

Last Updated: Aug. 18, 2020

NIH-Specific COVID-19 FAQs

Background to this Update: These FAQs have been updated to reflect the requirements of [OMB M-20-26 Extension of Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus \(COVID-19\) due to Loss of Operations, June 18, 2020](#), [NIH's implementation of OMB M-20-26](#), and all modifications made to [NIH's FAQs COVID-19 Flexibilities for Applicants and Recipients](#) ("NIH COVID FAQs") up to August 3, 2020.

The flexibilities provided in [OMB M-20-17](#) and [OMB-20-20](#) were set to expire on June 16, 2020 and those in [OMB M-20-11](#) on July 26, 2020. OMB M-20-26 extended only two of the original flexibilities provided in the OMB M-20-17: (a) allowability of salaries and other project activities with additional restrictions (OMB M-20-17, item 6) until September 30, 2020 and (b) extension of single audit submission (OMB M-20-17, item 13) until December 31, 2020. All other flexibilities specified in OMB M-20-11, -17 and -20 expired on the aforementioned dates. NIH has stated that requests for non-extended flexibilities under OMB M-20-17 and M-20-20 received before June 16, 2020 may still be approved by a funding Institute or Center (IC). [\[NIH COVID FAQs, Section I.12.\]](#)

Updated FAQs:

1. Question: Has NIH considered permitting institutions to give a blanket notification to NIH regarding an institution's status vis-à-vis COVID restrictions and the impact on grant activities? Is there a timeframe by which notification of delays should be made?

Answer: Based on the guidance contained in Appendix A to [OMB Memorandum M-20-17, Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus \(COVID-19\) due to Loss of Operations](#) ("M-20-17"), NIH is requiring institutions to notify NIH of problems, delays or adverse conditions related to COVID-19 on a grant-by-grant basis. NIH initially indicated that it would accept high-level, overarching notices about institutions generally ramping down research due to COVID-19, with award specific notices directed to the funding Institute/Center (IC). On May 21, 2020, however, NIH modified its FAQs to make clear that "[r]ecipients are not to submit standard letters, but rather report on these details within the RPPR." [\[NIH COVID FAQs, Section IV.1.\]](#)

NIH recognizes that institutions may not yet know the full impact of COVID-19 restrictions on their operations, but it expects to be notified as soon as practicable of delays and changes through the RPPR mechanism, so that the funding IC can "consider the effects that are reported by the recipient when reviewing and approving the RPPR." [\[Id.\]](#). With respect to research

outcomes, NIH states that for RPPRs due within the next 90 days, recipients “should document COVID-19 effects and state that research outcomes are not available at this time,” and provide an outline of when they believe they will be able to include details about COVID-19 disruptions to their research. [[NIH COVID FAQs, Section IV.3](#)]. If COVID-19 related delays affect the ability of an institution to submit a closeout report, the institution must provide a detailed justification for the delay to the NIH Closeout Center via email to NIHCloseoutCenter@mail.nih.gov. Each case will be reviewed, and extensions of time to submit the closeout report will not exceed one year. [[NIH COVID FAQs, Section IV.4](#)].

Note that for awards using supplemental funding provided by the Coronavirus Preparedness and Response Supplemental Appropriations Act, CARES Act or Paycheck Protection Program and Healthcare Enhancement Act, recipients are not required to submit separate RPPRs for these activities; rather, recipients should follow reporting requirements set forth the terms and conditions of these awards. [[NIH COVID FAQs, Section IV.2](#)].

2. Question: Do temporary changes in clinical trial protocols necessitated by COVID-19 exigencies require updates in ClinicalTrials.gov?

Answer: Yes, if a clinical trial protocol is amended such that the changes are communicated to the trial participants, then, as set forth in the regulations governing ClinicalTrials.gov (42 CFR 11.64), the information regarding the protocol in ClinicalTrials.gov must be updated within 30 days after the change is approved by the authorized IRB. [[NIH COVID FAQs, Section VII.1](#)]. ClinicalTrials.gov has published FAQs specific to questions about updating the information in ClinicalTrials.gov and what parties responsible for making updates can do if required information or parties are unavailable, or if they face delays in making updates. [See, [ClinicalTrials.gov, Responses to Top Questions from Responsible Parties Related to Coronavirus \(COVID-19\)](#)]. Additionally, NIH has generally acknowledged that the effects of COVID may cause delayed updates and corrections in ClinicalTrials.gov [[NIH COVID FAQ, Section VII.3](#)]. NIH has specifically stated that it will accept late results reporting in ClinicalTrials.gov by recipients covered by the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#), who are unable to make reports in a timely fashion due to COVID-19 effects. [[NIH COVID FAQs, Section VIII.5](#)]. Finally, if an institution must cancel or suspend a study involving human subjects or move it from in-person visits to telemedicine, the institution should contact the responsible IRB(s), as well as the funding IC. [[NIH COVID FAQs, Section VII.2](#)].

