Hunter College
Office of Research Administration
Information Alert

NOVEMBER 2017
ALERT # 36

New National Institutes of Health (NIH) Clinical Trials Definition and Requirements

With recent changes in the definition of a clinical Trial by NIH, some researchers conducting human subjects research may not be aware that NIH considers their study to be a clinical trial.

For application due dates on or after January 25, 2018, identifying whether your study is a clinical trial will be important for:

1. picking the right NIH funding opportunity
2. ensuring your application includes all the information required for peer review
3. complying with the appropriate policies and regulations

ALERT

WHY THIS ALERT?

This publication has been created to serve the purpose of informing researchers of new information, trends and concerns as they occur.

NIH Definition of a Clinical Trial

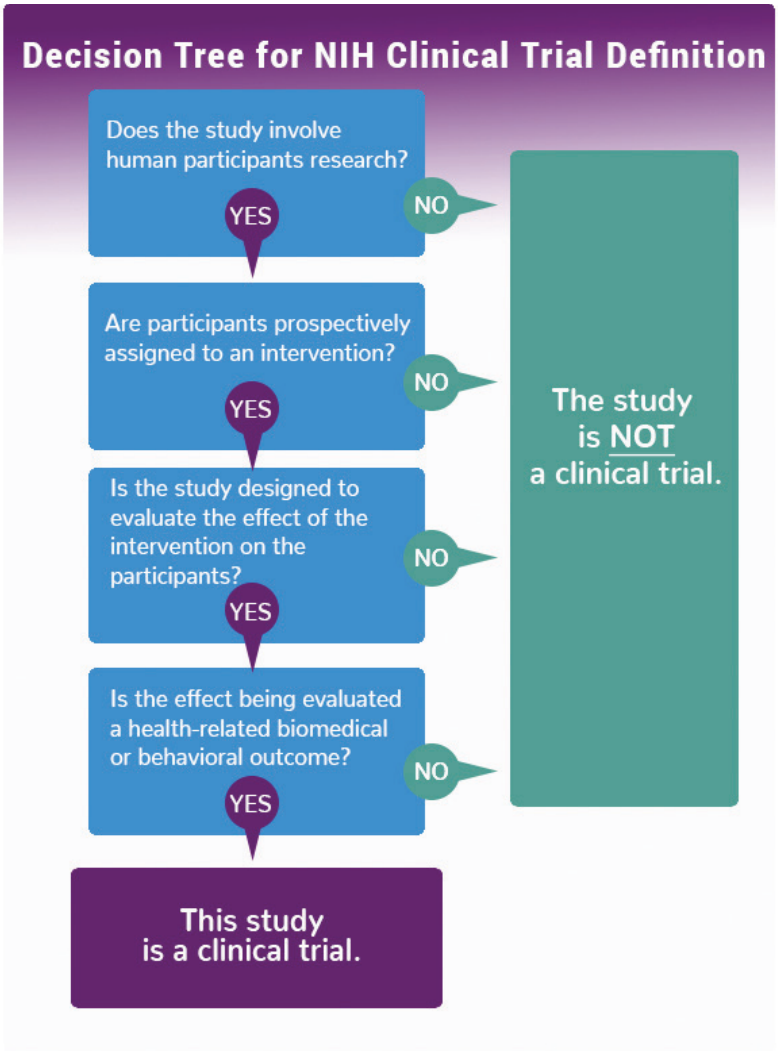
A research study in which one or more human subjects are prospectively assigned [1] to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on [2] health-related biomedical or behavioral outcomes.

[1] Prospectively assigned refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2] A health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Remember

The Office of Research Administration can assist you with these new requirements.



New Human Subjects and Clinical Trial Information Proposal Forms

Proposals submitted on or after January 25, 2018 must address new and additional human subjects requirements. NIH has provided a video of new forms. It can be found on their website at https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1.

The Office of Research Administration has a template that simplifies the required documents. When you are ready to submit a proposal, please contact us.

Additional Requirements for Funded Projects with Clinical Trials

The Institution and the Principal Investigator (PI) of an approved clinical trial must submit the required clinical trial information no later than 21 days after enrollment of the first participant to ClinicalTrials.gov.

For more information about the new National Institutes of Health (NIH) Clinical Trials definition and requirements, please refer to: https://grants.nih.gov/policy/clinical-trials.htm