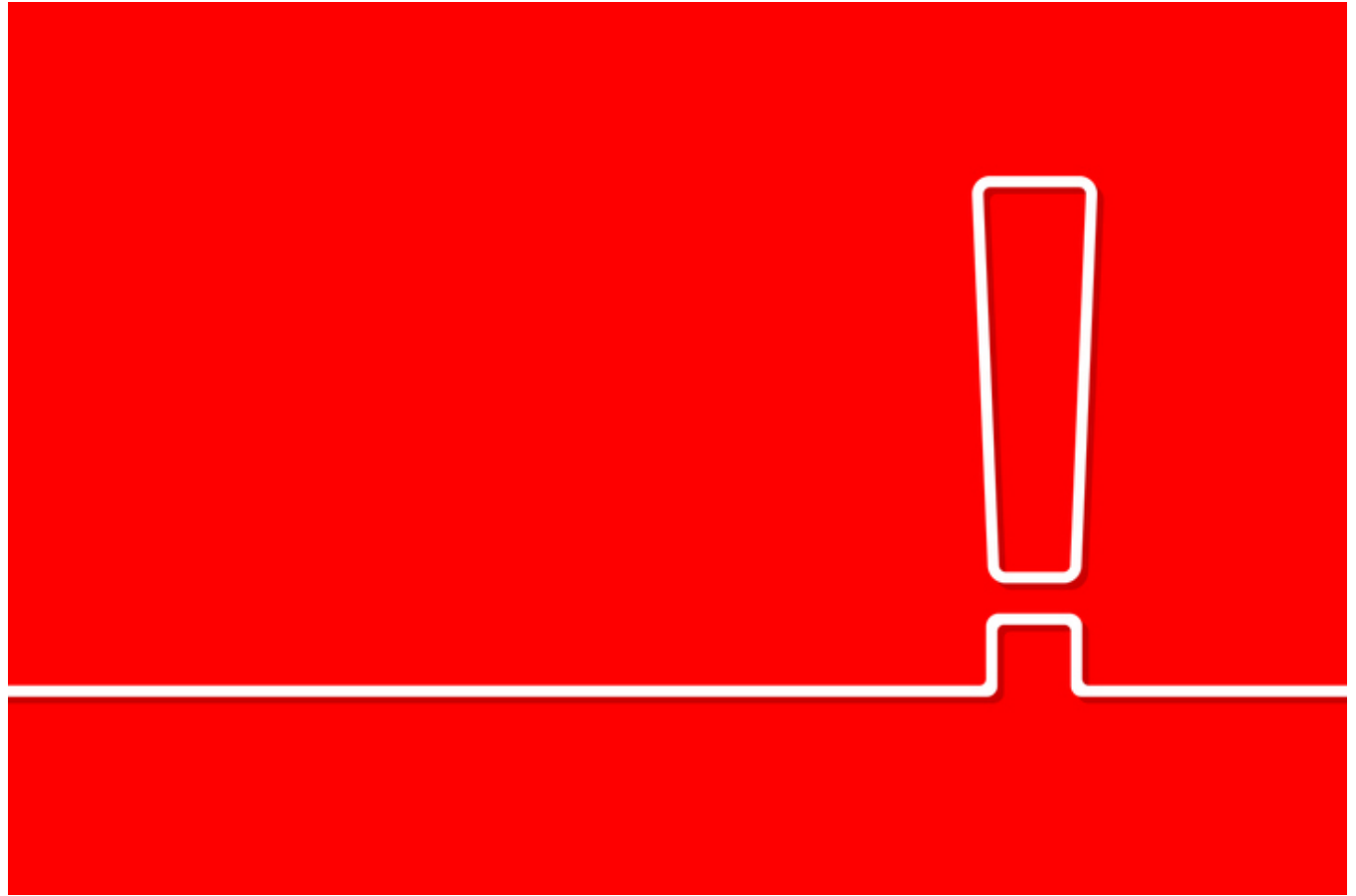


Major Change in NIH Policy for Clinical Trials Applications

November 28, 2016



In a significant departure from current practices, the National Institutes of Health (NIH) has issued new policies relating to grant applications involving clinical trials, including one ([NOT-OD-16-147](#)) mandating that all applications involving clinical trials must be in response to a Funding Opportunity Announcement (FOA) specifically designed for clinical trials. The changes will affect applications submitted on or after September 27, 2017.

This policy change will have a clear impact on the application process for psychological scientists, given that the NIH definition of a clinical trial (see [NOT-OD-15-015](#)) includes all research involving one or more human subjects who are prospectively assigned to one or more interventions (that may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Investigator-initiated applications involving clinical trials will no longer be accepted by NIH; instead, applicants seeking to conduct clinical trial research must find an FOA that specifically allows the submission of clinical trials *and* covers an area of scientific interest relevant to the proposed research. NIH will no longer accept clinical trial applications through Parent Announcements (broad funding opportunity announcements for investigator-initiated applications) or other FOAs that are not specifically designed to accept clinical trials. Each NIH Institute and Center (IC) will be required to publish its own clinical trials FOA which will emphasize that IC's scientific area(s)

of interest.

While NIH is making these changes in an effort to “to identify more easily clinical trial applications and ensure that key components of clinical trial information are included and uniformly considered in review,” vigilance from the scientific community is needed to ensure that all areas of science are represented in the IC-specific FOAs involving clinical trials research.

For more information on NIH policy announcements, check out the information posted at the NIH Office of Extramural Research, [Notice of NIH Policy Changes site](#). For information on the implications of the NIH clinical trials policies on behavioral and social sciences, see the [OBSSR Director’s Voice blog from October 18, 2016](#).