

Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19

Notice Number: NOT-OD-20-087

Key Dates

Release Date: March 16, 2020

Related Announcements

[NOT-OD-20-082](#)

[NOT-OD-20-083](#)

[NOT-OD-20-086](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

The purpose of this notice is to provide guidance outlining the flexibilities available to recipients conducting NIH-funded clinical trials and human subject studies, that are impacted by the [declared public health emergency](#) for COVID-19. NIH recognizes the significant effects that this emergency is having on NIH-funded clinical trials and other human subjects studies. First and foremost, NIH is concerned about the safety and welfare of human subject participants and research staff. Institutions should take all steps necessary to ensure the safety of all human participants and research staff involved in NIH-funded clinical trials and human subjects studies.

At this time, NIH encourages recipients to consult with their IRB and institutions about potential measures to protect participants and research staff. Examples of such measures are:

- Limiting study visits to those needed for participant safety or coincident with clinical care.
- Conducting virtual study visits
- Arranging flexibilities for required laboratory tests or imaging needed for safety monitoring to occur at local laboratories or clinics
- Canceling large gatherings of 50 or more people
- Limiting or suspending unnecessary travel

Recipients will likely encounter delays to ongoing research based on the effects of COVID-19. As outlined in [NOT-OD-20-086](#), recipients may submit late financial and progress reports, if research is delayed due to COVID-19, and may carryover unobligated balances on active grants without requesting prior approval.

Below are additional details related to current and expanded flexibilities.

Delays in Research Progress:

As outlined in the NIH Grants Policy Statement [8.1.1.3](#), recipients may extend the final budget period of the approved project on active grants one time for up to 12 months without requesting prior approval from NIH.

To support participant health and safety, and continuity of research during this public health emergency, NIH will allow for additional extensions, including mid-project period extensions, for awards supporting NIH-funded clinical trials and human subjects research. Recipients should contact the awarding Institute or Center (IC) to provide details on the effects of COVID-19, and the need for an extension. NIH is committed to working with its recipients during this public health emergency.

Typically, project periods for NIH awards supporting clinical trials and other human subjects research are limited to seven years. NIH will allow project periods to extend beyond the 7-year timeframe for extensions related to COVID-19.

Unanticipated Costs

As a result of COVID-19, recipients may incur unanticipated costs. For example:

- Costs incurred to arrange for participants to receive care at their local sites or virtually, rather than the study site, for required visits.
- Supply chain disruptions
- Personnel disruptions due to illness or closure of facilities
- Additional lab testing (e.g. for COVID-19)
- Increased transportation costs

If unanticipated costs are identified due to impacts of COVID-19, and unobligated balances are not available to rebudget, recipients may request administrative supplements from the funding ICs (see [PA-18-591 Administrative Supplements to Existing NIH Grants and Cooperative Agreements \(Parent Admin Supp Clinical Trial Optional\)](#)). ICs will make funding decisions on a case by case basis in an effort to support the safety and welfare of participants and sustain research during any delays.

Additional NIH resources related to COVID-19 are available [here](#) which includes FAQs that include, but are not limited to, human research and clinical trials specific questions. NIH is continuing to monitor the situation and will publish any additional information regarding this ongoing public health emergency in the [NIH Guide](#).

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research
Telephone: 301-435-0949
GrantsPolicy@nih.gov

[Weekly TOC for this Announcement](#)
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