

Policy Number: 33

Title: Emergency Care and Compensation for Injury

Date of Last Revision: July 5, 2007

I. Introduction

UCLA investigators and the UCLA IRB share responsibility for complying with University of California *Policy for Medical Treatment of Human Subjects for Injuries Resulting From Participation in Research*, and ensuring that, for all research involving more than minimal risk¹, subjects are provided with an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.²

II. University of California Policy

- A. 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.
- B. The obligation of the University to provide treatment as described in ‘A’ shall be subject to the following conditions:
1. It must be demonstrated that the injury resulted directly from participation in the specified activity.
 2. Written notification of any such injury is to be given to the University by the human subject within a reasonable time after discovery.
 3. Any claim for reimbursement is to be supported by appropriate documentation.
 4. It is the preference of the University that the medical treatment available under this policy be provided at a University of California medical facility.

¹ **Minimal risk**, as defined by the federal regulations, is "where the probability and magnitude of harm or discomfort anticipated in the proposed 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". [45 CFR 46.102(i)]

² 45 CFR 46.116(a)(6) and 21 CFR 50.25(a)(6)

- C. Agreements with private industry sponsors must make explicit that the sponsor assumes responsibility for reimbursing the University for the reasonable cost of medical treatment for injuries directly resulting from participation in the study. It is not acceptable for such agreements to require billing of third party insurance companies in lieu of recovery of such costs from the sponsor, nor is it appropriate to accept provisions restricting participation of human subjects on the basis of medical insurance coverage status or on the subject's ability to pay.
- D. Applicable University of California policies are appended to this policy.

III. Informed Consent Requirements

- A. A statement regarding "Emergency Care and Compensation for Injury" is a required element of the consent form for all research that presents more than minimal risk as determined by the UCLA IRB. Investigators should explain in the consent form whether any compensation/medical treatments are available if injury occurs and, if so, describe the extent and nature of the compensation.

- B. The standardized language currently approved by the University of California for research which is privately sponsored describes compensation for research-related injuries as follows:

If you are injured as a direct result of research procedures, you will receive treatment at no cost. The University of California does not normally provide any other form of compensation for injury.

- C. The standardized language currently approved by the University of California for research which is not privately sponsored describes compensation for research-related injuries as follows:

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not normally provide any other form of compensation for injury.

- D. Investigators may not modify the language listed in B and C above with the exception of modifying the second sentence to also list the sponsor as not providing any other form of compensation for injury. Listing the sponsor in that sentence is optional.

IV. Investigator Responsibility

- A. UCLA Investigators are responsible for complying with all applicable University policies regarding emergency care and compensation for injury for research subjects.

- B. UCLA Investigators must include - in all consent forms for research involving more than minimal risk – the University of California-approved language in Section III above to describe compensation and/or medical treatments available if injury occurs.

V. IRB Responsibility

- A. The UCLA IRB will ensure that all consent forms for research involving more than minimal risk include the University of California-approved language in Section III to describe compensation and/or medical treatments available if injury occurs.

Regulations:

- 45 CFR 46.102(i)
45 CFR 46.116(a)(6)
21 CFR 50.25(a)(6)

Attachments:

- OPRS-8 UCLA OPRS Human Research News, "Guidance Documents- Descriptions of Emergency Care & Compensation for Injury in Consent Forms," March 16, 2006.
http://www.oprs.ucla.edu/human/news/item?item_id=149247
- UC-6 University of California Presidential Memorandum, "University Policy for Medical Treatment of Human Subjects for Injuries Resulting From Participation in Research", January 19, 1979.
<http://www.ucop.edu/research/policies/ucpols.html>
- UC-11 University of California Presidential Memorandum, "Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects", February 3, 1995.
<http://www.ucop.edu/research/policies/ucpols.html>