NIH CLINICAL TRIALS UPDATE

WHAT
NIH’s broadened definition of clinical trial now includes some research approaches not traditionally considered clinical trials. [https://grants.nih.gov/policy/clinical-trials.htm](https://grants.nih.gov/policy/clinical-trials.htm)

WHEN
January 25, 2018

PURPOSE
• Enhance accountability and transparency of clinical research
• Support scientific and ethical obligation to ensure that the burden and risk that volunteers assume as research participants ultimately contributes to scientific knowledge

DEFINITION
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.

DETAILS
Your study is a clinical trial if you answer YES to all four questions:
• Does the study involve human participants?
• Are the participants prospectively assigned to an intervention?
• Is the study designed to evaluate the effect of the intervention on the participants?
• Is the effect being evaluated a health-related biomedical or behavioral outcome?

HOW
• Submit the application through a Funding Opportunity Announcement (FOA) that accepts clinical trials.
• Fill out new form in FORMS-E application that consolidates all Human Subjects and Clinical Trial related information into one place.
• Provide additional information in the application, which will be subject to different and distinct review criteria for clinical trials.

HELP
[General Instructions](#) | [Video](#) | [Case Studies](#) | [FAQs](#) | Please contact your Program Officer with any questions (information available in your Commons account).