>8. Are there flexibilities available to IACUCs regarding the conduct of IACUC meetings and semiannual facility inspections?</u>

IACUCs may consider flexibilities in the conduct of official business and semiannual animal facility inspections during this emergency, as stated in NOT-OD-20-088.

# <u>9. Can one person broadcast virtual tours to other IACUC members as part of the semiannual facility inspections?</u>

Yes, one person that the IACUC considers qualified may broadcast the virtual tour to other members. The PHS Policy affords flexibility in that "The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report." The PHS Policy allows flexibility in how IACUCs may conduct semiannual facility inspections including the use of ad hoc consultants.

10. Do institutions need to request a waiver if implementing the flexibilities described in OLAW's Guide Notice NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business? If the IACUC can safely complete the semiannual facility inspections no later than 30 days beyond the six-month interval from the institution's last inspections, there is no need to notify OLAW or request a waiver since this timeframe is compliant with OLAW's guidance. However, Assured institutions that are unable to conduct facility inspections within this six month plus 30-day timeframe because of the COVID-19 pandemic, may request a waiver from OLAW (see NOT-OD-20-088).

### 11. How can institutions request waivers if the IACUC cannot safely complete the semiannual facility inspections 30 days beyond the six-month interval from the last facility inspections?

Assured institutions that are unable to conduct facility inspections at least once every six months plus 30 days because of COVID-19 restrictions may request a waiver (see NOT-OD-20-088). An authorized institutional representative (Institutional Official, IACUC Chair, IACUC Coordinator, or Attending Veterinarian) may request a waiver of the semiannual inspections or other provisions of the PHS Policy by submitting a request with justification related to the COVID-19 outbreak to olawdpe@mail.nih.gov. OLAW expects institutions granted waivers to conduct the inspections that were postponed as soon as the IACUC can safely do so and then conduct another semiannual facility inspection, no more than six months and 30 days from that time.

#### 12. Will OLAW approve waivers for the semiannual program review?

A waiver request will only be required if deviating from a provision or provisions of the PHS Policy. At this point, OLAW expects Assured institutions to explore and implement available flexibilities when conducting the semiannual program (and protocol) review and only request waivers for justifiable reasons (see NOT-OD-20-088). Semiannual program review and in particular, review of the institution's disaster plan, is even more critical and necessary to ensure the health and safety of personnel and animals during the pandemic.

The PHS Policy affords flexibility in that "The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report." One option is for the semiannual program review to be conducted at a convened IACUC meeting or by using teleconferencing, or video conferencing, with a quorum present.

An example of program review using social distancing is for IACUC members to be assigned various elements of the program using the OLAW checklist and have them provide written reviews identifying changes in the program. The reviews are compiled and shared via email for the entire IACUC to consider. Members add any comments to the compiled report and the final version is signed via email with digital or scanned signatures. However, keep in mind the following:

- No IACUC member should be involuntarily excluded from participating in the program review.
- The majority of the IACUC must sign the resulting semiannual report to the Institutional Official. This may be handled via email with digital or scanned signatures.
- IACUCs may institute alternatives to face-to-face meetings such as teleconference or video conferencing (see NOT-OD-06-052) as social distancing measures to prevent the spread of disease.

### 13. Will quorum requirements be waived in case the IACUC has to be convened to make decisions on short notice?

No, quorum requirements will not be waived. Quorums are mandated by the PHS Policy under two conditions:

- Suspension of a protocol, and
- Full committee review of protocols or significant changes.

The number of IACUC meetings may be reduced to as few as one every six months. IACUCs may meet virtually in accordance with OLAW's Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals (see NOT-OD-06-052). IACUCs may also conduct official IACUC functions using designated member review. If the IACUC has an approved policy, Veterinary Verification and Consultation may be used for applicable significant changes to protocols (see NOT-OD-14-126).

#### 14. Will there be any flexibility for the three year complete review?

No, protocols must be renewed prior to the three-year expiration date. IACUCs should consider using the flexibilities described in our Guide Notice NOT-OD-20-088. Continuing review of previously approved ongoing animal activities may be conducted using designated member review. Alternatively, full committee review may be conducted virtually using electronic meeting formats or teleconferences in accordance with OLAW's telecommunications guidance NOT-OD-06-052.

# <u>15. How can we continue to perform post-approval monitoring activities when access to animals or</u> animal housing areas are minimized or restricted due to COVID 19?

The PHS Policy requires continuing IACUC oversight of animal activities, but it does not explicitly require specific post-approval monitoring (PAM) procedures. PAM may be accomplished through many different mechanisms which may include daily observation of animals by trained animal care personnel (see OLAW FAQ G.6.). There is no requirement that the formal PAM program described in the Animal Welfare Assurance continue, especially if there are reduced or limited research activities going on at the facility. If, as a result of the pandemic, changes are made to the PAM program and it becomes part of the ongoing program of oversight, those changes should be described in the next annual report to OLAW.

