RPAC Research Policy Analysis & Coordination
Office of Research & Graduate Studies
University of California, Office of the President

Memo

Operating Guidance

No. 13-01

February 6, 2013

To: Clinical Trial Negotiators
Contract & Grant Officers

Subject: Guidance on Issues Relating to Subject Injury in University of California Research

Purpose

This memorandum clarifies UC Operating Requirement No. 95-5, University of California requirements regarding sponsor reimbursement of medical treatment where the University research is conducted pursuant to a private sponsor's protocol.

University policy requires that, subject to certain conditions, in the event that a human research participant is injured as a direct result of his or her participation in an authorized University research activity, the University must provide all reasonably necessary medical treatment to the subject (Presidential Memorandum of January 19, 1979). Moreover, where the injuries are a direct result of a subject's participation in a study testing an intervention (such as a drug, device, biologic, gene therapy, or new therapeutic system) pursuant to a private sponsor's protocol, the sponsor must assume responsibility for reimbursing the University for the reasonable cost of such treatment. (UC Operating Requirement No. 95-5.)

UC Operating Requirement No. 95-5 does not require payment for complications or other injuries that do not directly result from participation in University research, such as injuries or illnesses due to normal or expected disease progression or those resulting from care that would have been provided regardless of the subject's participation in the research. However, private sponsors must reimburse the University for the treatment and diagnosis of injuries directly resulting from a subject's participation in research, even if the purpose of the intervention causing the injury was intended to benefit the subject directly.

Background

On February 15, 1995, the University, through Operating Requirement No. 95-5, provided requirements regarding the provision or reimbursement of medical treatment to subjects participating in the testing of drugs or devices pursuant to a private sponsor's protocol. Certain terms of UC Operating Requirement No. 95-5 have been subject to varying interpretation.

This memo provides guidance on the meaning of the highlighted terms in UC Operating Requirement No. 95-5:

> In cases where a proprietary drug or device is to be tested under the **private sponsor's protocol**, an agreement between the sponsor and The Regents must be signed by a University official who has been delegated authority for contracts and grants. Such an agreement should be in process prior to the protocol being submitted to the IRB for review. In any case, IRB final approval will be contingent upon completion of an appropriate signed agreement between the University and sponsor. The agreements are subject to applicable policies and procedures, including those promulgated by in the University of California Contract and Grants Manual, and must be reported in the Corporate Contracts and Grants System.
>
> The agreement 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.

1. Private Sponsor's Protocol

Definition: A human clinical trial initiated by or on behalf of a pharmaceutical, biologic or device company in which the company provides the study protocol to the University or contracts with the University to develop a protocol on its behalf.

2. Reimbursing the University

Definition: Costs incurred directly by the University, other health care providers, or the study subject.

Operating Requirement No. 95-5 does not preclude the University from seeking sponsor payment directly to a non-UC facility for treatment provided by the non-UC facility. Similarly, the University may also require the sponsor to directly reimburse the subject for any costs of treatment the subject has directly incurred.

3. Reasonable Cost

Definition: The fair market value of the items or services provided to treat a subject injury.

4. Medical Treatment

Definition: Diagnosis or treatment of human injury, illness, or disease by a health care facility or by a licensed medical professional acting within the scope of his or her license.

5. Directly Resulting

Definition: A result that would not have occurred but for the subject's participation in the trial.

UC Operating Requirement No. 95-5 requires the sponsor to reimburse for injuries that extend beyond those caused by a study drug or device – including, for example, injuries that may result from failures of the subject to follow protocol procedures, or the study subject's negligence. However, sponsors are not obligated to reimburse the University for the following injuries or illnesses, to the extent the injury or illness is due to the: (i) failure of the University or its employees to follow a sponsor's protocol or the sponsor's written instructions regarding use of the study drug or device or the conduct of the study; (ii) failure of the University or its employees to comply with FDA or other government requirements with respect to the conduct of the study; (iii) negligence or willful misconduct of the University or its employees; or (iv) natural progression of the subject's disease or a preexisting condition.

It is the responsibility of the institution, not the investigator, to determine whether an injury or illness is the "direct result" of participation in a clinical trial.

Contact:

Hillary Kalay
Hillary.Kalay@ucop.edu
(510) 987-0355

Wendy D. Streitz
Executive Director
Research Policy Analysis and Coordination