3. Question: How can an institution seek an extension of the period for conducting IACUC semi-annual site inspections? Are waivers available for semi-annual program reviews? For three-year complete reviews for protocols?

Answer: The Office of Animal Laboratory Welfare’s (OLAW) [NOT-OD-20-088, Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees \(IACUCs\) Due to COVID-19](#) (“NOT-OD-20-088”) sets forth flexibilities for facility inspections and the conduct of IACUC meetings that institutions can implement without the need for obtaining a waiver from OLAW of a requirement under the [Public Health Service Policy on Humane Care](#)

[and Use of Laboratory Animals \(“PHS Policy”\)](#). Meeting flexibilities include conducting IACUC meetings by teleconference or videoconference per [NOT-OD-06-052, Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals](#), expanding the use of designated member review, and reducing IACUC meetings to a minimum of one every six months. Aside from the flexibilities listed in this notice, any waiver of PHS Policy provisions must continue to be requested and approved in writing by OLAW on a case-by-case basis. Notably, flexibilities do not include a waiver of quorum requirements, which must be maintained for full IACUC review of new protocols or significant changes to existing protocols and for protocol suspension. [[NIH COVID FAQs, Section VIII.13](#)].

Semi-Annual Site Inspections – Under [NOT-OD-20-088](#), an IACUC may have a 30-day extension of the period in which to conduct its next semi-annual site inspection without seeking specific approval from OLAW. Institutions do not need to contact OLAW to use this 30-day flexibility. For extensions of longer than 30 days, an authorized institutional representative (e.g., Institutional Official, IACUC Chair, IACUC coordinator) must request a waiver of the IACUC inspection period pursuant to [PHS Policy Section V.D](#), and provide a justification related to COVID-19. Institutions that are granted waivers must conduct the next semiannual inspection within no more than six months and 30 days from the date of the last inspection. [[NIH COVID FAQs, Section VIII.10](#); [NOT-OD-20-088](#)]. Institutions may use consultants to assist in the conduct of inspections and one qualified person may broadcast a “virtual tour” of facilities to other IACUC members. [[NIH COVID FAQs, Section VIII.9](#)].

Semi-Annual Program Review – OLAW has stated that institutions should avail themselves of the flexibilities set forth in the [PHS Policy](#) and [NOT-OD-20-088](#) in determining how to best conduct semi-annual program reviews and to “request waivers only for justifiable reasons.” Further, NIH cautions that semi-annual reviews are particularly important “to ensure the health and safety of personnel and animals during the pandemic.” Flexibilities that institutions can use in conducting semi-annual program reviews include use of teleconference or video conference meetings, use of consultants, conduct of the review at a convened meeting of the IACUC, and use of email and digital or scanned signatures to circulate/finalize the program review report. [[NIH COVIDFAQs, Section VIII.12](#)].

IACUC Member Signatures for Semi-Annual Program Reviews and Semi-Annual Inspection Reports: The [PHS Policy](#) requires that all members of the IACUC sign the final versions of these reports. The U.S. Department of Agriculture (USDA) has agreed during the pandemic to temporarily accept as a “signature” an email from an IACUC member in which the member states “This serves as my signature for the semi-annual report” (or semi-annual program review, as applicable). OLAW also permits these “email signatures” and requires IACUCs to retain copies of the emails as part of their records. [[NIH COVID FAQs, Section VIII.19](#)].