#### <u>16. Do institutions need to notify OLAW or request a waiver from OLAW if implementing the flexibilities</u> <u>described in Guide Notice NOT-OD-20-088 that are not currently described in their Animal Welfare</u> <u>Assurance?</u>

No, a waiver from OLAW is not required for institutions employing the flexibilities provided in the PHS Policy that are applicable to a pandemic situation. This includes provisions that may be instituted as social distancing measures to prevent the spread of disease (see NOT-OD-20-088). However, institutions must ensure that all IACUC members are kept apprised of the flexibilities prior to implementation, and that any permanent program changes are included in the 2020 annual report to OLAW. The Assurance should then be updated at the time of renewal if these become part of the institution's ongoing plan.

#### 17. Do we need to report institutional closures to OLAW?

OLAW's current plan is that as institutions request a waiver for semiannual inspections or other IACUC activities, we are documenting the request. OLAW does not need to know about the closure itself if the institution is maintaining appropriate care for the animals during the closure. Any conditions that jeopardize the health or well-being of animals must be promptly reported to OLAW.

# 18. How may the IACUC extend a protocol that is due to expire and still meet the PHS Policy requirements?

The IACUC may extend the three-year approval by IACUC review using the procedures of IV.C.2, Designated Member Review (DMR). An example of how to expedite the continuing three-year review of the current protocol using DMR includes the following steps:

- Due to the pandemic or other disaster, the IACUC establishes a shortened response time for calling for full-committee review (FCR) that is agreed to by the members, for example two business days.
- The IACUC also agrees to a policy with a standard period to extend the protocols due to expire, for example 6 months.
- All IACUC members receive a list of proposed research protocols due to expire and access to the necessary information on the protocols to be reviewed.
- If any member asks for certain protocols to go before the full committee, then the indicated protocols must be deferred for FCR. Any member may ask to send the protocol to FCR at any time during the agreed time period.
- If no member calls for FCR, the Chair refers the protocols to a designated reviewer. The Chair may select one or more members, qualified to review the protocols, who act on behalf of the entire IACUC to either approve the protocols, request additional information from the PI to approve them, or refer for FCR.
- Once approved, the protocols are extended based on the IACUC's policy.
- Only the procedures described in the protocol approved by the designated member may be performed unless a subsequent amendment is submitted and reviewed and approved.

The designated-reviewer approval has equal validity to FCR approval and does not require subsequent reapproval or notification by a convened meeting. It is always possible for the IACUC to discuss protocols approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns.

IX. Training, Fellowship and Career Development Awards

### <u>1. For phased awards (e.g. K22, K99, etc.) or other training, fellowship and career development awards</u> where extensions are typically limited, will NIH consider extensions due to COVID-19?

Yes, as outlined in NOT-OD-20-086 recipients may extend awards affected by COVID-19 through a notification to the funding Institute or Center (IC). For awards where such an extension impacts research progress, the IC may consider providing support to help address any impact on the NIH-funded research. Extensions may be provided. Please contact the funding Institute or Center to provide information about the specific project.

### 2. For phased awards such as the K22 and K99/R00, where recipients are not able to transition due to COVID-19, will NIH consider extensions for obtaining faculty positions?

NIH is providing maximum flexibility and will accept these requests from recipients affected by COVID-19. Individuals and mentors should contact the funding IC in writing to provide details on the delays related to COVID-19. Extensions may be provided, and administrative supplements are at the discretion of the funding IC. Please contact the funding Institute or Center to provide information about the specific project.

#### 3. Will University closings due to COVID 19 be allowed as a reason for ESI end date extensions?

Yes, investigators that have been affected by COVID-19 (e.g. university closure) may submit requests for an extension of ESI status through eRA Commons via the ESI Extension request button in the Education section of their Personal Profile. Refer to the ESI FAQs and eRA Online Help for more information on how to request an extension of ESI status.

#### 4. Our institution's Office of Sponsored programs has been mandated to work from home and they are not able to send in the original signed Payback forms. How should we provide NIH the forms? There is no need to submit these forms at this time. NIH will allow for delayed submission of NRSA Payback Agreements due to COVID-19. Recipients should notify the funding IC of the delay and submit the form as soon as feasible.

# 5. Can I request an extension for a Ruth L. Kirschstein National Research Service Award (NRSA) and/or fellowship award?

Yes. Recipients may submit extension requests to the funding IC for consideration when the effects of COVID-19 have had a substantial impact on the planned course of the research training/activities. Extension requests must include a description of how COVID-19 affected the NRSA and/or other fellowship award, and clearly outline how much additional time is needed. All such requests must be signed by the fellow, the Authorized Organization and the fellowship sponsor. Extensions may be provided. Please contact the funding Institute or Center to provide information about the specific project.

<u>6. For awards with an effort level requirement (e.g., Career Development Awards), can PI effort be</u> <u>temporarily reduced below program effort requirements due to the impact of COVID-19?</u> Yes, recipients can contact the funding IC to request reductions in effort due to COVID-19, which may go below the required effort levels for the grant. 7. Can a K99 applicant apply for an extension of the 4-year eligibility window (for initial applications or resubmissions) due to COVID-19?

Yes, K99 applicants can request an extension to their K99 eligibility window due to the effects of COVID-19 on their research productivity. Affected applicants should consult with the funding IC for further guidance.

