

UCLA - Clinical Trials Definition September 2006

UCLA is adopting a new clinical trial definition for use by the campus. This definition is based on a definition promulgated by UCOP for use in determining those projects that qualify for the special 26% Total Direct Costs (TDC) indirect cost rate.

At UCLA a clinical trial is defined as:

The controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol. Financial support for a clinical trial must be provided by a for profit entity.

Applicability:

Please note that the sole purpose of this definition is to determine whether a specific project qualifies for the use of the 26% TDC indirect cost rate. It has no impact on the intellectual property policies applicable to various types of agreements, the allocation and distribution of recovered indirect costs, the applicability of various policies (including FDA regulations) about disclosure of conflicts of interest, or other University or UCLA policies.

Guidance:

These studies are most often conducted in conjunction with obtaining new drug or device approval from the U.S. Food and Drug Administration, under Phase I, II, III, or IV, although they can be designed with the sole purpose of collecting and analyzing data about approved drugs or devices in order to contribute to medical knowledge about the treatment of a disease or medical condition. In all cases, the study must include the prospective enrollment of human subjects and the controlled testing of a drug, device, or diagnostic under an approved protocol. Retrospective chart reviews, analysis of existing medical data and records, laboratory research, animal studies, and federally funded projects are not categorized as clinical trials for purposes of applying the approved clinical trial indirect cost rate.

Contact Information:

Any questions about industry-supported clinical trials or the applicability of the special 26% TDC indirect cost rate should be directed to Helene Orescan, Director of Contracting, Office of Clinical Trials (x40137).