IRB GUIDANCE: Definitions for "Clinical Research" and "Clinical Trials"

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INTRODUCTION

Clinical Research and Clinical Trials are described below.

CLINICAL RESEARCH

Clinical research involves medical studies to understand, prevent, and treat diseases or promote health, often including clinical trials. It can involve patient interactions, specimen analysis, observational studies, or experimental trials. Observational studies include cohort and case-control studies. Experimental studies, like randomized controlled trials (RCTs), introduce interventions and randomly assign participants to groups.

CLINICAL TRIALS

FDA

IDE REGULATIONS:

Investigation means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

IND REGULATIONS:

Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

IRB REGULATIONS

Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of Title 21, regarding nonclinical laboratory studies.

APPLICABLE CLINICAL TRIAL

Applicable Clinical Trial (ACT) means an applicable device clinical trial or an applicable drug clinical trial. Expanded access use under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is not an applicable clinical trial.

To evaluate whether a Clinical Trial is an Applicable Clinical Trial, please consult with the FDA ACT Checklilst, which is available on the Downstate IRB Policy and Guidance website.

APPLICABLE DEVICE CLINICAL TRIAL

Applicable Device Clinical Trial means:

> (1) A prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes);
>
> (2) A pediatric postmarket surveillance of a device product as required under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601); or
>
> (3) A clinical trial of a combination product with a device primary mode of action under 21 CFR part 3, provided that it meets all other criteria of the definition under this part.

APPLICABLE DRUG CLINICAL TRIAL

Applicable Drug Clinical Trial means a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where “clinical investigation” has the meaning given in 21 CFR 312.3 and “phase 1” has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

COMMON RULE

A Clinical Trial, as defined by the Common Rule, 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.

NIH

An NIH Clinical Trial is 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.

REFERENCES

- Common Rule: 5 CFR 46.102(b)
- FDA Applicable Clinical Trials: 42 CFR 11.10 (a)
- FDA IDE Regulations: 1 CFR part 812.3(h)
- FDA IND Regulations: 21 CFR part 312.3(b)
- FDA IRB Regulations: 21 CFR 50.3 (c)
- NIH Definition of a Clinical Trial
- NIH, Notice of Revised NIH Defination of Clinical Trial. October 23, 2014. Available: NIH NOT-OD-15-015
- Institute of Medicine (US) Clinical Research Roundtable; Tunis S, Korn A, Ommaya A, editors. Washington (DC): National Academies Press (US); 2002. The Role of Purchasers and Payers in the Clinical Research Enterprise: Workshop Summary. Available: https://www.ncbi.nlm.nih.gov/books/NBK220717/
- NCI: What are observational studies. Available: https://www.cancer.gov/research/participate/what-are-observational-studies
- Institute for Work & Health: Observational vs. Experimental Studies. Available at: https://www.iwh.on.ca/what-researchers-mean-by/observational-vs-experimental-studies

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