

# Major Changes Ahead for Funding of Human Subjects Research at NIH

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The National Institutes of Health (NIH) has announced several policy changes related to NIH-funded research involving human subjects—and starting with application due dates on or after January 25, 2018, these changes will significantly impact how studies conducted by psychological scientists are supported by NIH. All psychological scientists interested in NIH funding should be aware of these changes.

The NIH policy changes stem from the 2016 revised definition of a *clinical trial*. According to NIH's new definition, clinical trials are research studies “in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” This means that much of the research conducted by psychological scientists is now recognized by NIH as a clinical trial.

The clinical trial classification has major implications for researchers applying for grant funding from NIH. The most significant is that as of January 25, 2018, [scientists proposing clinical trial studies cannot apply for NIH funding through broad funding announcements](#). Rather, researchers can only apply for funding through funding opportunity announcements that are specifically designed for clinical trials. This means that scientists seeking NIH support must find a funding announcement that allows the

submission of clinical trials *and* covers an area of interest relevant to the proposed research project.

When research is classified as a clinical trial, there are additional requirements, too—researchers [must participate in a training course](#) to be eligible to conduct the research, and they must register and report their studies on ClinicalTrials.gov, for example.

NIH Deputy Director for Extramural Research Michael Lauer further clarified these upcoming changes [in an August 11 blog post on the NIH website](#).

“The breadth of the NIH definition is intentional, given the nature of the NIH portfolio and imperatives for maximal transparency,” he wrote, confirming that these changes are intended to be applied to social and behavioral science research, too.

Many researchers, including psychological scientists, are concerned that NIH’s changes will negatively affect the research process. APS wrote a letter to NIH in June noting that NIH’s new clinical trial definition is “exceptionally broad and appears to encompass any manipulation of a variable hypothesized to have an impact on a measured behavioral outcome.” This letter was featured in [a recent article in Science](#). One concern is that researchers, unaware of these changes, will submit grant applications to the wrong funding announcement and have their applications rejected without review, potentially delaying subsequent grant submissions by months.

APS is continuing to monitor these changes at NIH. [Concerned scientists should read an update by NIH’s Office of Behavioral and Social Sciences Research for more information](#).