Three-Year Complete Protocol Reviews – Protocols must continue to be reviewed before their 3-year expiration date, and no flexibilities are being provided with a regard to

this requirement. Such reviews may be conducted via the designated member review process (DMR) and/or full IACUC meetings may be conducted virtually through teleconferences or videoconferencing [[NIH COVID FAQs, Section VIII.14](#)]. The NIH COVID FAQs provide an example of how the designated member review (DMR) process can be used to expedite the 3-year protocol review process by having all IACUC members agree to establish: (a) a shortened response time for calling for full-committee review for a protocol that is proposed for DMR; and (b) a policy with a standard period to renew protocols due to expire (e.g., 6 months or 1 year). [[NIH COVID FAQs, Section VIII.18](#)].

4. Question: Are there any flexibilities available with respect to halting animal research protocols as a result of the pandemic?

Per the [Guide for the Care and Use of Laboratory Animals](#) (the “Guide”), all institutions that conduct animal research are expected to have an a disaster plan in place that addresses animal care in emergency-type situations such as the current COVID-19 pandemic. These plans must include provisions for veterinary care and husbandry, as well as euthanasia. If an institution is required to shut down because of the pandemic, then the institution should consider the use of holding protocols. Animals that have not yet been used in an experiment may be placed on a holding protocol while the research is stopped, and recipients may re-budget costs to accommodate these changes without prior approval unless awards terms prohibit this action or the scope of the research is changed. [[NIH COVID FAQs, Section VIII.5](#)]. For animals that are already involved in experiments, the IACUC may transfer the protocols “en masse” to holding protocols with the expectation that changes to the protocols will be necessary once research resumes. [[NIH COVID FAQs, Section VIII.6](#)]. If animals must be relocated because of a shut down, institutions may move the animals to another building, or to another institution that has an animal care and use program. [[NIH COVID FAQs, Section VIII.7](#)]. Euthanasia of animals in these situations should be used only as a last resort. Institutions are not required to notify OLAW of institutional closures provided appropriate animal care continues, but OLAW must approve any exceptions to the PHS Policy and must be notified of any conditions that jeopardize the health, safety or welfare of the animals. [[NIH COVID FAQs, Section VIII.17](#)].

5. Question: Are any flexibilities available for IACUCS to streamline approval of requests to increase previously approved animal numbers as a result of the effects of the pandemic?

IACUCs may implement temporary changes to existing IACUC policies to adjust the total number of animals allowed, or a percentage increase, from the originally approved protocol due to the pandemic provided: (a) study objectives are unchanged; and (b) the “original rationale for the number of animals to be used [supports] the requested change.” Any policy changes should be documented in the institution’s disaster plan and be approved by the IACUC prior to implementation. Such a temporary change does not require OLAW notification or a PHS Policy waiver. IACUCs also may employ the more typical process of reviewing and approving requests for replacement animals by full committee or DMR. All animal numbers should be monitored and documented. [[NIH COVID FAQs, Section VIII.20](#)]

6. Question: How will COVID-19 exigencies affect institutions' ability to apply for new funding opportunities?

Answer: NIH stated in [Notice NOT-OD-20-091](#) that "all grant applications submitted late for due dates between March 9, 2020, and May 1, 2020, will be accepted through May 1, 2020," and that funding opportunities that expire before May 1, 2020, will be extended for 90 days to accept late applications. NIH has extended some application deadlines on a case-by-case basis.

7. Questions Regarding Charging of Salaries and Stipends to Grants:

- Can the salaries of employees who have been reassigned from research projects to providing clinical care for COVID-19 patients continue to be charged to NIH grants? If such salary charges are permissible, may summer salaries be charged if no work is performed?
- Can salary charges for personnel re-assigned to COVID-19 research be charged to awards?
- What type of policy will the institution need to have in place to charge salaries in this manner?
- Must prior notice be given to NIH before re-assigning personnel to clinical efforts and/or charging such salaries to a grant?
- Can stipends of trainees still be charged if they are similarly reassigned to clinical activities?
- Is it appropriate to activate new awards and charge salaries and benefit to them when work can't be performed due to COVID-19?

Answers:

[OMB M-20-26](#) extended the flexibility in [OMB-20-17](#) to continue to charge "salaries and benefits to currently active Federal awards consistent with the recipient's policy of paying salaries (under unexpected or extraordinary circumstances) from all funding sources Federal and non-Federal" until September 30, 2020, subject to the following restrictions ("Restrictions"):

- (a) Recipients "must exhaust other available funding sources to sustain its workforce and implement necessary steps to save overall operational costs" (e.g., rent renegotiations) during the pandemic period to preserve NIH funds for ramp-up efforts.
- (b) Recipients must "retain documentation of their efforts to exhaust other funding sources and reduce overall operational costs." Additionally, records and documentation required under [2 CFR Sections 200.302](#) and [200.333](#) also must be maintained.
- (c) Payroll costs paid with Paycheck Protection Program loans or any other CARES Act programs may not also be charged to current NIH awards.

