TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.17, **Research Related Injury in Privately Sponsored Research Studies**

PURPOSE: The purpose of this Texas Tech Health Sciences Center El Paso (TTUHSCEP) Operating Policy and Procedure (HSCEP OP) is to establish requirements of responsibility for payment of medical expenses arising from research related injuries during a research study sponsored by private industry.

REVIEW: This HSCEP OP will be reviewed in October of every even-numbered year (ENY) by the Director of the Office of Research Resources (ORR) and the Director of the Office of Sponsored Programs (OSP) or designee, with recommendations for revision submitted to the Vice President for Research (VPR) or designee by December 15.

DEFINITIONS:

Research Study: is a human subject research study of a drug or device or the scientific evaluation of a drug or device, which conforms to the terms and conditions of a specified protocol.

Industry-sponsored Research: research sponsored or funded by a private for-profit company.

Investigator-initiated Research: a human Research Study initiated by a TTUHSCEP employee who has developed the original protocol, which may or may not be funded by a Sponsor.

Medical Treatment: the diagnosis or treatment of human injury, illness, or disease by a health care facility or by a licensed medical professional acting within the scope of his or her license.

Minimal Risk: 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.

Principal Investigator: The scientist or scholar under whose immediate direction the study procedures are carried out.

Protocol: written description of a Research Study which includes the study's objectives, design, and methods.

Reasonable and Customary Costs: the fair market value of the items or services provided to treat a subject injury.

Research Related Injury(ies): injuries, illnesses, complications and/or adverse events arising from performance of a Research Study in accordance with the Protocol or use of the investigational drug or device. Research Related injuries do not include the normal progression of the subject's disease, injuries, illnesses or complications that would have incurred had they not participated in the Research Study, or injuries resulting from, or caused by, negligence or willful misconduct of TTUHSCEP study personnel.

Research Study Agreement: a written, dated, and signed agreement between TTUHSCEP and the study sponsor that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. This document may also be titled a "Clinical Trial Agreement."

Research Subject: an individual who is or becomes a participant in research, either as a recipient of the study drug/device or as a control. A subject may be either a healthy human or a patient. Synonym: subject/study subject.

Sponsor: a private for-profit company that takes responsibility for the initiation and management of a research study, although it may or may not be the main funding organization.

Sponsor-initiated Protocol: a human research study initiated by or on behalf of a for-profit company in which the company provides the company originated protocol to TTUHSCEP or contracts with TTUHSCEP to develop a protocol on its behalf.

POLICY:

Federal Regulations [45 CFR 46.116(a)(6); 21 CFR 50.25(a)(6)] require that for research involving more than Minimal Risk, an explanation as to whether any compensation and an explanation as to whether any medical treatment is available if injury occurs and, if so, what it consists of, or where further information may be obtained. It is the position of TTUHSCEP that for research studies initiated by a Sponsor, conducted pursuant to a Sponsor-initiated Protocol, and involving more than Minimal Risk to Research Subjects, provisions must be made for the coverage of all costs of necessary treatment for any injury, illness, adverse event or complication that arises from medications, devices, interventions, procedures, or tests that a Research Subject would not have been exposed to had he or she not volunteered to participate in a research study.

PROCEDURE:

1. **Research Study Agreement Language**

a. During negotiation of a Research Study Agreement between TTUHSCEP and a Sponsor, language must be included which requires the Sponsor to pay for treatment of any illness or injury suffered by a Research Subject that results from participation in the Research Study. This language shall include an obligation for the Sponsor to provide the same level of medical care as described in the informed consent document signed by a Research Subject.

(i) Preferred Language:

Sponsor will pay Institution and/or any other emergency care provider for all reasonable and customary fees incurred and billed for standard-of-care diagnosis and treatment, including hospitalization, of any injury, illness, or adverse reaction of a research subject that results from the administration of the study drug/device in accordance with the Protocol or the proper performance of any Protocol procedure, provided such injury was not caused by the negligence of TTUHSCEP, its officers, agents, employees, or Principal Investigator or the failure of TTUHSCEP or Principal Investigator to follow the Protocol or comply with applicable law. TTUHSCEP may arrange for care for any research related injury. This section shall survive termination of this Agreement.

b. Prior to execution of the Research Study Agreement, OSP and ORR, will compare the Research Study Agreement to the informed consent document approved for the study by the TTUHSCEP Institutional Review Board (IRB) to confirm that the language between the two documents is consistent. If the language is inconsistent, one of the documents must be modified appropriately to reflect the agreement of the parties. If the informed consent document is modified, then it must be reapproved by the IRB.

c. In addition, it is the policy of TTUHSCEP that no Research Study Agreement will permit a Sponsor to limit indemnification for its own acts or omissions, or to shift to Research Subjects its indemnification risk with respect to claims or causes of action that arise from the Sponsor's conduct, whether related to the manufacturing, distribution or quality of a test article, or with respect to the actions of the Sponsor in design, conduct and reporting of the research.

d. Exceptions to this policy require review and written approval by the TTUHSCEP VPR.

2. **Industry-Sponsored Research Studies With Greater Than Minimal Risk:**

a. For Industry-sponsored research studies involving greater than Minimal Risk, the Sponsor is responsible to pay for the cost of care for Research Related Injuries. In providing this coverage the Sponsor is not allowed to condition coverage on the Research Subject first obtaining a denial from third party insurance companies, government programs or other third party; nor may the Sponsor require TTUHSCEP to bill third party insurers.

(i) Approved TTUHSCEP informed consent language for Industry-sponsored Research studies greater than Minimal Risk:

Texas Tech University Health Sciences Center El Paso and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, the Sponsor will provide payment for extra unanticipated tests, treatments, and hospitalizations unless such expenses were due to: (i) TTUHSCEP's and Principal Investigator's failure to strictly adhere to the terms of the Protocol; (ii) the negligence or misconduct of TTUHSCEP or its employees or agents; or (iii) a pre-existing medical condition or your underlying disease. You or your medical or hospital insurance company is not responsible for any costs of extra treatment.

If you think you have a research related illness or injury, you should promptly notify the Principal Investigator and seek care as you normally would. If you or your insurance company is billed for treatment for an illness or injury that is determined to be related to this Research Study, TTUHSCEP and your Principal Investigator will work with the Sponsor to reimburse you or the insurance company for the cost of that care.

3. **Investigator-Initiated Research or Industry-Sponsored Studies Involving No Greater Than Minimal Risk:**

a. For TTUHSCEP Investigator-initiated Research or Industry-sponsored Research involving no greater than Minimal Risk of harm a statement is required in the informed consent document to inform the patient that Medical Treatment(s) will be available if a Research Related Injury occurs and, if so, what is available, and where further information may be obtained [45 CFR 46.116(a)(6); 21 CFR 50.25(a)(6)].

b. For TTUHSCEP Investigator-initiated Research: Generally, an industry Sponsor will not be responsible for any Research Related Injuries of Research Subjects. However, injury liabilities will be negotiated on a case-by-case basis for Investigator-initiated Research, and will be dependent upon the specifics of the work being performed and the drugs or devices provided by the Sponsor.

(i) Approved informed consent language for Investigator-initiated Research and Industry-sponsored Research involving no greater than Minimal Risk:

Texas Tech University Health Sciences Center El Paso and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.