3364-70-09 Compensation for treatment of injuries to subjects in covered commercially sponsored clinical trials.

(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 /devices or FDA approved drugs/devices for a new indication, 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 one ("Phase I") trials and any phase clinical trial involving healthy subjects or 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 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, a waiver to this rule requiring full

indemnification may be made by the vice president for research or the executive vice president for clinical affairs. Consideration 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 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 or the executive vice president for clinical affairs may consult others with knowledge of the aforementioned topics prior to making a decision.

(c) 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) of this rule 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 and the director of the Jacobson center for clinical and translational research.

(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”).

(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) A copy of the fully executed clinical trial agreement must be provided to the appropriate UT institutional review board ("IRB") prior to final IRB approval of the study. 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 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 (a) data through intervention or interaction with the individual, or (b) 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) "Phase I" clinical trials are designed to determine a safe dosage range, determine side effects, or to evaluate pharmacokinetic and/or pharmacodynamics properties of the drug in healthy subjects or patients with a medical condition and do not present an expectation of benefit.

(5) "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.

(6) "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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