[NIH implemented OMB-20-26 with a statement](#) that was nearly verbatim to the language that

appeared in the memorandum itself and without additional guidance or commentary.

- After June 16, 2020 and through September 30, 2020, subject to the aforesaid Restrictions, NIH will permit salaries (including salary for academic or summer salaries) of personnel who have been re-assigned to providing clinical care to COVID-19 patients or who are otherwise unable to work on the award because of COVID-19 to continue to be charged to NIH grants, if permitted under institutional policy that applies to all funding sources. Specifically, [NIH COVID FAQs, Section VI.C.1](#) permits [c]harging salaries to NIH grants when no work is being performed . . . [if the] 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.” Further [NIH COVID FAQs, Section VI.C.2](#) states that the ability to charge personnel costs to NIH awards when no work is being performed due to COVID also applies to summer salaries.

- NIH draws a distinction between providing clinical care for COVID patients and involvement in COVID research. For the period June 16 to September, 30, 2020, subject to the aforesaid Restrictions, NIH extended the flexibility that permits salary of research personnel re-assigned to clinical care to be charged to NIH awards if allowed under institutional policy as described above. [\[NIH COVID FAQs, Section VI.C.4\]](#). COVID research also is a priority, but to use award funds to support such research, institutions must follow normal NIH procedures for determining whether the proposed COVID research falls within the scope of the research contemplated by the original grant award. [\[NIH COVID FAQs, Section VI.D.4\]](#). If the COVID-related activities are within the scope of the original grant, then activities may proceed, and an administrative supplement to provide additional funding may be provided if the IC believes that the change is worthwhile. If, however, the COVID related research is outside the scope of the original grant, then a competitive revision would need to be submitted. [\[NIH Grants Policy Statements Sections 8.1.2.5 & .12\]](#). NIH has emphasized that although certain processes are being streamlined to address exigencies arising during this public health emergency, other processes remain in effect and unchanged, and all award recipients must take care to remain good stewards of federal funds.

- To charge salaries to NIH grants when no work is performed on the grant, the institution must have internal institutional policies (which can include emergency policies, internal guidance and best practices) that permit charging of salaries and benefits in extraordinary circumstances regardless of funding source. Additionally, for the period June 16 to September 30, 2020 (ending date for this flexibility), institutions also must meet the aforesaid Restrictions. NIH advises that institutions should consult with their Human Resources Departments “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.” [\[NIH COVID FAQs, Section VI.C.1.\]](#)

- When all the flexibilities under OMB M-20-17 were in place, NIH did not require prior approval to reassign personnel to work on COVID clinical care or COVID research. With the expiration of these flexibilities on June 16, 2020, however, NIH reverted to the standing requirement in the [NIH Grants Policy Statement \(GPS\) Section 8.1.2.6](#). Under this section, prior approval is required for a “significant change in the statute of the PI/PD or senior/key personnel.” Further, if the

reassignment causes a Program Director/Principal Investigator to be absent from a project for three or more months, the institution must notify the IC to identify a temporary replacement until the public health emergency is over, or the research will be placed on hold and delays reported in the RPPR. [[NIH COVID FAQs, Section VI.D.8](#)]. 8]. When the NIH COVID FAQs regarding salary charges to awards were initially published, they did not include a requirement that NIH permission be sought *prior* to charging salaries to awards for personnel who were unable to work on the awards due to COVID-19. On April 13, 2020, however, NIH amended [NIH COVID FAQs, Section VI.C.1](#) to state that institutions should notify ICs prior to charging such salary and that NIH will confirm institutional policy and effects of COVID-19 on the grant as a part of an approval process for charging such costs. In subsequent discussions, NIH indicated that notices should be given via the RPPR [see Question 1 above]; however, the revised NIH COVID FAQs issued after OMB M-20-26 contain the foregoing language that institutions should notify ICs prior to charging such salary. [[NIH COVID FAQs, Section VI.C.1](#)]

- Stipends for trainees and fellows can continue to be paid if the trainee cannot work on training activities because of COVID (e.g., due to an institution being closed or trainee being re-assigned to engage in clinical care activities for COVID patients). [[NIH COVID FAQs, Section VI.C.3](#)]. In such cases, the institution that receives the award should notify the pertinent grants management specialist and “provide documentation demonstrating the effect of COVID-19, and how long the institution will be affected.” [[Id.](#)].

