


<p><b>Name of Policy:</b> Clinical Trial Incentive</p> <p><b>Policy Number:</b> 3364-81-02-008-00</p> <p><b>Approving Officer:</b> Dean, College of Medicine</p> <p><b>Responsible Agent:</b> Assoc. Vice President for Finance &amp; Planning</p> <p><b>Scope:</b> All University of Toledo Campuses</p>	 <p><b>Effective date:</b> 03/01/2007</p>				
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(A) Policy statement

Faculty members in the College of Medicine participating in company-sponsored clinical trials shall be eligible to receive incentive compensation for physician investigator services.

(B) Purpose of policy

The intent of this policy is to compensate faculty members for their participation in eligible company-sponsored clinical trials.

(D) Procedure

For the purposes of this policy, the term "Eligible Company-Sponsored Clinical Trials" shall mean clinical trials that meet the following criteria:

1. Clinical trials for which a pharmaceutical or device company is the sole sponsor;
2. The University of Toledo (UT) is the contractor for the local study site;
3. The study budget exceeds \$25,000 in direct costs;
4. There is an identified component of the clinical trial budget that is designated for physician investigator services;
5. The company budget for the clinical trial is reviewed, approved and attested to as appropriate and sufficient by the departmental chair; and
6. More than 90% of non-investigator personnel study expenses are paid for through grant or other designated accounts (*e.g.* 96 accounts).

After the first 12 months of initiating an Eligible Clinical Trial, 75% of the revenue received each quarter attributable to the "physician investigator services" component of the trial budget will be returned a department designated account of the Principal Investigator (PI) controlled by the Chair of the department, for the purpose of providing monetary incentives to the PI and other physicians who are co-investigators or sub-investigators on the clinical trial, as stated on the

FDA 1572 forms for the UT study site. Incentive payments must be authorized by the department Chair and will be in addition to an individual's UT contract salary.

The following also will apply to the incentive payments and to the clinical trial accounts from which they originate:

1. No distribution will be made from an account, if that distribution would create a deficit in the account or a balance insufficient to maintain payroll for at least three (3) months for employees paid from that account.
2. The balance in the clinical trial account must remain positive.
  - a. Any account that incurs a deficit for three (3) months in succession will become ineligible for use as an incentive account for a minimum of 6 months.
  - b. If a PI has multiple accounts, a deficit balance in any one account that exists for greater than six months will render that PI ineligible for incentive payments.
  - c. All cumulative deficits for a PI's account(s) shall be covered by the department chair.

<p>Approved by:</p> <p>Jeffrey Gold, M.D.</p> <hr/> <p>Name</p> <p>Dean, College of Medicine</p> <hr/> <p>Title</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by:</i></p>	<p><b>Policies Superseded by This Policy:</b></p> <p><b>None</b></p> <p><b>Initial effective date:</b></p> <p><b>Review/Revision Date:</b></p> <p><b>Next review date:</b></p>
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