

Is This Study a Clinical Trial?

Please click on the icon below to determine.



CT-decision-tree.pdf

Please see the details below.

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.

The term "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.

<https://grants.nih.gov/ct-decision/index.htm>

FDA's definition of an applicable clinical trial:

- Study is interventional
- Intervention includes an FDA-regulated product (Drug / Biologic/ Medical Device)
- Study is NOT a phase 1 or small feasibility study

NIH's definition of a clinical trial:

- The study involves human participants;
- The study enrolls people into at least one arm and assigns them to a procedure or task that they would not be doing if they weren't in the research study (i.e., prospectively assigned to an intervention);
- The study is designed to evaluate the effect of the intervention on the participants; **AND**
- The effect being evaluated is a health-related biomedical or behavioral outcome.

OHRP's definition of a clinical trial:

- The study involves human participants;
- The study enrolls people into at least one arm and assigns them to a procedure or task that they would not be doing if they weren't in the research study (i.e., prospectively assigned to an intervention);
- The study is designed to evaluate the effect of the intervention on the participants; **AND**
- The effect being evaluated is a health-related biomedical or behavioral outcome.