

**UMN Definition of Clinical Trial**

UMN defines a clinical trial as “a prospective, biomedical or behavioral research study of human or animal subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, biologics, treatments, devices, or new ways of using known drugs, biologics, treatments, or devices). Behavioral interventions are intended to prevent or treat an acute or chronic disease or condition.”[1] Pre-clinical research is not considered clinical trial activity.

[1] UMN has adopted a modified NIH definition of clinical trials to track and monitor organizational metrics. However, your trial may be subject to legal or regulatory requirements that may depend on other definitions (e.g., registering your trial and trial results in ClinicalTrials.gov.)

**Procedural Application for Industry Sponsored or Funded Clinical Trials**

For purposes of qualifying for the University-approved reduced indirect cost rate of 26% TDC, a clinical trial must be industry sponsored and/or industry funded and must meet **one of the following three conditions**: 

- Determine the ability of a new drug, device, or biologic to diminish the symptoms, prevent recurrences, or reduce the risk of death from that disease; or
- Test drugs, devices, diagnostics, treatments, interventions, or preventive measures including testing for an unapproved indication; or
- Collect data to increase knowledge that would lead to enhanced safety and efficacy of a specified drug, a disease or device; or

**and include one of the following requirements:**

- involve contact with humans or animals; or
- be a retrospective review of medical records, clinical data or specimens obtained from contact with subjects.

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1 This procedural application does not apply to non-industry funded clinical trials.
2 PI sponsored studies are included.
3 So called “preclinical studies” which test devices on animals for eventual human use do not qualify for the reduced rate. These projects are considered research and must bear full indirect costs.

**UMN F&A Rates**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Rate</th>
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</thead>
<tbody>
<tr>
<td>Research</td>
<td>52% MTDC</td>
</tr>
<tr>
<td>Federal Clinical Trial</td>
<td>52% MTDC</td>
</tr>
<tr>
<td>Industry Sponsored Clinical Trials</td>
<td>26% TDC</td>
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<tr>
<td>PI Initiated Industry-Funded Clinical Trials</td>
<td>26% TDC</td>
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