Weill Cornell Medical College | NewYork-Presbyterian

JOINT CLINICAL TRIALS OFFICE (JCTO)

Clinical Research Categorization Guide

Study Type

Interventional: Clinical research category in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

Observational: Clinical research category in which the studies focus on both patients and healthy volunteers that involve no intervention or alteration to the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostics, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

Ancillary/Correlative:

Ancillary: studies are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

Correlative: laboratory based studies using specimens to assess disease risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

Primary Purpose

Diagnostic: Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.

Health Services Research: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Other: Not in other categories

Prevention: Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition

Screening: Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).

Supportive Care: Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.

Basic Science: Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.

Treatment: Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition.

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Study Source

National: NIH-supported National Trial Networks (i.e., NCI National Clinical Trials Network (NCTN), AIDS Clinical Trials Group (ACTG), HIV Prevention Trials Network (HPTN), Stroke Trials Network (NIH StrokeNet), etc.).

Externally Peer Reviewed: R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or an approved peer-reviewed funding organization.

Institutional: In-house clinical research studies authored or co-authored by WCMC/NYPH investigators and undergoing scientific peer-review solely by the WCMC/NYPH Clinical Study Evaluation Committee (CSEC). The WCMC/NYPH has primary responsibility for conceptualizing, designing and implementing the clinical research study and reporting results.

- It is acceptable for industry and other entities to provide support (i.e., drug, device, other funding) but the trial should clearly be the intellectual product of the center investigator.
- This category may also include institutional studies authored and implemented at another center and multi-institutional studies authored and implemented at WCMC/NYPH.

Industrial: The design and implementation of these clinical research studies is controlled by a pharmaceutical company.

Phase

For interventional studies acceptable phases include: pilot, feasibility, 0, I, II, II, IV or combinations such as I/II. For epidemiologic, behavioral, observational, ancillary/correlative, or biological studies indicate N/A.