

## NewsFlash!

**Announcement:** The National Institutes of Health (NIH) has released a [notice](#) detailing expanded flexibilities related to NIH-Funded clinical trials and human subjects studies affected by COVID-19.

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.

### **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](#)). 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.

**Questions?** Please review the [COVID-19 research-related updates](#) section of the Office of Research website. If you have any additional questions, contact the [Contracts and Grants Officer](#) assigned to your unit.