- NIH has stated that it is not appropriate to “initiate charges for salaries and benefits on new awards” if the work on those awards has not yet started. The charging of salaries to awards when no work is being performed due to COVID is limited to currently active awards. [[NIH COVID FAQs, Section VI.C.5](#)]. NIH, however, makes clear that salaries and benefits may be charged to an NIH grant “if the recipient’s performance site/facilities are open and/or telework options are available for work to begin.” [[Id.](#)]

8. Question: Will NIH permit the carry-over of trainee support funds under the COVID-19 flexibilities afforded by [NOT-OD-20-086](#), *Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19*?

Answer: NIH will permit carry-over of trainee support funds as part of the flexibilities it has extended concerning training, fellowship and career development awards. [NOT-OD-20-086](#) states that “recipients may extend awards affected by COVID-19” by notifying the funding Institute or Center (IC). Even in the case of phased awards where extensions are usually limited, NIH may consider extensions on a case-by-case basis, including extensions for obtaining faculty positions. [See, [NIH COVID FAQs, Section IX, Questions 1 & 2](#)]. In these cases, the recipient should write to the IC and provide details. Similarly, recipients may contact the IC to request extensions to National Research Service Awards and fellowships, as well as an extension of the period in which to apply for a K99 Pathway to Independence Award. [See, [NIH COVID FAQs, Section IX, Questions 5 & 7](#)].

9. Question: What does NIH consider in determining whether to provide administrative funding supplements for awards impacted by COVID?

Answer: The [NIH COVID FAQs Section VI.D.6](#) that while Institutes and Centers may, “based on availability of funding,” issue administrative supplements “when absolutely necessary,” supplemental requests “in the next 2-3 months would be premature.” NIH recommends that institutions hold off on requesting supplemental funding until the full impact of the pandemic on the project are clear and options have been discussed with NIH staff. Nevertheless, NIH will consider requests for administrative for projects in the following two situations:

- (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.

In determining what is considered “mission-critical” institutions should consider whether the additional funding is required to accomplish the award goals irrespective of the impact of COVID-19. [[NIH COVID FAQs, Section VI.D.6](#)].

10. Question: How is NIH handling certain costs that researchers may incur related to teleworking (e.g., cost of laptop, childcare costs, private transportation costs)?

Direct charges for laptop computers or other equipment must be specific to a grant project to be allowed, and many institutional policies assign these costs to facilities and administrative (F&A) costs in accordance with [NIH Grants Policy Statement Section 7.2](#). [[NIH COVID FAQs, Section VI.E.1](#)]. Commuting costs are not allowable charges to NIH grants. [[NIH COVID FAQs, Section VI.E.2](#)], and childcare costs are only allowable for participants in human subjects research projects or as a fringe benefit for persons working on a grant-supported project. [[NIH COVID FAQs, Section IX.20](#)].

11. Question: Is there a single IRB of record for NIH-Supported COVID research?

Answer: No, NIH has not selected a single IRB of record for this research. [See, recording of teleconference hosted by Dr. Michael Lauer and Dr. Larry Tabak, March 16, 2020 at https://register.gotowebinar.com/recording/5326440450340596481?sm_guid=MzI4NzMxflDlyNzE0NjM4fC0xfHplaWRsaWNrQGNzaGwuZWR1fdI2MTM5NDV8fDB8MHw2ODc3ODY4MXw5NTN8MHwwfHwyOTQ1MTc1].

12. Question: Can international graduate students and post-docs who were working on NIH-funded grants in the U.S., but who temporarily returned to their home countries and cannot currently return to the U.S. because of COVID-related travel restrictions continue to conduct NIH-funded work?

