For “clinical trials” as defined below that are conducted at the University of Nevada, Reno School of Medicine (UNSOM), the applicable facilities and administrative (F&A) cost rate (also called “indirect cost rate”) is 26% for off-campus research. This off-campus rate is applicable only to the UNSOM because the preponderance of UNSOM clinical trial projects are conducted in leased facilities where space related costs (e.g., rent, utilities and maintenance) are charged directly to the program. This rate applies regardless of whether a clinical trial is based upon a sponsor-initiated or an investigator-initiated protocol and is consistent with clinical trial F&A rates employed by other research universities. The 26% rate applies to total direct cost (TDC); no budgeted item is excluded from the base to which the F&A rate is applied.

**DEFINITION OF “CLINICAL TRIAL”**

For the purpose of applying the 26% F&A rate, “clinical trial” is defined as follows:

The controlled, clinical testing in human subjects of investigational devices, treatments, or diagnostics or comparisons of approved drugs, devices, treatments or diagnostics to assess their safety, efficacy, benefits, reactions and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol.

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