NIH Cautions Researchers: Submit Applications to the Appropriate Funding Opportunity Announcements



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In <u>a recent blog post</u>, the National Institute of Health's (NIH) Deputy Director for Extramural Research, Michael Lauer, has cautioned researchers to submit clinical trial and non-clinical trial applications to NIH via the proper Funding Opportunity Announcement (FOA). His blog post provides additional information and advice regarding submitting grant proposals to NIH in 2018.

Followers of <u>APS's Federal Research, Funding, and Policy Page</u> know that from January 25, 2018 onwards, all applications for NIH funding proposing clinical trials must be submitted through an FOA designated specifically for clinical trials. And due to NIH's revised definition of a clinical trial, many research projects conducted by psychological scientists are now classified in this category. NIH's policy not only affects clinical applications, as nonclinical applications must be submitted to nonclinical or clinical-optional FOAs as well.

"Responding to the correct type of FOA ensures that you know what information you are expected to include in your application and that you can develop an application that is responsive to the review criteria. It also ensures that reviewers apply the correct criteria and give your application the best review possible," explains Lauer.

According to Lauer's post, researchers looking to submit a clinical trial application should look for the FOAs that "make clinical trial allowability clear in both the title and in section 2, and they include <u>clinical trial review criteria</u>." Many NIH FOAs are being reissued to make the clinical and nonclinical distinctions clear.

Lauer also recommends researchers read each FOA carefully for another reason: Not all NIH Institutes and Centers (ICs) participate in parent announcements that allow clinical trials, and some limit their participation to certain types of studies, such as mechanistic studies, as <u>APS pointed out recently</u>. For instance, the National Institute of Mental Health will only accept clinical trial applications to certain FOAs and will only accept application that propose mechanistic studies.

Researchers concerned about whether their studies are classified as clinical trials and/or if they are selecting the most appropriate FOA for their study should consult NIH program staff. NIH has also issued a <u>clinical trial tool</u> that can be used to determine whether research involving human subjects will be considered a clinical trial. APS will continue to monitor NIH's clinical trials policies as they are implemented in 2018.

To read more about the recent major changes at NIH for research involving human subjects, including the revised definition of a clinical trial, click <u>here</u>.

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