Answer: The first consideration with respect to such individuals is whether they are considered a “foreign component.” [NIH Grants Policy Statement \(GPS\) Section 1.2](#) defines a “foreign component” as “the performance of any significant scientific element or segment of

a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.” [Section 8.1.2 of the NIH GPS](#) requires prior approval of the addition of a foreign component to an award. On May 21, 2020, NIH amended its COVID FAQs to provide guidance regarding the application of the foreign component definition to these individuals. NIH stated so long as no grant funds are going to a foreign entity, it does not consider a post-doc continuing work on a NIH-award in a foreign country due to COVID travel restrictions a “foreign component” because this activity “does not constitute the performance of a significant scientific element or segment of the project outside of the U.S.” [[NIH COVID FAQs, Section V.1](#)]. This application of the definition of a foreign component could likewise be applied to graduate students and others in similar circumstances, who do not meet the definition of “foreign component.”

With respect to the payment of salaries/expenses of trainees outside of the U.S., NIH draws a distinction between individuals who never came to the U.S. to begin their training and those who did. In the case of trainees who did not start training in the U.S. because of COVID travel restrictions, NIH does not permit the payment of stipends or other expenses (e.g., tuition for online courses). [[NIH COVID FAQs, Section IV.21.1](#)]. Up until September 30, 2020, and subject to the Restrictions described above in Question 5, NIH permits charging grants for salaries of trainees who began work on the grant in the U.S. but were unable to return to the U.S. to continue the work because of COVID travel restrictions. Such charges, however, are permitted only if the institution’s policy allows charging of salaries and benefits to currently active awards under extraordinary circumstances “from all funding sources, Federal and non-Federal. [[NIH COVID FAQs, Section IX.22](#)].

In addition to the foregoing considerations, institutions that have post-docs or graduate students in this situation also must consider the following issues: (a) legalities and logistics of making payments to a person in a country (e.g., must the institution register to do business in the country, what tax laws are involved, visa status, how can payment be sent); and (b) export control considerations, including OFAC considerations regarding payments. Accordingly, human resources, legal counsel and export control offices should be consulted in this regard.

13. Question: Will NIH provide flexibility with respect to delays that institutions may encounter in handling other NIH-related compliance issues, such as research misconduct matters?

Answer: NIH understands that institutions are spending a great deal of time and resources in association with the COVID-19 public health emergency and will seek to be accommodating with respect to deadlines associated with the handling of other compliance issues. NIH should be notified as soon as practicable regarding the need for any delays/extensions and will address each matter on a case-by-case basis. [See, recording of teleconference hosted by Dr. Michael Lauer and Dr. Larry Tabak, March 16, 2020 at https://register.gotowebinar.com/recording/5326440450340596481?sm_guid=MzI4NzMx fDIyNzE0NjM4fC0xfHplaWRsaWNRQGNzaGwuZWR1fDI2MTM5NDV8fDB8MHw2ODc3ODY4M

[Xw5NTN8MHwwfHwyOTQ1MTc1](#)]. With respect to research misconduct matters, the Office of Research Integrity has issued [guidance regarding sequestration of materials during closure of institutions because of the pandemic](#).

14. Question: Can grant funds that were originally designated to support conferences that were cancelled due to COVID-19 be used to support re-scheduled conferences or conferences modified to be conducted in a virtual format? What about changes to training programs?

Answer: NIH has issued relatively little written guidance in the area of conference grants. NIH is aware that many conferences and workshops supported by NIH awards may be cancelled due to COVID-19. NIH advises recipients to contact their grants management specialist and provide documentation of COVID's impact. Funding ICs will work with recipients "to address the effects on the NIH grant," [[NIH COVID FAQs, Section VI.B.1](#)], but NIH cautions repeatedly that there is no guarantee of receiving such supplemental funding. Consequently, conferences and workshops that are delayed or changed to a virtual format may be acceptable, provided the grant recipient stays within the confines of the original grant budget. [[NIH COVID FAQs, Section VI.D.7](#)].

NIH has issued much more written guidance in the area of training grants. In the case of T32/T35 grants, NIH stated that it will handle requests to cancel or shorten programs on a case-by-case basis, and that grant recipients should contact their IC in this regard. [[NIH COVID FAQs, Section IX.8](#)]. NIH also has stated that an electronic curriculum can be substituted for an in-person T35 program "if the alternative methods would provide a meaningful experience related to the goals of the program." [[NIH COVID FAQs, Section IX.13](#)].

