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# New NIH "Clinical Trials" Definition to Impact Basic Social and Behavioral Science Research | October 3, 2017

By Wendy A. Naus, Executive Director

The National Institutes of Health (NIH) has been working for the last few years to enhance its stewardship of and increase transparency over the clinical trials it funds. The agency, which is the largest funder of clinical trials in the U.S., issued a ***Notice of Revised NIH Definition of "Clinical Trial"*** (NOT-OD-15-015) in late 2014 laying out a new, expanded definition to govern which research projects are to be categorized as a "clinical trial" from here on out.

According to the NIH definition (2014), **a "clinical trial" is:**

> *"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

Following up on 2014 definition, in September 2016, NIH released a ***Policy on Funding Opportunity Announcements (FOAs) for Clinical Trials*** (NOT-OD-16-147), which further laid out how the new definition would be applied and steps for complying with the policy.

According to the policy:

> *"NIH will require that all applications involving one or more clinical trials be* ***submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials****. This means that the NIH will no longer accept clinical trial applications through 'parent' FOA announcements or through other FOAs that are not specifically designed to accept clinical trials. The purpose of this policy is to improve our ability to identify proposed clinical trials, ensure that key pieces of trial-specific information are submitted with each application, and uniformly apply trial-specific review criteria."*

**The effective date for the policy is September 27, 2017, impacting projects to be funded in 2018.** NIH has created a webpage where it is housing additional resources related to the policy and its implementation: https://grants.nih.gov/policy/clinical-trials.htm.

## Impacts on Social and Behavioral Science

While this change has been in process for the last few years, it wasn't until more recently that the biomedical and behavioral research community started to take notice of the potentially significant impacts this new definition could have on a variety of basic research activities funded by the NIH, which

will now be considered clinical trials. Although it was developed with the traditional NIH biomedical research clinical trial in mind and in response to concerns about study results going unreported, the social and behavioral sciences are impacted as well.

The 2016 notice states that "the revision is designed to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials." While it further states that the intention is not to "expand the scope of the category of clinical trials," the resulting policy does just that.

In an August 29, 2017 blog post, Office of Behavioral and Social Sciences Research (OBSSR) Director Bill Riley stated that "it is the intent of the NIH to interpret the clinical trials definition broadly to include any NIH-supported study of humans that involves experimental manipulation (described as 'prospectively assigned to one or more interventions' in the clinical trials definition)." In other words, research that involves a **prospective experimental manipulation of an independent variable** would fall under the definition of a clinical trial.

As such, the following steps will now be required by social and behavioral science research studies falling under the definition:

1. **Submit applications through FOAs that are specifically designed for clinical trials**, no longer to parent FOAs or non-clinical trial FOAs (https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm).
2. **Register the study with clinicaltrials.gov** within 21 days of the first participant entering the study (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm).
3. **Report findings in clinicaltrials.gov** within one year of the last participant completing the last assessment (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm).
4. Participate in a **Good Clinical Practice training** (https://grants.nih.gov/policy/clinical-trials.htm#b).

NIH has developed a set of case studies to help prospective grantees determine whether their study would need to be submitted through a clinical trials FOA. This includes a number of behavioral case studies that are intended to serve as examples of projects that do and *do not* qualify as clinical studies under the new definition.

## Remaining Questions

What is less known at this point is how these requirements will impact things like training and fellowship programs for which the work conducted could now be considered a clinical trial; the peer review process (for example, how can we be assured that social and behavioral science expertise will exist on the clinical trials study sections to which applications will now be referred?); and how basic research will be supported and handled by NIH more generally in the future. Additionally, there are concerns about the increased administrative burden associated with having to classify more projects as clinical trials as well as possible implications for informed consent requirements with a broadening of the definition.

Even with the policy now in effect, there appear to be more questions than answers about the true impact of policy on research that has traditionally not be viewed in this way.

## Looking Ahead

Despite efforts by many in the research community (see the letter from higher education associations and an online petition, both sent to NIH) to alter or at least delay the implementation of the new policy and definition, the new requirements are moving forward as planned. Therefore, current and prospective NIH grantees are urged to familiarize themselves with the new definition and policy and to plan accordingly for any future submissions.

The agency is said to be working with those responsible for implementing the policy (i.e. Centers for Scientific Review, individual institutes and centers, and clinicaltrials.gov) to ensure that the implementation of the policy is as workable as possible for the social and behavioral research community.

Stay with COSSA for additional coverage about this and other important topics.

## Additional reading

- Joint AAMC, AAU, APLU, COGR Letter to NIH (2017)
- Open Letter to NIH Director Francis Collins (2017)
- Clinical Trials Policies: A Rose by Any Other Name, *OBSSR Director's Voice* (2017)
- New NIH Clinical Trials Policies: Implications for Behavioral and Social Science Researchers, *OBSSR Director's Voice* (2016)
- Viewpoint: Toward a New Era of Trust and Transparency in Clinical Trials, *JAMA* (2016)
- Building Better Clinical Trials through Stewardship and Transparency, *NIH Extramural Nexus* (2016)
- Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency, Government Accountability Office (2016)