

**University of California, Irvine
Human Research Protections
Standard Operating Policies and Procedures**

Policy Number: 26

Title: Compensation for Injury that Occurs During Participation in Research

Date of Last Revision: 08/10/2005, 09/23/2019, 09/25/2019, 09/15/2022

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to assure that research participants have knowledge of compensation and treatment availability for injury that may occur as a result of participation in research activities.

- I. For studies that involve greater than minimal risk, unless waived by the IRB, all participants must be provided with an explanation in the consent form as to whether any medical treatments are available if injury occurs and, if so, what they consist of and where further information may be obtained.

- II. 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 contractual agreement between the sponsor and UC Irvine. In general, if a participant is injured as a direct result of participation in this study, the sponsor is required to reimburse the University for reasonable and necessary medical care to treat the injury. Contractual agreements are negotiate through Sponsored Projects in the Office of Research Administration.

References:

45 CFR 46

UC Operating Requirement No. 95-5: Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects

OHRP Report Emergency Medical Care, May 15, 1991.

Procedure Number: 26.A

Title: Procedure for Compensation for Medical Treatment if Injury Occurs During Participation in Research

Procedure:

This procedure provides guidance for compensation or medical treatment if injury occurs while participating in research conducted at UCI or by UCI investigators as part of their institutional responsibilities.

I. Lead Researcher (LR) Responsibilities

- A. The LR conducting greater than minimal risk research must ensure that UCI template language regarding compensation for immediate necessary care for study-related injury is included in the informed consent document template. The informed consent template is located on the IRB website at <https://research.uci.edu/human-research-protections/irb-forms/> under "IRB Consent Forms."
- B. Sponsors often request different wording for the treatment and compensation for injury policy statement, minor changes to the UC statement, or conditions for when the sponsor will pay for injury. **Such requests cannot be honored.** The wording of the statement was formulated with the advice of UC legal counsel with the intent of adhering to the requirements of federal regulations and UC's subject injury policy. The sponsor may include its name or the sponsor may remain silent on this point, in which case the reference to the sponsor should be removed from the treatment and compensation for injury policy statement. The clinical trial contract language specifies under what conditions and process a Sponsor has a duty to reimburse the University for any costs the University incurs in meeting its obligation to participants.

II. IRB Committee Responsibilities

- A. The IRB will review and approve the proposed compensation and injury language as a part of the new study submission.
- B. The IRB will render its determination for approval of compensation or medical treatment for medical injury as follows:
 - 1. The IRB will verify that the template language for injury is contained in the informed consent document.
 - 2. The IRB may verify that the compensation language is congruent with the sponsor's contract as approved by Sponsored Projects in the Office of Research Administration.
 - 3. The IRB will review the injury language to assure readability and comprehension in relation to the proposed target study population.
 - 4. For studies that involve an IRB reliance, UCI will maintain consent template injury language, as applicable in the UCI consent form/ document and for those sites where the UCI Lead Researcher is engaged in conducting research at the non-UCI site.

III. IRB Administrator Responsibilities

- A. The Administrator will review the informed consent documents verifying

that the UCI template language for compensation for immediate necessary care is detailed in the informed consent document.

- B. The Administrator may verify with Sponsored Projects that the compensation for injury language in the sponsor's agreement is congruent with the compensation for injury statement in the informed consent document.