

NIH Delays Some Clinical Trials Requirements Imposed Earlier on Basic Behavioral Research

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Psychological scientists doing basic behavioral research can take a deep breath—kind of. The National Institutes of Health (NIH) is delaying for two years some of the clinical trials requirements it earlier attempted to impose on basic research.

Over the past two or more years, APS and other organizations and individuals have actively opposed a series of NIH policy changes that classified basic research with humans as clinical trials and introduced new requirements for scientists conducting basic research with human subjects, including that scientists register and report basic research with humans on ClinicalTrials.gov, a website designed for clinical trials research. There was unanimous agreement in the scientific community in support of appropriate registration and reporting—the opposition in this case was to the requirement that ClinicalTrials.gov be the platform.

Following this pushback, NIH delayed enforcement of the parts of these policies related to ClinicalTrials.gov and released a request for information (RFI) to the scientific community seeking feedback on best practices for registration and reporting of basic research. This new notice ([NOT-OD-19-126](#)) follows the community's response to the RFI and further extends the period of delayed enforcement to September 2021.

[Click here to read the new NIH notice, “Extension of Certain Flexibilities for Prospective Basic Experimental Studies with Human Participants.”](#)

NIH says it now recognizes that the clinical trials platform doesn’t work for basic research and will work with the basic research community to identify best practices for registering and reporting basic studies. More than one insider at NIH has expressed regret that the community wasn’t consulted from the start so that all of the subsequent difficulties could have been avoided.

While a step in the right direction, this latest change at NIH may only add to the confusion caused by relabeling basic research as clinical trials. And it is important to note that NIH has not backed away from that relabeling.

APS has been working to educate members of Congress about the differences between basic behavioral research and clinical trials, and that different sets of policies are necessary to encourage transparency and openness in both types of research. In fact, the delayed enforcement period originally arose thanks to Congress’s March 2018 instruction [that NIH pause enforcement of these policies](#) to give sufficient time to consult with the basic research community to determine reporting standards best suited for basic research.

“There is concern that policy changes could have long-term, unintended consequences for this research, add unnecessary regulatory burdens, and substantially increase the number of studies in the ClinicalTrials.gov database that are not clinical trials,” noted Congress.

[For more background on this issue, including APS activities, click here.](#)

This issue will continue to unfold, and APS will work to reverse the labeling of basic research as clinical trials. Scientists interested in applying to NIH for research funding should [read the new notice carefully](#). Because of the complicated nature of NIH’s policies and the varying degree to which they affect basic research with humans, APS recommends that scientists speak with an NIH program officer about any planned research prior to beginning the grant application process.

[To read a recent article in *Science* about the delay in registration and results reporting requirements, click here.](#)