MEG BOUVIER MEDICAL WRITING

# NIH INFORMED

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

## APRIL TIP

**eRA Commons says that my ESI status is about to expire, so I guess I have to just apply without it, right?**

***It is crucial to determine with a program officer the exact date of your ESI status expiration.***

**For those who do not know,** Early Stage Investigator **status means that you have never been a PI on an R01 or equivalent, and are 10 years or less from your terminal degree. ESI status confers a significant funding advantage, so it is the topic of many questions I get from grantees. ESI status also allows you to apply for specific funding mechanisms (e.g.,** Katz R01, DP2**). Your ESI status is listed in eRA Commons but it might not be correct and warrants a conversation with the program officer to determine when it expires. For example, years spent in clinical residency or fellowship are typically not counted on the ESI clock. Women who give birth during their ESI period get an automatic one-year extension when they apply. Parents may request ESI extensions due to newborn care, depending on their specific circumstances. And many grantees are eligible for extensions based on COVID research interruptions. Your pre-award support office can help you apply for ESI extensions. Remember that** all **PIs must have ESI status for the application to be reviewed as such. Also ESI is not relevant on other mechanisms (e.g., R21, R03) – you neither get a funding advantage as an ESI nor do you lose your ESI status if you land one as a PI. You also don't lose your ESI status if you are a co-I on an NIH grant.**

**Have a grant-related question?**
Submit what's on your mind
**and we'll answer it in a future newsletter.**

## APRIL NEWS

1. NIGMS guidance on acceptable CT applications to submit to its parent R01
2. NIH ORWH seeking input on research gaps and clinical practice needs on SARS-CoV-2 and COVID-19 and women's health
3. Improving safety and reducing harrassment at conferences
4. NIDA invites feedback on its Racial Equity Initiative Action Plan
5. The latest roundup of some NIH-sponsored COVID-19 research

## 1. NIGMS guidance on acceptable CT applications to submit to its parent R01

NIH institutes often have very specific rules concerning what types of trials they will accept under which specific mechanism, and what types of trials they won't fund at all. Grantees need to be familiar with this information before they formulate aims and write a submission. The following information from NIGMS is one recent example of IC- specific restrictions on clinical trial applications:

NIGMS issued guidance regarding the types of investigator-initiated clinical trial applications that may be submitted in response to its parent R01 FOA. NIGMS supports clinical trial applications that are highly-relevant to its mission, which includes research areas of injury and critical illness, sepsis, wound healing, clinical pharmacology, innate immunity, anesthesiology, and perioperative pain.

NIGMS will accept:

- Applications that meet NIH's definition of a clinical trial and are mechanistic in nature. The primary objective of the trial should be to provide mechanistic understanding of the biology underlying one or more of the NIGMS clinical research areas. Examples of of mechanistic clinical trials in NOT-OD-18-010.
- Studies that meet the definition of Basic Experimental Studies Involving Humans (BESH), conditionally accepting R01 PA-20-184, for these applications.
- "Hybrid" applications, i.e., applications that propose non-interventional fundamental science aims along with the clinical trial(s) described above.

The following types of clinical trials **WILL NOT** be accepted under the NIGMS R01:

- Studies that do not meet the NIH definition of a clinical trial
- Exploratory or pilot/feasibility clinical trials, that do not adhere to NIGMS' published priorities for clinical research (e.g., NOT-GM-19-054, NOT-NS-20-005)
- Studies in which the primary objective is to test a clinical outcome such as: specific questions about safety, tolerability, clinical efficacy/effectiveness, clinical management, and/or implementation of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions, as well as preventive, therapeutic, and services interventions.
- Studies that propose clinical dissemination and implementation research, comparative effectiveness research, and/or pragmatic clinical trials.
- Studies specifically designed to support and seek regulatory approval of future clinical diagnostics or treatments, e.g., an IND is anticipated.

It's always a good idea to talk to program officers or NIGMS staff (NIGMS-CT-Inquiries@nih.gov) prior to submitting an application. Full text regarding this guidance can be found here.

