

STANDARDS FOR PRIVATELY FUNDED CLINICAL TRIALS  
THE UNIVERSITY OF TEXAS AT AUSTIN

- Privately supported clinical trials listed in the registry of clinical trials at [ClinicalTrials.gov](http://ClinicalTrials.gov) are eligible for a 25% F&A rate, applied to the project's total direct costs.
  
- Privately supported clinical trials **NOT** listed in the registry but meeting the following conditions may qualify for the 25% F&A rate:
  1. A) Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome, including the evaluation of investigational new drugs, devices, treatments, interventions or diagnostics, or alternative indications of approved drugs, devices, treatments, interventions or diagnostics; **OR**  
  
B) The collection or review of data generated or acquired in a clinical setting for the purpose of assessing the safety, efficacy, benefits, costs, adverse reactions or outcomes;
  
- OR**
  
- 2. Contact with human subjects or the review of patient care clinical data; and
  
- 3. Performed in an off-campus clinical setting or patient care facility.
  
- The University may accept a F&A rate other than 25% where
  1. The clinical trials meet the condition(s) outlined above,
  
- AND**
  
- 2. The private entity funding the clinical trial has a previously published F&A rate for support of clinical trials that is different from 25%
  
- Preclinical laboratory studies or studies in animals are not included under the term clinical trial.

Adapted from [ClinicalTrials.gov](http://ClinicalTrials.gov)