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

New policy

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

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