8. Will there be a single NIH-wide policy to cancel, shorten the duration, or create alternate (e.g., remote) training opportunities for summer T35 programs?

In order to accommodate the varying needs of our recipients, NIH will handle these on a case-by-case basis. Please consult with the funding IC to obtains details and options for your specific case.

<u>9. If a T32/T35 is cancelled or shortened, or is unable to fill all slots because of COVID-19, what will happen to the unused funds?</u>

It may be possible to carry over funds, as outlined in NOT-OD-20-086. Please contact the funding IC.

<u>10. For non-phased K awards (K01, K08, K23, K25) will NIH permit requests for continued support or extensions due to COVID-19?</u>

NIH is providing maximum flexibility and will accept these requests from recipients affected by COVID-19. K awardees and mentors should contact the awarding Institute or Center to provide details on the impact of COVID-19

<u>11. If a T35 program is shortened, will the trainees' stipend be decreased?</u> Yes, if the appointment is shortened, the stipend will decrease accordingly.

12. Are institutions obligated to pay students if they have recruited them to a short-term T35 training program, but the training program was cancelled before it started? Students may be paid only for the duration of time they are formally appointed to the program.

13. Can recipients change the originally proposed format of a T35 program by devising an electronic curriculum rather than in-person experiences?

Yes, if the alternative methods would provide a meaningful experience related to the goals of the program.

14. Can recipients shorten a T35 program, from 3 months to shorter periods (e.g. July and August)? Yes, with prior approval from the funding IC.

<u>15. Can recipients cancel the T35 program for this summer due to COVID issues?</u> Yes. Contact the funding IC to notify NIH of the cancellation.

16. If a T35 program is shortened or cancelled can the unused funds carryover to the following year? Recipients may request prior approval for carryover by contacting the funding IC. Potential options include a mid-project extension, where an extra year added to the end or, if a summer period is shortened, 'offset' the award (add unobligated funds from the prior year) to the following year.

<u>17. What should K awardees do if they need to stop all research activities in order to provide clinical care (to COVID19 patients)?</u>

Options such as reduced effort, leave of absence (break in service) or an extension may need to be explored. Please contact the awarding NIH Institute or Center to inquire. Also consider this additional FAQ regarding costs.

#### 18. How will carryover for institutional training grants (e.g. T35, T32, K12) be handled?

As outlined in the Prior Approval section of these FAQs, recipients may contact the funding IC to request carryover. NIH is providing maximum flexibility in the review of these requests. Reminder: the charges must be allowable costs within the scope of the original award.

<u>19. Given the current COVID-19 situation resulting in office closures, are fellows still required to mail</u> <u>Individual Fellowship Activation Notice forms containing original signatures or are emailed forms with</u> electronic or typed signatures adequate?

During the COVID-19 emergency, emailed forms with digital signatures are sufficient for Individual Fellowship Activation Notice forms. Recipients must submit the hard copy form with original signatures as soon as feasible.

20. Are childcare costs allowable charges to grants? Can they be charged for both PIs and for trainees for childcare costs need? Is this a usual allowable cost or a flexibility during the COVID pandemics? NIH encourages institutions to work within their Human Resource departments to develop or implement existing policies to provide guidance to faculty to ensure internal practices for supporting employee and trainee needs (e.g., telework, etc.) are consistently applied regardless of the source of funds.

NIH advises faculty to work within their respective institutions to identify options that are available to support trainees who will have childcare needs as labs begin to solidify plans to reopen.

Currently, NIH does not plan to provide supplemental funds on a class basis to support childcare costs above and beyond that which is currently allowable under the NIH GPS - Section 7.9 Allowability of Costs/Activities.

21. Can an international student who is unable to physically arrive in the U.S. to start their program this fall because of COVID-related travel restrictions, but who is participating in on-line distance education, be supported from federal grants? Can tuition be charged to the grant on which the faculty member intends for them to work when they arrive in the U.S.?

NIH understands that travel restrictions may continue to occur through the remainder of the public health emergency and may affect international students and post-docs. For trainees and fellows who have not yet been appointed and cannot travel to the U.S. to start work on their NIH-funded projects, stipends and other expenses may not be charged.

### 22. Can international students and post-docs continue to be supported on NIH grant projects if they are not able to return to the U.S. because of COVID-19 related travel restrictions?

NIH understands that travel restrictions may continue to occur through the remainder of the public health emergency and may affect international students and post-docs. Charging salaries to NIH grants when no work is being performed is allowable, if your organization's policy allows for the charging of salaries and benefits to currently active awards (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal. However, due to the varying requirements of student and work visas, recipient institutions should consult with their Human Resources Department to ensure that such charges, if anticipated, comply with all requirements. 23. Is NIH providing any COVID-19 related flexibilities to post-doctorates who've received Kirschstein-NRSA support and have payback obligations?

Under normal circumstances, postdoctorates who have payback obligations due to their Kirschstein-NRSA support have up to two years after the termination of a training grant appointment or fellowship to initiate service payback. For those postdoctorates who experience additional delays due to COVID-19, NIH is granting an additional year extension, on request. Please contact the NRSA Payback Service Center for further details.