## 2. NIH ORWH seeking input on research gaps and clinical practice needs on SARS-CoV-2 and COVID-19 and women's health

The NIH Office of Research on Women's Health (ORWH) seeks public input on research gaps, clinical practice needs, and research opportunities regarding SARS-CoV-2 and COVID-19 and/or post-acute sequelae of SARS-CoV-2 and women's health including, but not limited to, sex and gender differences, reproductive health issues, circumstances of domestic violence or intimate partner violence (IPV), and diseases such as cancer, cardiovascular disease, pulmonary disease, obesity, metabolic conditions, mental health conditions, and substance use disorders. Input regarding persistent symptoms after acute infection and/or pathology in multiple organ systems leading to adverse health outcomes in women is also encouraged. Data gathered from the beginning of the COVID-19 pandemic has demonstrated sex differences in infection and mortality rates, and in immune response. Feedback is due by May 6, 2022.

NIH frequently solicits input from stakeholders regarding topics of interest and issues Requests for Information (RFI) announcements to make these solicitations. The purpose of RFIs is informational and for future planning. For example, information received via RFIs may help shape future FOAs. Stakeholders may be from within or outside of the NIH. They may be researchers, clinicians, or members of the general public.

The RFI contains information regarding how to respond to submit feedback, a history of ORWH's mission, and references supporting the COVID-19 outcomes mentioned above.

## 3. Improving safety and reducing harassment at conferences

NIH requires R13/U13 applications seeking funding for scientific conferences and meetings to include a plan demonstrating how diversity will be enhanced and strengthened at the event for with funding is sought. The guidance requires award recipients to proactively show how safety and harassment will be addressed in the NIH-funded meeting. While the requirement is part of a broader NIH initiative to increase diversity in the biomedical workforce, research has found that off-campus events such as conferences may present environments where harassment and discrimination may present themselves among attendees.

A 2019 report from The National Academies of Sciences, Engineering, and Medicine included results from a study, which found that women "will skip professional events when they feel unsafe at work." Additionally, the study found "a correlation between numbers of witnessed harassing professional events and the experiences of sexual harassment." (Clancy et al., 2017) Avoidance of professional meetings due to harassment concerns can have negative effects on the career progression of a member of a minority group. Federal agencies, research institutions, and individuals have the power to drive the necessary change.

Follow this link for results and publications from The National Academies' report.

## 4. NIDA invites feedback on its Racial Equity Initiative Action Plan

NIH is committed to supporting diversity and equality in the scientific workforce. Additionally, many of its ICs also develop their own initiatives to address racism, exclusion, and inequity specific to their respective research areas. NIDA is inviting feedback on its draft of the NIDA Racial Equity Initiative Action Plan. While all feedback is welcome, the institute is particularly interested in hearing from groups and individuals who may have been directly or indirectly affected by discriminatory practices or policies within NIDA's mission space. Feedback is due by April 30th. A link to the Plan, detailed information regarding feedback sought, and the email to which feedback should be submitted can be found in the NOT.

## 5. The latest roundup of some NIH-sponsored COVID-19 research

Over the past year, the NIH has maintained the scientific community abreast of COVID-19 developments via a website with news releases regarding research findings and clinical trials attempting to address the pandemic. As the situation evolved, so has NIH's information.

The site now lists NIH's strategic priorities for COVID-19 research, as well as a PDF of the 2021 NIH-wide COVID-19 Strategic Plan. Additionally, there is a page outlining COVID-19 research initiatives across its centers and institutes.

We'll continue sharing COVID-19 related headlines, but we encourage you to visit the resources above.

Here are some other COVID-19 related headlines:

- NIH begins clinical trial evaluating second COVID-19 booster shot in adults
- Studying immune responses to treat COVID-19
- Early studies suggest CBD may help prevent COVID-19
- More evidence that COVID-19 vaccines do not cause infertility

**Exciting News!**
Our new course library platform is now live!

Margaret Bouvier received her PhD in 1995 in Biomedical Sciences from the Mount Sinai School of Medicine. After an NINDS post-doctoral fellowship, she worked as a staff writer for current NIH Director Dr. Francis Collins in the Office of Press, Policy, and Communications for the Human Genome Project and NHGRI. Since 2007, Meg has specialized in editing and advising on NIH submissions, and began offering virtual courses in 2015. She currently supports 2 of the top 3-ranked hospitals; 4 of the top 6 cancer hospitals; and 3 of the top 6-ranked medical schools for research in the country. She has helped clients land over $400 million in federal funding. Meg Bouvier Medical Writing, LLC is a woman-owned, small business.

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