

FAQ Addendum #1 NIH-Specific FAQs

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 Appendix A to the [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 will accept high-level, overarching notices about institutions generally ramping down research due to COVID-19, but award specific notices should be directed to the funding Institute/Center (IC). NIH recognizes that institutions may not yet know the full impact of COVID-19 restrictions on their operations, but it expects grants and program management staff to be notified as soon as practicable of delays and changes. In this regard, NIH has issued specific guidance stating that RPPRs due within the next 90 days should include a description of any COVID-19 effects and impact on research outcomes, as well an outline of when recipients believe they will be able to include more detail about disruption to research efforts. [\[See NIH FAQs COVID-19 Flexibilities for Applicants and Recipients \("NIH COVID FAQ"\), Section IV\]](#).

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. [\[NIH COVID FAQ, Section VIII\]](#).

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. [\[NIH COVID FAQ, Section VI.5.\]](#)

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 for "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. Late applications received after May 1, however, may not be reviewed until the “meeting for the January 2021 council round.” NIH also is considering delaying new funding opportunities for the remainder of FY2020 to FY2021 because of the impact that COVID may have on institutions’ ability to competitively apply for such funding. [[NIH COVID FAQ, Section I.7.](#)]

Question: 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 salary charges to grants for reassigned employees are permissible, what type of policy will the institution need to have in place to do this? Can stipends of trainees still be charged if they are similarly reassigned? What if personnel are reassigned to COVID research instead of clinical care activities?

Answer: NIH will permit salaries of personnel who have been reassigned to providing clinical care to COVID-19 patients to continue to be charged to NIH grants, if permitted under institutional policy. 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 prior approval is not required for such reassignment, 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 FAQ, Section V.C.3.](#) (“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.”)].

Similarly, stipends for trainees can continue to be paid if the trainee cannot work on training activities because COVID. Trainees can be reassigned to engage in clinical care activities for COVID patients, but NIH policies limit the amount of time trainees can spend on these additional activities to 25% of total time, and the additional activities may not interfere with or lengthen the training. [[NIH COVID FAQ, Section V.C.2.](#); [NIH NOT-OD-17-095](#)].

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 and the NIH. COVID research is also a priority, but researchers must follow normal NIH procedures for determining whether or not the proposed COVID research falls within the scope of the research contemplated by the originally awarded grant. 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. [[NIH COVID FAQ, Section V.C.3 & D.5](#)].