15. Question: What other flexibilities has NIH provided regarding training grants?

Answer: In its guidance, NIH has made clear that it will consider a variety of types of extensions (e.g., eligibility extension, extension of time to complete, extension of time to transition to faculty positions, extension for payback obligations) due to COVID-19 in connection different types of training/fellowship/career development awards, including phased awards (e.g., K22, K99); non-phased K awards; NRSA and fellowship awards; and ESI status. [[NIH COVID FAQs, Section IX](#)]. In each of these cases, recipients should contact the IC to discuss specific requests, and although the IC may consider supplements to support the extension, there is no guarantee that funds are available. [See, e.g., [id.](#) at Questions 1 & 2]. In the case where funds are not completely used, NIH also may consider the carry-over of such funds. [See, e.g., [id.](#) at Questions 9, 16 & 18].

16. Question: Many researchers are using time away from lab activities due to COVID to perform data management tasks. Does NIH consider charges relating to data management and data sharing such as costs for curating data, developing supporting documentation, formatting data, and de-identifying data allowable charges to NIH grants?

Answer: Charges for the foregoing data management activities may be allowed as direct charges to a grant unless an institution has already negotiated its indirect cost rate to cover

charges for these activities. NIH also may consider costs associated with making data scientifically useful (e.g., costs associated with making data useful for publication in an open-access journal) to be part of the scientific process and allowable as a direct cost.

17. Question: Will NIH accept notices about protocol changes after the fact and defer to the institutional IRB?

The need for obtaining prior sponsor approval before making changes to a protocol and/or IRB approval depends on the type of research (e.g., clinical v. non-clinical) and the type of change that must be made. For a discussion of notice requirements regarding protocol changes, see [COGR, Research Ethics & Compliance – Human Subjects FAQs](#), Question 3.

18. Question: Will NIH permit donation of Personal Protective Equipment (PPE) and reagents from NIH-funded research to clinical activities? Can government owned/funded equipment, space and materials be used to support the clinical mission?

Answer: Prior to June 16, 2020, [OMB Memorandum 20-20, Repurposing Existing Federal Financial Assistance Programs and Awards to Support the Emergency Response to the Novel Coronavirus \(COVID-19\)](#) permitted federal agencies to repurpose awards to support the COVID-19 response, including the donation of medical equipment (e.g., PPE, medical devices, medicines, and medical supplies) and other resources, including labor, to local entities providing COVID-19 emergency response. Pursuant to this flexibility, NIH permitted award recipients to donate PPE and supplies to clinical facilities and other local entities that are directly “serving the public health emergency crisis COVID-19 response. NIH required recipients who make such donations to maintain documentation that demonstrated:

- (a) the donated equipment/supplies are not currently needed because the project is temporarily suspended or are no longer necessary to meet grant objectives;
- (b) if the equipment remains useable after the loan, it is returned to its original purpose at the end of the public health emergency;
- (c) the donation is documented for single audits and the documentation will be provided to NIH on request of the IC; and
- (d) the title for the equipment and supplies remains with the recipient institution.

[\[NIH COVID FAQs, Section VI.D.6\]](#).

The flexibilities in [OMB-20-20](#) expired on June 16, 2020. Presently, NIH will consider on a case-by-case basis future requests to donate PPE and other lab supplies purchased with grant funds to hospitals and other local entities for use in responding to the COVID-19 emergency.

[\[NIH FAQs VI.D.5\]](#).

19. Question: Is any advance notice required to submit a late grant application to NIH?

Answer: NIH issued [Notice NOT-OD-20-091](#) per which late applications for grants with due dates between March 9, 2020 and May 1, 2020 would be accepted through May 1, 2020. No prior notice or permission from NIH was required to submit a late application, but the Notice did not extend this flexibility past May 1, 2020. On May 11, 2020, NIH issued [NOT-OD-20-](#)

[105](#), *NIH Late Application Policy for Institutional Training Grants for PA-20-142 and PA-20-162 Due to Public Health Emergency for United States Coronavirus Disease 2019 (COVID-19)* permitting acceptance of training grant applications under the foregoing announcements until June 30, 2020. ICs also have issued late notices for specific funding opportunities. NIH has stated that it will be flexible with respect to applications submitted within the 2-week standard late policy window. [[NIH COVID FAQs, Section II.3](#)].

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For any questions related to this document, please contact Research Ethics and Compliance Director Kristin West at kwest@cogr.edu