[redacted]

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER Operating Policy and Procedure (HSC
is to establish requirements of responsibility for payment of medical expenses aris
from research related injuries during a research study sponsored by private industry.

REVIEW: This HSC OP will be reviewed in October of every even-numbered year (ENY)
Asst. Vice President for Sponsored Programs and the Asst. Vice President of Re
Integrity, with recommendations for revision forwarded to the Senior Vice Presid
Research & Innovation (SVPRI).

DEFINITIONS:

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

Investigator-initiated Research: a human Research Study initiated by a Texas Tech University Health Sciences Center (TTUHSC) 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: the wri5.7 (oc)-3DC uttreat a subject injury.

Research Related Injury(ies): injuries, illnesses, complications or adverse events arising from the 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 TTUHSC study personnel 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 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 TTUHSC or contracts with TTUHSC 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 TTUHSC 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 the Research Study.

PROCEDURE:

1. **Research Study Agreement Language**

   a. During negotiation of a Research Study Agreement between TTUHSC 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. pon 143 Td( )

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