

Research & Sponsored Programs
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THE UNIVERSITY OF TOLEDO
MEDICAL CENTER

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TO WHOM IT MAY CONCERN:

It is the policy of The University of Toledo (UT) that clinical trial agreements, or other forms of sponsor commitment, for company-sponsored Clinical Trials, which employ company-originated protocols, must contain a provision by which the sponsor agrees to pay the full cost of treatment for Protocol-Induced Injuries (defined below) resulting from their participation in the study. For the purposes of this policy the term "Clinical Trial" shall mean a study, involving human subjects, designed to assess the safety and/or efficacy of drugs, devices, diagnostics, treatments, or preventive measures and the term "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. [NOTE: Protocol-Induced Injuries do NOT include normal progression of the subject's disease, conditions not directly resulting from interventions that the subjects would not have incurred had they not volunteered to participate in the study, or injuries resulting from, or caused by, negligence or willful misconduct of UT study personnel.]

COSTS FOR TREATMENT OF PROTOCOL-INDUCED INJURY TO SUBJECTS: Company-sponsored Clinical Trials of non-FDA approved drugs and devices using company-originated protocols which require review/approval at a convened meeting of a UT IRB or another IRB authorized by UT to review/approve UT-related research will be accepted by UTHSC only if the sponsor assumes full responsibility for the reasonable cost of medical treatment for Protocol-Induced Injuries to study subjects. It is not acceptable for a sponsor to restrict its responsibility for payment for treatment of Protocol-Induced Injuries to only those injuries directly associated with the administration/use of the study drug or device. Sponsor must also be responsible for injuries related to procedures/interventions that are performed solely to satisfy the requirements of the protocol. It is also not acceptable for the sponsor to limit its responsibility to immediate or emergency care for Protocol-Induced Injuries. Normally, this provision will be a part of the Clinical Trial agreement between UTHSC 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. It is not acceptable for such arrangements to require billing of third party insurance companies in lieu of recovery of such costs directly from the sponsor, nor is it acceptable for such agreements to include provisions restricting participation of human subjects on the basis of medical insurance coverage status or the subject's ability to pay.

Exemptions to this policy will be considered, on a case-by-case basis, for company-sponsored, clinical trials, which employ company-originated protocols for open-label, non-randomized studies which utilize only pharmaceutical agents approved by the FDA for sale in the U.S. in all arms of the study, and for Clinical Trials that involve the use of medical devices approved by the FDA for sale in the U.S., as well as those non-experimental/investigational (Category B) devices which have been approved for Medicare payment by the Centers for Medicare and Medicaid Services (CMS).

The section of informed consent documents describing payment for Protocol-Induced Injuries must reflect accurately the language in the Clinical Trial agreement or other form of sponsor commitment covering the topic of payment for subject injury. In the event that a Clinical Trial is deemed to be exempt from this policy, the informed consent documents must state accurately how payment for treatment of protocol-induced injuries will be handled, if such payment 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 University of Toledo Medical Center, but study subjects will be responsible for payment for this treatment.

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