

Effective January 1, 2017 – Good Clinical Practice Training required if study involves a Clinical Trial- available through UTK CITI training

If Proposal Due date is after 1/25/2018 –New Clinical Trial definition and requirements apply

<https://grants.nih.gov/policy/clinical-trials/definition.htm>

<https://grants.nih.gov/ct-decision/index.htm> -Simple test to determine if your study meets this criteria

NIH's Definition of a Clinical Trial

This page provides information, tools, and resources about the definition of a clinical trial. Correctly identifying whether a study is considered by NIH to be a clinical trial is crucial to how you will:

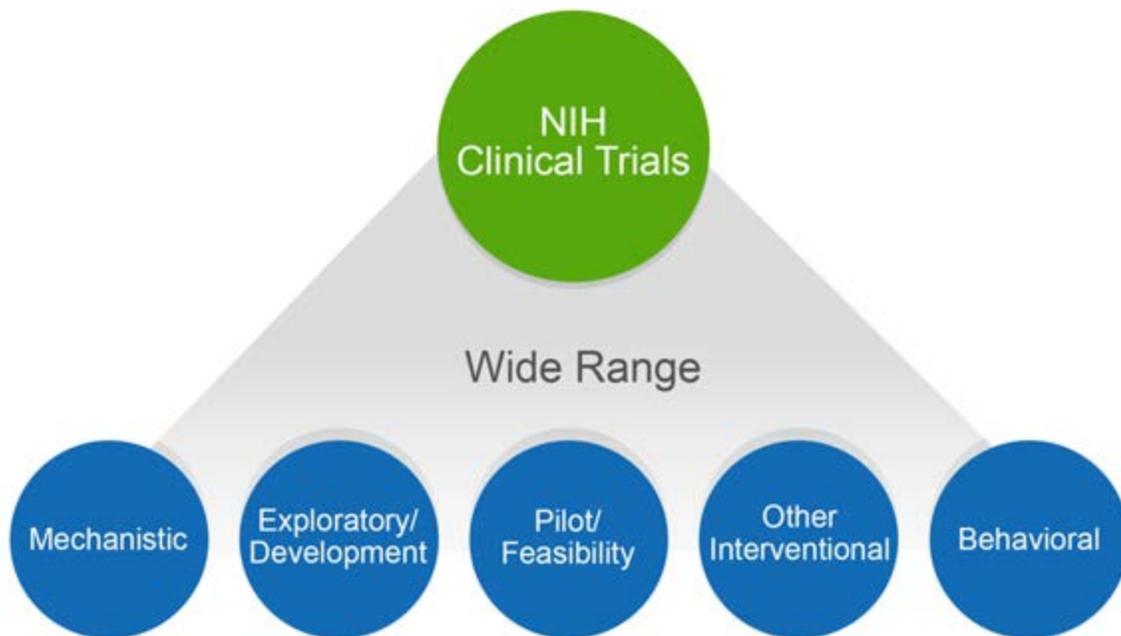
- Select the right NIH funding opportunity announcement for your research study
- Write the research strategy and human subjects sections of your grant application and contact proposal
- Comply with appropriate policies and regulations, including registration and reporting in ClinicalTrials.gov

Background

In 2016, NIH launched a multi-faceted effort to enhance its stewardship over clinical trials. The goal of this effort is to encourage advances in the design, conduct, and oversight of clinical trials while elevating the entire biomedical research enterprise to a new level of transparency and accountability. The NIH definition of a clinical trial was revised in 2014 in anticipation of these stewardship reforms to ensure a clear and responsive definition of a clinical trial. [Learn more about why NIH has made changes to improve clinical trial stewardship.](#)

NIH Definition of a Clinical Trial

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.



**Your human subjects study may meet
the NIH definition of a clinical trial.**

[FIND OUT HERE](#)

Important features that distinguish a clinical trial from a clinical study are whether there is prospective assignment of an intervention, a study design that evaluates the effect of the intervention on the participants, and a health-related biomedical or behavioral outcome.

If these features are present, the study is a clinical trial. Our case studies [\[link\]](#) illustrate how to apply these questions.

Note that studies of surveys, questionnaires, user preferences, and studies involving focus groups are not clinical trials. Likewise, studies that involve secondary research with biological specimens or health information are not clinical trials. Finally, educational studies, such as those with outcomes focusing on memorization, or retention and recall of information to assess teaching methods, are not clinical trials.