



Clinical Trial FAQ's

What is the common rule definition of a clinical trial?

According to the [Revised Common Rule § .102\(b\)](#): "Clinical trial means 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 the interventions on biomedical or behavioral health-related outcomes."

What is the NIH definition of a clinical trial?

The [National Institutes of Health \(NIH\) defines a clinical trial as](#): "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 healthrelated biomedical or behavioral outcomes." (Oct 23, 2014). For information on multisite research see the [NIH FAQ's](#)

How do I determine if my study qualifies as a clinical trial?

The following elements required for a study to be considered a clinical trial:

- Involvement of human subjects
- Participants are prospectively assigned to an intervention
- Study is designed to evaluate the effect of the intervention on the participants
- The effect being evaluated is a health related biomedical or behavioral outcome.

Where are clinical trials registered?

<https://clinicaltrials.gov/>

Who is responsible for registering clinical trials at ClinicalTrials.org? The Principal Investigator is responsible for registering their trial.

Who can I contact to obtain an account for ClinicalTrials.org or if I have questions?

Please contact Director of Research Subjects Compliance - Leslie Teixeira-Porto lteixeira@ucmerced.edu

For more information please visit our [website](#).