Definition of a Clinical Trial

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1. The U.S. 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 health-related biomedical or behavioral outcomes."

- Click here to evaluate whether your NIH-funded study meets the NIH definition of a clinical trial

2. The FDA defines an Applicable Clinical Trial (ACT) as follows:

- Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- Trials of biomedical devices: 1) controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post-market surveillance.
- Click here to evaluate whether your study is an Applicable Clinical Trial (ACT) under 42 CFR 11.22(b)

3. The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as “any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.”

For complete statutory definitions and more information on the meaning of Applicable Clinical Trial, see Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (PDF).

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

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