

**Guidance and Procedures Number: 32
Title: Financial Obligations
Date of Last Revision: July 5, 2007**

I. Introduction

UCLA investigators and the UCLA IRB have a shared responsibility to comply with Federal, State, and University policies regarding research subjects' financial obligations, and to ensure that subjects are informed of any additional costs to the subject that may result from participation in the research.¹

II. University of California Policy for Research Sponsored by Private Sponsors

- A. The cost of clinical trials of drugs or devices conducted according to the sponsor's protocols should always be fully funded by the sponsor and not supported in whole or in part with other funds, including gift or foundation funds.
- B. All costs associated with the conduct of the clinical trial must be charged to the clinical trial fund and should not be charged to other University funds or be billed to third party medical insurance, unless FDA approval for such charge is documented.
- C. The Chancellor may approve exceptions to the above requirements in individual cases in areas within his/her jurisdiction when it is in the best interest of the University.
- D. Approval by The Regents is required in all cases where the University assumes liability for a third party's actions.
- E. The sponsor must assume responsibility for reimbursing the University for reasonable cost of medical treatment for injuries directly resulting from participation in the study.
 - 1. 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.
- F. Applicable University of California policies are appended to this guidance.

III. Investigational Devices

- A. A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not commercialize an investigational device by charging the subjects or

¹ 45 CFR 46.116(b)(3) and 21 CFR 50.25(b)

investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.²

- B. If subjects will be charged for an investigational device, investigators are required to submit documentation from the FDA indicating the amount that subjects may be charged. IRB approval is contingent upon receipt and acknowledgement of such a document from the FDA.

IV. Investigational Drugs

- A. Charging for an investigational drug in a clinical trial under an Investigational New Drug exemption [IND] is not permitted without the prior written approval of FDA.³ IRB approval of such charges is contingent upon receipt of documentation of FDA approval.
- B. A sponsor or investigator may charge for an investigational drug for a treatment use under a treatment protocol or treatment IND provided:⁴
 - 1. There is adequate enrollment in the ongoing clinical investigations under the authorized IND;
 - 2. charging does not constitute commercial marketing of a new drug for which a marketing application has not been approved;
 - 3. the drug is not being commercially promoted or advertised; and
 - 4. the sponsor of the drug is actively pursuing marketing approval with due diligence.
- C. The charge shall not be larger than that necessary to recover costs of manufacture, research, development, and handling of the drug or biologic.
- D. The sponsor or investigator must notify the FDA in writing in advance of commencing any such charges.
- E. Authorization for charging goes into effect automatically 30 days after receipt by FDA of the information amendment, unless the sponsor is notified to the contrary.⁵
- F. Investigators must provide to the IRB written assurance of FDA notification of such charges.

V. Investigator Responsibility

- A. UCLA Investigators are responsible for complying with all applicable Federal, State, and University policies regarding research subjects' financial obligations, including, but not limited to those described elsewhere in this guidance.

² 21 CFR 812.7(b)

³ 21 CFR 312.7(d)

⁴ 21 CFR 312.34 and .35

⁵ 21 CFR 312.7(d)

- B. UCLA Investigators must include the following in their application to the UCLA IRB:
1. a description of the financial obligations which the subjects will incur as a result of participating in the study, if any;
 2. an explanation of the party responsible for the cost of procedures associated with the research and those associated with standard clinical care, if applicable; and
 3. specification of which procedures are being conducted solely for research purposes and which are conducted as part of standard of care, if applicable.
- C. UCLA Investigators must include the following in consent forms for research where subjects may incur costs as a result of participating:
1. describe the financial obligations which the subjects will incur as a result of participating in the study (e.g., for physician fees, hospital charges, medication, pharmacy preparation and dispensing charges, laboratory tests, post-treatment follow-up, etc.);
 2. indicate if drugs, devices, tests or services will be provided free-of-charge;
 3. explain the party responsible for the cost of procedures associated with the research and those associated with standard clinical care, and specify which procedures are being conducted solely for research purposes and which are conducted as part of standard of care;
 4. advise potential subjects that most health benefit plans do not cover experimental treatments; and
 5. indicate that their insurance company(ies) will be billed, if applicable.

VI. IRB Responsibility

- A. The UCLA IRB will ensure that research where subjects may incur costs as a result of participating complies with all applicable Federal, State, and University policies regarding research subjects' financial obligations.
- B. The UCLA IRB will ensure that financial obligations of the subjects relative to participation in the study are reasonable and do not unnecessarily pose additional financial burden on the subjects.
- C. The UCLA IRB will ensure that consent forms for research where subjects may incur costs as a result of participating fully inform subjects of the information outlined in Section V(C).

Regulations:

45 CFR 46.102(i)
45 CFR 46.116(b)
21 CFR 50.25(b)
21 CFR 312.7(d)
21 CFR 812.7

References:

FDA, *IRB Information Sheets: Charging for Investigational Products*, September 1998.
<http://www.fda.gov/oc/ohrt/irbs/toc4.html#products>

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>

University of California Presidential Memorandum, "University Policy on Protection of Human Subjects in Research", September 2, 1981. <http://www.ucop.edu/research/policies/ucpols.html>

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>