

NIH INFORMED

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Insights from NIH notices & reviewer comments, so you can focus.

SEPTEMBER TIP

When describing recruitment for your clinical trial, do you address competition for patients from other open trials?

It isn't enough to tell reviewers that REDCap indicates you have plenty of potential patients. You need to discuss how other open trials might affect recruitment. NIH is sensitive to money wasted on trials that are set up and then fail to recruit. The more open trials at your medical center, the more carefully you need to describe how recruitment for your trial will be prioritized over others—and it is not enough to say “NIH-funded trials have priority”, because reviewers cannot ascertain how many other NIH trials might be competing for the same patients. I learned this on a multi-center clinical trial grant win a few years ago. It was one of the few criticisms reviewers gave us, and I never forgot it.

SEPTEMBER NEWS

- 1. NCI releases FY2022 annual plan & budget proposal
2. Inclusion Across the Lifespan recording now available
3. Institutes & Centers Award Rates & Funding Disparities
4. NIH extends allowance of preliminary data as post-submission materials
5. NIH issues reminder regarding the use of hypertext in applications
6. The latest Roundup of some NIH-sponsored COVID-19 research

1. NCI releases FY2022 annual plan & budget proposal

NCI released its fiscal year 2022 annual plan & budget proposal. Some of the institute's scientific priorities outlined in this year's report include cancer drug resistance, molecular diagnostics for cancer treatment, obesity and cancer, and cancer survivorship. Additionally, the report notes that the FY2022 budget proposal would allow NCI to improve the R01 grant timeline from 10th to 12th percentile with a goal of achieving 15th percentile by FY2025. The full report can be accessed here.



2. Inclusion Across the Lifespan recording now available

NIH held an all-day virtual workshop regarding its Inclusion Across the Lifespan policy on September 2nd. Inclusion Across the Lifespan is an important rigor scoring criterion that was recently changed (as of FORMS-F, this past spring). The recording of the workshop is now available online. Although it is one continuous recording, the original agenda can serve as a helpful guide for the presentation sequence.

3. I&C Award Rates & Funding Disparities

Research studies confirm that African American and Black (AAB) applicants receive NIH grant awards at a lower rate than their white counterparts. More recent findings indicate that AAB PIs sent applications to NIH ICs with lower award rates compared to other ICs (e.g. Minority Health Disparities, Nursing Research, Child Health and Human Development, Environmental Health Sciences, and Allergy and Infectious Diseases). In addition, AAB PIs are more likely to propose research on topics that are less likely to be funded – and after considering a number of confounders, it accounts for over 20% of the gap in funding success for applications that are discussed. The complete findings and analyses are available here.

4. NIH extends allowance of preliminary data as post-submission materials

NIH extended the ability to accept preliminary data as post-submission materials to applications submitted for the Sept 25, 2020 due date (May 2021 council). A few conditions to note: (1) Preliminary data update is limited to 1 page for a single component application or 1 page for each component of a multi-component application; (2) the FOA must allow preliminary data; and (3) the data for submitting all post-submission materials, including preliminary data, will be 30 days before the study section meeting, unless specified otherwise in the FOA. The full notice can be viewed here.



5. NIH issues reminder regarding the use of hypertext in applications

Due to an increase in the use of hypertext in applications, NIH issued a reminder that hyperlinks and URLs are not allowed. Among the concerns regarding this practice are:

- “Overstuffing”: All content and materials required for the review must be contained within the allowable page limits. Linking to outside resources provides additional material to reviewers and may, thus, give one applicant the unfair advantage of additional content.
• Reviewer Confidentiality: Web-based tracking systems may allow applicants to identify reviewers who access external materials via hyperlinks.
• Malware: Reviewers accessing materials outside of NIH web sites may be exposed to malware or other breaches on their computer and/or system.
• Review Consistency: Review quality can be negatively impacted by inconsistency among reviewers if some access hypertext whereas others do not.

The NIH policy, as stated in the SF 424 (R&R) application guide, remains in effect:

- Hyperlinks and URLs are allowed only if specifically noted in the FOA. This is usually limited to citing publications in biographical sketches and publication lists.
• Hyperlinks and URLs may not be used to give additional information necessary to the application under review.
• When allowed, the full URL must be included in the text, not embedded behind text.
• Reviewers are instructed against viewing linked sites.

NIH's full communication regarding this topic is available here.

6. Latest roundup of NIH-sponsored COVID-19 research

More research developments are emerging as scientists continue the pursuit for a COVID-19 treatment. Here is a sampling of some recent NIH-sponsored COVID-19 research. For more reading on NIH resources and news releases related to COVID 19, click here.

- Scientists discover genetic and immunologic underpinnings of some cases of severe COVID-19
• Fourth large-scale COVID-19 vaccine trial begins in U.S.
• NIH expands clinical trials to test convalescent plasma against COVID-19
• NIH awards contracts to develop innovative digital health technologies for COVID-19
• NIH ACTIV initiative launches adaptive clinical trials of blood-clotting treatments for COVID-19
• Phase 3 Clinical Testing in the US of AstraZeneca COVID-19 vaccine candidate begins

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