Institutional Handbook of Operating Procedures Policy 11.01.06	
Section: Research Services	Responsible Vice President: Executive Vice President and Provost
Subject: General Research	Responsible Entity: Research Services

I. Title

Research Related Injury of a Subject Participating in a Clinical Investigation

II. Policy

Federal regulations require that prospective subjects be provided with information "for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments will be provided if an injury occurs and if so, what they consist of, or where further information may be obtained." Those regulations also prohibit any informed consent, oral or written, from including "any exculpatory language through which the subject or their representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence".

UTMB Health is dedicated to the protection of persons who participate in research as human subjects. Protecting subjects requires respecting and enforcing regulations that prohibit requiring subjects to waive their rights to compensation and proactively using methods reasonably calculated to provide for direct medical care of a subject without any need for legal recourse by a subject.

In situations where a subject could cover the cost of research-related treatments insurance, insurance may be billed consistent with applicable laws, agreements, and regulations. In situations where insurance will not cover treatment for research-related injuries or illness or the subject is uninsured, UTMB Health will provide acute treatment at no cost to the subject, but will not cover costs at another facility except by special arrangements made and approved by the Provost or their designee. UTMB Health does not routinely cover long-term care although this does not preclude the subject exercising their legal rights. All claims are subject to limitations provided by Texas Torts Claims Act.

Industry-Sponsored Research

As part of the clinical trial agreement negotiations, the sponsor will be required to pay for treatment of illness or injury suffered by a research subject that directly results from participation in the research. These terms are negotiated as part of the clinical trial agreement (sample clauses from UTMB Health's clinical trial contract template can be found in Addendum A).

In addition, it is the policy of UTMB Health that no clinical trial contract shall permit the sponsor to limit its own indemnification, or shift to subjects its indemnification risk with respect to claims or causes of action that arise from the conduct of the sponsor, 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.

Exceptions to this policy require review and approval by the UTMB Executive Vice Presidents.

Government-, Philanthropic- or UTMB- Funded Research

In situations where the funding source is the government, a philanthropic institution or foundation, or UTMB itself, UTMB Health will provide reasonably necessary acute treatment for an injury or illness

suffered by a human subject which is directly related to participation in the study, provided that the IRB has approved the study and the investigator has performed it in the manner in which the IRB has approved it.

For government-funded, philanthropically funded, and internally funded research, coverage is limited by the following terms:

- The injury or illness must be a direct result of the subject's participation in a research study. In consultation with the Principal Investigator, Risk Management will determine whether the illness or injury is the direct result of the research activity (including events resulting from study drugs, biologics or devices; as well as events resulting from tests, procedures, and evaluations required by the protocol). Risk Management at their sole discretion may request independent review of relationship of the injury or illness to the study participation.
- The subject must have notified UTMB Health within 30 days following discovering the research related injury or illness, and consideration of this timetable should be included in patient consent language.
- The injury or illness must not be simply the normal progression of the subject's disease or underlying illness.

Violation of this policy may result in disciplinary action up to and including termination for employees; a termination of employment relationship in the case of contractors or consultants; or suspension or expulsion in the case of a student. Additionally, individuals might be subject to loss of access privileges and civil and/or criminal prosecution.

III. Procedures

A. Informing Subjects

All consent forms that involve research with greater than minimal risk will contain the research injury statements found in the IRB approved consent template.

Investigators are responsible for discussing obligations for research related injuries as part of the informed consent process.

B. Notification Procedure for suspected Research Related Injury

If the investigator becomes aware of a subject injury or illness for which UTMB Health is financially responsible for under this policy, the is required to notify:

- Risk Management
- IRB: Unanticipated Problem or Adverse Event Reporting per policy

Risk Management will be responsible for further notification to the appropriate individual and communication to the Investigator as to the authorization of treatment under this policy.

IV. Definitions

Acute Treatment: Are inpatient medical care, outpatient medical care and other related services for surgery, acute medical conditions, or injuries, usually for a short-term illness or condition. Short-term rehabilitative services lasting no more than sixty (60) days associated with a research related injury might be covered under this definition on a case-by-case basis, as determined by Risk Management. This care would not encompass long-term rehabilitative services, long term nursing home care or Long Term Acute Care (LTAC) hospitalization care.

Clinical Trial: is a research study involving human subjects that is designed to seek basic biological knowledge or assess the safety, efficacy or both of drugs, devices, diagnostics, treatments, or preventive measures.

Human Subject: is 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.

Minimal Risk: is the probability and magnitude of harm or discomfort anticipated in the research is 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.

Study Subject Insurance: is a non-governmental employer or commercial sponsored health plan, policy or program to pay for health care costs.

Study Related Injuries: are 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 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.

Research: as 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.

V. Relevant Federal and State Statutes

Protection of Human Subjects - General Requirements for Informed Consent 21 CFR 50.20
Protection of Human Subjects - IRB Records 45 CFR 46.116

VI. Dates Approved or Amended

Originated: 09/07/2012	
Reviewed with Changes	*Reviewed without Changes*
	6/21/2016

VII. Contact Information

Research Services
(409) 266-9400