

Notice of Revised NIH Definition of “Clinical Trial”

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Key Dates

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Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

The purpose of this Notice is to inform the research community that NIH has revised its definition of “clinical trial.” The revision is designed to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials. It is not intended to expand the scope of the category of clinical trials. No changes have been made to the NIH definition of a “Phase III clinical trial.”

In addition, because clinical trials are subject to additional oversight, a clearer definition will help investigators ensure that they are meeting all of their obligations, and it will help NIH ensure that the additional oversight is occurring when it is needed. For example, NIH policy requires clinical trials to be monitored, and applicants and offerors seeking NIH support are expected to describe their plans for data and safety monitoring in their applications and proposals. Final data and safety monitoring plans must be approved by the NIH prior to award. In addition, throughout the life of the award, NIH staff monitors the clinical trial’s progress to ensure that milestones are met and that any safety concerns are addressed.

The revised definition will replace the current clinical trial definition in relevant extramural and intramural NIH policies, guidance, and instructional materials. It will apply to competing grant applications that are submitted to NIH for the January 25, 2015 due date and subsequent due dates and contracts proposals that are submitted to NIH on or after January 25, 2015.

The revised NIH definition of clinical trial is:

NIH Clinical Trial Definition
A research study ¹ in which one or more human subjects ² are prospectively assigned ³ to one or more interventions ⁴ (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. ⁵

¹See Common Rule definition of *research* at 45 CFR 46.102(d).

²See Common Rule definition of *human subject* at 45 CFR 46.102(f).

³The 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.

⁴An *intervention* is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

⁵*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.

Further information and resource materials about the NIH definition of clinical trial are available on the NIH Office of Science Policy website at <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>.

Inquiries

Please direct all inquiries to:

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