

<b>Name of Policy:</b> Compensation for treatment of injuries to subjects in covered clinical trials.		 <b>Most Recent Revision:</b> May 28, 2009 <b>Original effective date:</b> June 1, 2008	
<b>Policy Number:</b> 3364-70-09			
<b>Approving Officer:</b> President			
<b>Responsible Agent:</b> Senior Director for Research Administration			
<b>Scope:</b> All University of Toledo Campuses			
	New policy proposal		Minor/technical revision of existing policy
X	Major revision of existing policy		Reaffirmation of existing policy

(A) Policy statement

It is the policy of The University of Toledo (UT) that clinical trial agreements for covered clinical trials will contain a provision by which the sponsor agrees to the conditions of payment for protocol-induced injuries to human subjects as set forth in this policy. A covered clinical trial is one that is sponsored by a for-profit company, employs a company-originated protocol, includes non-FDA approved drugs or devices, and involves more than minimal risk to study subjects.

(B) Purpose of Policy

The purpose of this policy is to set forth the conditions under which company sponsors of covered clinical trials must be responsible for the cost of treatment of protocol-induced injuries that result as a consequence of human subject participation in the clinical trial.

(C) Procedures

(1) Responsibility for costs for treatment of protocol-induced injury to subjects:

- (a) Clinical trial agreements for covered clinical trials will be accepted by UT and its Health Science Center only if the sponsor agrees to fully indemnify the university for the reasonable cost of medical treatment for protocol-induced injuries to study subjects, unless exempted by conditions listed in paragraph (C) (6) or (7) below. If exempted, the sponsor must provide indemnification to the extent required by the exemption.
- (b) The sponsor must be responsible for protocol-induced injuries directly associated with the administration or use of the study drug or device, and injuries directly related to procedures or interventions that are performed solely to satisfy the requirements of the protocol. A sponsor may not limit its responsibility to protocol-induced injuries directly associated with the study drug or device.
- (c) It is not acceptable for the sponsor to limit its responsibility to immediate or emergency care for protocol-induced injuries.

- (d) It is not acceptable for the sponsor to require the subject to obtain treatment for injury at UTMC. Subjects must be permitted to obtain treatment at a medical facility of their choice.

(2) This policy does not apply to:

- (a) clinical trials that utilize only pharmaceutical agents approved by the FDA for sale in the U.S. in all arms of the study; and clinical trials that involve the use of medical devices approved by the FDA for sale in the U.S.; or
- (b) non-experimental or investigational (Category B) devices that have been approved for Medicare payment by the Centers for Medicare and Medicaid Services (CMS).

These will usually be Phase IV trials.

- (3) Clinical trial agreements may not contain provisions restricting participation of human subjects on the basis of medical insurance coverage status or the subject's ability to pay.
- (4) Normally, the required indemnification provision will be a part of the clinical trial agreement between UT and the sponsor, but this requirement may also be met by receipt of an appropriate letter meeting the requirements of this policy and signed by an authorized representative of the sponsor making this commitment. When a separate letter is used to meet the requirements of this policy, the letter must be fully binding on the parties that are providing the indemnification.
- (5) A clinical trial agreement generally may not condition the sponsor's responsibility on the requirement that the subject's insurance be billed first, unless exempted under paragraph number 6 or 7 below.
- (6) Exemptions to this policy will be considered by UT, on a study by study basis, only if:
  - (a) the trial is registered on [Clinicaltrials.gov](http://Clinicaltrials.gov), and
  - (b) the convened IRB determines that the risks of the clinical trial drugs, devices, and protocol-required procedures are commensurate with standard of care therapy.

This will generally be accorded only for trials whereby the risks of all agents or devices are reasonably known and predictable for the trial under consideration. If the study qualifies for this exemption, the sponsor must agree to indemnify UT for any qualifying medical expenses that are not covered by insurance.

- (7) For those studies not exempted under provision #6 above, the clinical trial agreement may condition the sponsor's responsibility on the requirement that a subject's insurance be billed first if:
  - (a) this is clearly communicated in the written informed consent form for the study;
  - (b) following an injury, the insurance company agrees that the any claims paid for protocol induced injury will not apply toward the subject's lifetime maximum benefit, and
  - (c) billing insurance does not violate Medicare rules or other applicable laws or regulations.

Prior to being billed for any injuries, the insurance company shall be informed that the subject participated in a clinical research trial. If the insurance company determines that claims paid for protocol-induced injuries will count toward the subject's lifetime maximum benefits, then the sponsor must fully indemnify UT as set forth in paragraph (c)(1) above. To accommodate the nature of this exemption that requires a determination after the execution of the clinical trial agreement, the sponsor must agree to indemnify UT for any qualifying medical expenses that are not covered by insurance, and any bills that the subject chooses to not have paid by their insurance because of a determination that the payment would count toward the subject's lifetime maximum. If a subject does not have a lifetime maximum benefit, then the subject's insurance may be billed under the parameters set forth in this section, and the sponsor shall indemnify UT for any medical expenses that are not covered by insurance.

- (8) The section of informed consent documents describing payment for protocol-induced injuries must:
- (a) Be written in accordance with the informed consent form template provided by the reviewing IRB;
  - (b) Accurately state how payment for treatment of protocol-induced injuries will be handled, whether or not payment is available;
  - (c) Accurately reflect the language in the clinical trial agreement or other form of sponsor commitment covering the topic of payment for subject injury; and
  - (d) Inform the subject if all or part of the research related injuries may be charged to their health care insurance. For example: "If you are injured directly from the study drug (or device) or study-required procedures, the Sponsor will pay for the reasonable costs of medical treatment to the extent they are not covered by your medical or hospital insurance. If your medical or hospital insurance is billed for injuries related to the study drug (or device) or procedures, the insurer will be informed that the bills are related to the research study you are participating in. No other form of compensation is available."

If there are no funds available to pay for the costs of treatment of subject injury, it must be stated clearly that treatment of subject injury will be provided by the University of Toledo Medical Center, but study subjects will be responsible for payment for this treatment.

(D) Definitions

- (1) "Clinical Trial" shall mean a research study involving human subjects that is designed to assess the safety, efficacy or both of drugs, devices, diagnostics, treatments, or preventive measures.
- (2) "Protocol-Induced Injuries" shall mean injuries directly resulting from interventions that study subjects would not have been exposed to had they not volunteered to participate in the clinical trial. Protocol-induced injuries do not include normal progression of the subject's disease, injuries or complications that they would have incurred had they not participated in the clinical trial, or injuries resulting from, or caused by, negligence or willful misconduct of university study personnel. The final determination of whether an injury is "Protocol-Induced" will rest with the UT Principal Investigator.

<p>Approved by:</p> <p><u>/s/ laj</u> Lloyd A. Jacobs, M.D. President</p> <p><u>May 28, 2009</u> Date</p> <p><i>Review/Revision Completed by: Vice President for Research Administration</i></p>	<p><b>Policies Superseded by This Policy Revision:</b></p> <p><i>None</i></p> <p>Initial effective date: June 1, 2008 Review/Revision Date: May 28, 2009 Next review date: May 28, 2012</p>
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