Name of Policy: **Compensation for treatment of injuries to subjects in covered commercially sponsored clinical trials** **Policy Number:** 3364-70-09 **Approving Officer:** President **Responsible Agent:** Vice President for Research **Scope:** **All** University of Toledo Campuses	 **Effective date**: August 12, 2024 **Original effective date:** June 1, 2008
Keywords:	

	New policy	X	Minor/technical revision of existing policy
	Major revision of existing policy		Reaffirmation of existing policy

(A) Policy statement

It is the policy of the university of Toledo ("UToledo") that clinical trial agreements for covered clinical trials will contain a provision by which the sponsor agrees to be responsible for the cost of diagnosis and treatment of study related injuries as set forth in this policy.

(B) Purpose of policy

The purpose of this policy is to set forth the conditions under which commercial sponsors of covered clinical trials must be responsible for the cost of diagnosis and treatment of study related injuries that result as a consequence of participation in the clinical trial.

(C) Policy

(1) Clinical trial agreements for covered clinical trials will be accepted by UToledo only if the sponsor agrees to fully indemnify the university for the reasonable and necessary costs associated with the diagnosis

and treatment for study related injuries, according to the following parameters:

(a) In clinical trials with no potential of direct benefit to study subjects, including phase one ("Phase I") trials and any phase clinical trial involving healthy subjects or clinical trials with a reasonable expectation of benefit to the study subjects, the sponsor must agree to fully indemnify UToledo for the reasonable and necessary cost of diagnosis and treatment for study related injuries without a requirement of billing a subject's insurance.

(b) In clinical trials with a reasonable expectation of benefit to study subjects, a request to waive the rule requiring full indemnification may be made to the vice president for research. Consideration in granting a waiver includes the phase of the trial, all known risks to human subjects, and other relevant business issues. When submitting a request for a full indemnification waiver, the requesting party must submit the protocol and proposed informed consent document, along with the phase of the study, all known risks to human subjects, and a summary of any relevant business issues. The vice president for research may consult with the dean of the college of medicine and life sciences and others within UToledo prior to making a decision.

(c) A waiver of under paragraph (C)(1)(b) of this rule allows a clinical trial agreement to be approvable without full indemnification to the university.

(d) A waiver under paragraph (C)(1)(b) of this rule must be issued in writing by the vice president for research, either via electronic mail or hard copy. A copy should be provided to the IRB contract manager and requesting party.

(2) This policy does not apply to the following, which will typically be post-approval studies:

(a) Clinical trials that utilize only pharmaceutical agents that are 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").

(D) Institutional review board reconciliation and approval of informed consent documents

The reimbursement language in the clinical trial agreement or associated waiver must be reconciled with the informed consent.

(E) Definitions

(1) "Clinical trial" is a research study involving human subjects designed to assess the safety, efficacy or both of drugs, devices, biologics, diagnostics, treatments, or preventive measures.

(2) "Covered clinical trial" is a human subject research study that is: (a) sponsored by a for-profit company, (b) employs a company-originated protocol, (c) includes investigational drugs, devices, or biologics, and (d) involves more than minimal risk to study subjects.

(3) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research: (a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(4) "Minimal risk" means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(5) "Phase I" clinical trials are designed to determine a safe dosage range, determine side effects, or to evaluate pharmacokinetic and/or pharmacodynamic properties of the drug in healthy subjects or patients with a medical condition and do not present an expectation of benefit.

(6) "Research" is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable

knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

(7) "Study-related injuries" are injuries, illness or complications arising from the performance of the study, or use of the investigational drug, device, or biologic. Study-related injuries do not include the 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 or university study personnel.

Approved by: /s/ Matthew J. Schroeder Interim President **Date:** August 12, 2024 **Review/revision completed by:** • *Vice President for Research* • *Senior Leadership Team*	**Policies superseded by this policy**: • *None* **Original effective date:** *June 1, 2008* **Review/revision date:** *April 7, 2011* *September 23, 2011* *August 19, 2019* *August 12, 2024* **Next review date:** *August 12, 2027*