

Dear Investigators,

Please be aware that NIH has changed their definition of a clinical trial, which will only apply to NIH-funded studies. A clinical trial is now, “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.”

In making a determination that a study is a clinical trial, NIH looks at the answers to the following 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?

If the answer to all four questions above is “yes,” your study meets the NIH definition of a clinical trial even if any of the following are true:

- You are studying healthy participants
- Your study is utilizing a behavioral intervention
- Your study does not have a comparison group (e.g. placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigative drug

Studies that involve secondary research with health information or biological specimens, or studies that are intended solely to refine measures are not considered clinical trials.

For guidance in determining whether your NIH-funded study is a clinical trial or not, visit the link below or contact the IRB Office at irb@utsa.edu or (210) 458-6473:

Does your human subjects research study meet the NIH definition of a clinical trial?
(<https://grants.nih.gov/ct-decision/index.htm>)