

Guidance and Procedure: Treatment and Compensation for Research-Related Injury (last updated April 8, 2013)

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Introduction

For studies that involve more than minimal risk, Federal regulations require informed consent documents to contain information on the availability and nature of compensation and medical treatments available if injury occurs, what they consist of, and where further information may be obtained. UCLA investigators and the IRBs share responsibility for complying with University of California policy and operating guidance relating to treatment and compensation for research-related injury.

University of California Subject Injury Policy

The University of California will provide to any injured subject any and all medical treatment reasonably necessary for any injury or illness which a human subject suffers as a direct result of participation in an authorized University activity covered by University policy on the protection of human subjects in research or reimburse the subject for the costs of such treatment, ***except when the injury or illness is a consequence of a medical research procedure which is designed to benefit the subject directly.***

This obligation of the University shall be subject to the following conditions:

- It must be demonstrated that the ***injury resulted directly from participation*** in the specified activity.
- ***Written notification*** of any such injury is to be given to the University by the human subject within a reasonable time after discovery.
- Any claim for reimbursement is to be supported by ***appropriate documentation***.

It is the preference of the University that the medical treatment available under this policy be provided at a University of California medical facility.

Standard Wording Required in UCLA Informed Consent Documents

The UCLA treatment and compensation for injury statement is a ***required element of the consent form for greater than minimal risk research*** as determined by the UCLA IRB. The wording of the UCLA treatment and compensation for injury statement was formulated with the advice of UC General Counsel with the intent of adhering to the requirements of federal regulations and the UC subject injury policy.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor [sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.”

IMPORTANT NOTE: The references to the sponsor's provision of compensation should be inserted *only* if they accurately reflect the sponsor's policy. See below for more information.

Working with Industry Sponsors

Requests from Industry Sponsors to Change or Alter Standard Wording:

Sponsoring companies often request that their own wording be used for the treatment and compensation for injury policy statement or that minor changes be made in the UC statement. Such requests *cannot* be honored, except as noted below. The wording of the statement was formulated with the advice of General Counsel with the intent of adhering to the requirements of the federal regulation, and conveying the basic, necessary information to the subject.

Industry sponsor's have three options regarding provisions for treatment and compensation for injury in the consent form:

- First, the sponsor may include its name in the UCLA statement as written above.
- Second, the sponsor may remain silent on this point, in which case all reference to the sponsor should be omitted from the above statement, although the sponsor will be identified elsewhere in the form.
- Third, a brief paragraph (one or two sentences) may be added *below and separate from* the UCLA statement to explain the sponsor's policy. However, any description of the sponsor's policy must state what the sponsor *will* cover, not what it will *not* cover. As a further limitation, the sponsor's statement may not make reference to third party carriers, government programs, or lost wages.

The IRB does not have the authority to negotiate consent form language with respect to sponsor indemnification other than what is noted above. Any other changes will result in delays to IRB approval as they cannot be approved, except in the rarest of circumstances and with approval from UCLA Legal Counsel and/or UC General Counsel.

Agreements with Private Industry Sponsors:

Contact the Clinical Trials Administration Office (CTAO) for information about clinical contracts. The CTAO's [For Faculty/Staff](#) web pages are for INTERNAL USE ONLY and access is restricted to UCLA employees. To obtain log-in credentials to access these pages, please contact the Clinical Trials Administration Office at 310-794-8322 or clinicaltrials@mednet.ucla.edu

The clinical trial contract language specifies under what conditions and process a sponsor has a duty to reimburse the University for the costs the University incurs in meeting its obligation to participants. This information does not belong in the consent form.

For studies that are initiated by an industry sponsor, UC Operating Requirement 95-05, which governs these agreements, requires industry sponsors to assume responsibility for reimbursing the University for the reasonable costs of medical treatment for injuries directly resulting from participation in the study. This policy does not allow the billing of third party insurance companies in lieu of recovery of such costs from the sponsor, nor does it allow restricting participation of human subjects on the basis of medical insurance coverage status or on the participant's ability to pay.

UCLA Informed Consent Document Requirements for MMSEA 111

Section 111 of the Medicare, Medicaid and S-CHIP Extension Act, referred to as "[MMSEA 111](#)", requires liability insurers to report on certain payments made to or on behalf of Medicare beneficiaries in order to facilitate enforcement of the Medicare Secondary Payer rules. Such reports are required by law, may be a prerequisite to securing payment from sponsors for diagnosis or treatment of complications or injuries caused by a patient's participation in research, and qualify as coordination of benefits activities. Occasionally, sponsors request that information about this requirement be added to the consent form. Please use the following required UC treatment and compensation injury statement that includes information about [MMSEA 111](#):

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor [sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. If the study sponsor covers these costs they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu."

References and Regulations

DHHS Regulations:

- Elements of Informed Consent: [45 CFR 46.116\(a\)\(6\)\(7\)](#)

FDA Regulations

- Elements of Informed Consent: [21 CFR 50.25\(a\)\(6\)\(7\)](#)

References:

- [UC Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research](#)
- [UC Operating Requirement 95-05: Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects](#)