Clinical Trials Overview

Definition of Clinical Trial

UAB 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’.

Examples of intervention include: drugs; small molecules; compounds; biologics; devices; procedures (i.e., surgery); delivery systems (i.e., face-to-face interviews); strategies to change health-related behavior (i.e., diet, cognitive therapy, exercise, development of new habits); or prevention, diagnostic or treatment strategies. A clinical trial always involves: (i) human subjects and (ii) the testing of an investigational intervention or the testing of an approved intervention for an investigational purpose.

The Food and Drug Administration (FDA) classifies a clinical trial of a drug based on the study's characteristics, such as the objective and number of human subject participants. There are 5 phases:

Phase 0: Exploratory studies, involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

Phase I: Studies that are usually conducted with healthy human subject participants and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.

Phase II: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, human subject participants receiving the drug may be compared to similar human subject participants receiving a different treatment, usually an inactive substance, called a placebo, or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase III: Studies that gather more information about safety and effectiveness by studying different human subject populations and dosages and by using the drug in combination with other drugs.

Phase IV: Studies occurring after the FDA has approved a drug for marketing. These include post-market requirement and commitment studies that are required of or agreed to by the study
These studies gather additional information about a drug's safety, efficacy, or optimal use.

This section covers clinical trials that are supported by for-profit companies like pharmaceutical companies or device manufacturers, the federal government, or non-profit organizations. An investigational new drug application (IND) or investigational device exemption (IDE) are the mechanisms by which regulatory authorities approve and monitor the testing of investigational drugs and devices in clinical trials.

When a clinical trial is labeled **investigator-initiated** (IIT), it means that the UAB Principal Investigator (PI) wrote the protocol, rather than the pharmaceutical company or device manufacturer. The PI has made the intellectual contribution to the project, and the pharmaceutical company or device manufacturer is providing only funding and/or the study drug, device, or diagnostic. If there is an FDA-regulated product involved and it is considered to be investigational, generally UAB/PI will hold the IND/IDE. UAB is the sponsor of the study for IIT clinical trials.

**Sponsor-initiated clinical trials** are those in which a sponsor (company/person), rather than the PI, writes the protocol and also provides funding and the study drug or device. If there is an FDA-regulated product involved and it is considered to be investigational, generally the sponsor will hold the IND/IDE.

Industry-sponsored and sponsor-funded IIT clinical trials that meet UAB’s definition of a clinical trial (see Definition of a Clinical Trial or Clinical Trial F&A Flowchart) are eligible for the clinical F&A rate of 30%. All other clinical trials will be subject to the DHHS negotiated F&A rate (see DHHS Rate Agreement) for other sponsored activities or applicable UAB policy, calculated on the Modified Total Direct Cost (MTDC) basis.