

Approved by IRB Executive Committee: April 2, 2008
Supersedes Document Dated: December 12, 2005; May 1, 2004
AAHRPP Element IV.1.B.

POLICY

The University of Utah Institutional Review Board will assure that research participants have knowledge of compensation and treatment availability for injury that may occur as a result of participation in research activities. This policy does not apply to remuneration or other compensation for research participation. For commercially sponsored studies, compensation or payment of immediate necessary care for injury related to participation in research activities shall be provided according to the Informed Consent Document. The contractual agreement between the sponsor and the University of Utah made through the Office of Sponsored Projects will have a general statement which explains that the description of who will be responsible for medical care costs stemming from research related injuries is found in the Informed Consent Document.

PROCEDURES

1. The Investigator will insert language into the informed consent document regarding immediate necessary care in the event of a research related injury.
2. For research conducted at the Veteran Affairs Salt Lake City Health Care System (VASLCHCS) with participants who are veterans, the investigator will insert language regarding the immediate necessary care in the event of a research related injury.
3. For commercially sponsored studies, the investigator will include language regarding compensation or payment of immediate necessary care for injury related to participation in research activities. The contractual agreement between the sponsor and the University of Utah made through the Office of Sponsored Projects will have a general statement which explains that the description of who will be responsible for medical care costs stemming from research related injuries is found in the Informed Consent Document.
4. The IRB will review and approve the proposed compensation and injury language as a part of the new study submission.
5. The IRB will render its determination for approval of compensation or medical treatment for medical injury as follows:
 - 5.1. The IRB will verify that the template language for injury is contained in the informed consent document.
 - 5.2. The IRB will review the injury language to assure readability and understandability, and non-exculpation in relation to the proposed target study population.
6. In the event the sponsor requests conflicting language in the contract during negotiation with the Office of Sponsored Projects, the contract may not be finalized until the Informed Consent Document is verified to be congruent with the sponsor's contract language. The Office of Sponsored Projects and the IRB staff

will work together to ensure the accuracy of the language. If any changes are made to the approved Informed Consent Document, they must be approved by the IRB.