(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 medical expenses arising from study related injuries as set forth in this policy. A Covered Clinical Trial is a human subject research study 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 study related injuries that result as a consequence of participation in the clinical trial.

(C) Procedures

1. 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 cost of treatment of study related injuries, according to the following parameters:
   (a) In clinical trials with no potential of direct benefit, including phase I trials and any phase clinical trial involving healthy subjects, the sponsor must agree to fully indemnify the university for the reasonable and necessary cost of diagnosis and treatment for study related injuries. A subject’s insurance may not be billed for study related injuries in these trials.
   (b) In clinical trials with a reasonable expectation of benefit to study subjects, the sponsor must agree to fully indemnify the university for the reasonable and necessary cost of diagnosis and treatment of study related injuries without billing the subject’s insurance. Waivers to this rule requiring full indemnification may be made by the Vice President for Research or the Chancellor and Executive Vice President for Biosciences and Health Affairs or the Provost and Executive Vice President for Academic Affairs. Considerations
in granting a waiver include the phase of the trial, all known risks to human subjects, and other relevant business issues. When submitting a request for a 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 or the Chancellor and Executive Vice President for Biosciences and Health Affairs Considerations may consult others with knowledge of the aforementioned topics prior to making a decision.

(c) A waiver under paragraph (C)(1)(b) above may be either an insurance waiver or a waiver of full indemnification. An insurance waiver permits Study Subject Insurance to be billed for reasonable costs of care when there are study related injuries. With an insurance waiver, the sponsor must agree in the clinical trial agreement to fully indemnify the university for unreimbursed costs of treatment for study related injuries. Because of this waiver requirement, Medicare or other governmental payors will not be billed for study related injuries. A waiver of full indemnification allows a clinical trial agreement to be approvable without full indemnification to the university.

(d) A waiver under paragraph (C)(1)(b) must be issued in writing, either via electronic mail or hard copy. A copy of the waiver should be provided to the Vice President for Research, the Chancellor and Executive Vice President for Biosciences and Health Affairs Considerations, the Director of the Jacobson Center for Clinical and Translational Research, and the Biomedical IRB Chairperson.

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

(a) Clinical trials that utilize only pharmaceutical agents approved for the age population under investigation 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).

(3) Institutional Review Board Reconciliation and Approval of Informed Consent Documents:

(a) The section of informed consent documents describing payment for study related injuries must be written in accordance with the informed consent form template provided by the reviewing IRB.

(b) The informed consent form approved by the IRB shall inform the subject if all or part of the medical expenses for research related injuries may be charged to their health care insurance due to the fact that (1) the subject may receive invoices for co-pays, deductibles and non-covered services, (2) the charges paid by insurance may impact the subject’s insurance coverage limitations, or (3) less than full indemnification for research related injuries is available. A copy of the fully executed clinical trial agreement or letter of indemnification must be provided to the Biomedical Institutional Review Board (IRB) prior to final IRB approval of the study. A copy of any written waiver granted under this policy must also be provided to the IRB. The IRB will review the injury indemnification language. The informed consent document will be approved by the IRB only if the language in the consent form accurately reflects the language in the clinical trial agreement or other form of sponsor commitment satisfying the requirements of this policy.

(D) Definitions

(1) "Clinical Trial" means 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) “Human Subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

(3) “Minimal risk” means that 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.

(4) “Study Subject Insurance” – means a non-governmental employer or commercial sponsored health plan, policy or program to pay for health care costs.

(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) "Study related injuries" means injuries or complications arising from the performance of the study in accordance with the protocol, or use of the investigational drug or device. 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 of university study personnel.

(7) “Research” is defined in the Federal Regulations as 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.

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Approved by:

/s/ laj
Lloyd A. Jacobs, M.D.
President

September 23, 2011
Date

Review/Revision Completed by:
Vice President for Research

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Policies Superseded by This Policy:

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