

Last Updated: June 12, 2020

NIH-Specific FAQs

1. Question: Has NIH given consideration to 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 FAQs COVID-19 Flexibilities for Applicants and Recipients](#) ("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](#)].

NIH amended its FAQs to state that the RPPR should be used to report information on how COVID-19 has delayed or affected the progress of research activities on NIH awards. NIH also stated in this amendment that recipients should not provide standard letters, but rather use the RPPR to report details on COVID-19 effects on the research. Prior to issuing this amendment, however, NIH published a number of other FAQs with notice provisions, some of which may be inconsistent with NIH's recent amendment [see, e.g., [NIH COVID FAQs, Section VI.C.1](#) (requiring notice to the funding Institute or Center (IC) to continue charging personnel costs to awards when no work is being performed due to COVID exigencies)]. Accordingly, institution may wish to consult with program officials when there is inconsistency in guidance regarding reporting that they cannot reconcile in a particular situation.

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, Question 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](#)].

3. Question: How can an institution seek an extension of the period for conducting IACUC semi-annual site inspections?

Answer: Under [flexibilities for IACUC activities issued by NIH](#), IACUCs may have a 30-day extension of the period in which to conduct their next semi-annual site inspections without seeking specific approval from the Office for Laboratory Animal Welfare (OLAW). For extensions of longer than 30 days, the IACUC should contact OLAW on a case-by-case basis. [[NIH COVID FAQs, Section VIII.10](#)].

4. 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. NIH also is considering delaying some new funding opportunities for the remainder of FY2020 to FY2021 because of the impact that COVID may have on institutions' ability to apply for such funding competitively. [[NIH COVID FAQs, Section I.7](#)].

5. 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:

NOTE: The flexibilities discussed below are applicable until June 17, 2020; extension of these flexibilities beyond June 17 is under discussion but is uncertain.

• 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. NIH has stated that providing clinical care for COVID patients is a priority for all institutions, including the NIH, and that salary of research personnel re-assigned to clinical care may be charged to NIH awards if allowed under institutional policy as described above. NIH has further stated that award recipients "may use clinical revenue from the work done by faculty as voluntary cost sharing to support salaries under the NIH funded project." [[NIH COVID FAQs, Section VI.D.9](#)]. 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. 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. [See, [NIH COVID FAQs, Section VI.C.1 & D.5](#)].

• 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. 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.” [\[Id.\]](#)

- NIH prior approval is not required for reassignment of personnel, but 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. [\[NIH COVID FAQs, Section VI.D.9\]](#). 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, however, NIH indicated that notices should be given via the RPPR. [See Question 1 above.]

- 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 NIH grant “if the recipient’s performance site/facilities are open and/or telework options are available for work to begin.” [\[Id.\]](#)

6. 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, 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](#)].

7. 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., Question 7](#) states that requesting administrative supplements for additional costs related to COVID-19 exigencies is premature because the full impact of COVID is unknown. 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.

8. 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].

9. 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). [\[NIH COVID FAQs, Section IX.22\]](#). 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. [\[Id. at Section IX.23\]](#)."

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.

10. 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=MzI4NzMxflDlyNzE0NjM4fC0xfHplaWRsaWNrQGNzaGwuZWR1fDI2MTM5NDV8fDB8MHw2ODc3ODY4MXw5NTN8MHw wfHwyOTQ1MTc1].

11. 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 and have stated that non-refundable costs associated with these

meetings may be requested as an administrative supplement by contacting the IC and providing documentation of the effect of COVID. [[NIH COVID FAQs Section VI.B.1.](#)]. However, NIH has also cautioned 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 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](#)].

12. 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].

13. Question: Many researchers are using time away from lab activities due to COVID to perform a number of 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.

14. 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.

15. 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: [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 permits 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 requires recipients who make such donations to maintain documentation that demonstrates:

- (a) the donated equipment/supplies are not currently needed because the project is temporarily suspended or they 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.

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

16. 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 does not extend this flexibility past May 1. NIH has in some cases extended application deadlines on a case-by-case basis.

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