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Subject: Requirements for Administration of Agreements with Private Sponsors for
Drug and Device Testing Using Human Subjects

Enclosed is a statement outlining the Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects. Please note that the requirements only apply to testing of a private sponsor's proprietary product according to the sponsor's protocol; the requirements do not apply to drug or device development and testing under a University-initiated protocol that is financed intramurally or federally. At this time we are not issuing a systemwide indirect cost rate for these agreements. Under existing policy, each campus may request approval for an alternative indirect cost rate to be applied to these agreements.

Questions concerning specific aspects of these requirements can be directed to the Vice Provost for Research, the Research Administration Office, or the Office of Risk Management, as appropriate.

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Enclosure

**Requirements for Administration of Agreements with Private Sponsors
for Drug and Device Testing Using Human Subjects**

Background

The University Policy on the Protection of Human Subjects in Research (September 2, 1981) and the University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research (January 19, 1979) place special responsibilities upon the University for review, approval, performance, and monitoring of research involving human subjects. Problems can arise if the company for whom the clinical trial is being conducted enters into an agreement directly with a faculty member or with a legal entity other than the University, such as a foundation, for work which is to be conducted at the University or which will be conducted by a faculty member as part of his/her University obligations. These arrangements are contrary to the University Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University (December 15, 1994) and compromise the ability of the University Institutional Review Board (IRB) to perform duties mandated by Department of Health and Human Services regulations (45 CFR Part 46) and by Food and Drug Administration regulations (21 CFR Parts 50 and 56). Further, the University may be exposed to claims of liability for the faculty member's and the third party's actions, and other financial obligations pursuant to the University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research.

In consideration of these and other important issues concerning the conduct of research involving human subjects, and to insure minimum standards for acceptance and administration of agreements for testing proprietary drugs or devices for private entities, the following uniform requirements are established. These requirements do not apply to drug or device development and testing under a University-initiated protocol financed intramurally or federally.

I. Formal Agreement

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 in the University of California Contract and Grant Manual, and must be reported in the Corporate Contracts and Grants System.

II. Reimbursement for Injury

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.

III. Indemnification and Insurance

For sponsor-initiated clinical trials, the agreement must require the sponsor to indemnify, defend, and hold harmless the University from any claim or costs of injury or damage arising out of performance of the study, except when the claim or cost is due to the University's negligence or failure to comply with the study protocol. When a clinical trial management firm or other intermediary organization is contracting for the study on behalf of the drug or device manufacturer, evidence of indemnification by the manufacturer may be substituted for indemnification from the intermediary organization. In cases where the sponsor may not have adequate insurance or resources to cover its potential liability, the campus risk manager should be consulted about insurance requirements to be included in the agreement.

IV. Conflict of Interest Disclosure

Principal Investigators must complete the Disclosure of Financial Interest in Private Sponsors of Research (730U) form for all such projects as required by campus policy and procedures. In the instance that the project is being administered by an intermediary organization and the agreement is with a legal entity other than the drug or device manufacturer, the 730U must be completed for both the intermediary organization and for the entity whose drug or device is being tested.

V. Coordination Between ISRC and IRB

In cases where a positive financial interest is disclosed on the 730U form, the Independent Substantive Review Committee (ISRC) staff must notify the IRB to insure that the informed consent form for the project discloses such interest to the human subjects. Similarly, in cases where the informed consent form discloses a financial interest in the project, the IRB staff must notify the ISRC of such interest, so that review of any conflict of interest issues can be conducted and the project approved by the ISRC in cases where such has not already occurred under the 730U procedures.

VI. Recovery of Costs

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 may not be supported in whole or in part with other funds, including gift or foundation funds. All costs that are 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. The applicable federally negotiated indirect cost rate should be applied. An exception to this rate may be approved on an individual or class basis in accordance with procedures outlined in the Contracts and Grants Manual. In certain cases it may be appropriate to secure advance payment or progress payments rather than payment upon completion of the protocol to reduce the time between incurring the cost and receipt of reimbursement.

VII. Accounting

Each extramurally funded clinical trial must be separately accounted for in the private fund block, not in the Sales and Services of Educational Activities or Other Services fund block. The award type is either contract or grant, not gift or business service agreement. All indirect cost recovery from private sponsors, whether at a full or reduced rate, is subject to University policy on the President's Education Fund. The Office of the President Budget Office must approve any exception to the procedures regarding remittance to the Education Fund.

VIII. IRB Review of Projects

Under existing policy, all projects involving testing of a sponsor's drug or device that will be conducted by University employees within the course and scope of their University duties must be reviewed and approved by the University IRB. Faculty must report to the IRB whenever the FDA or any external agency, including the sponsor, conducts an audit of the clinical trial and must provide a copy of any report of the findings to the IRB. Similarly, the contracts and grants office should notify the IRB if information is received that may have an impact on human subjects, or result in changes to the protocol or changes in institutional responsibilities.

IX. Exceptions

The Chancellor may approve exceptions to these requirements in individual cases in areas within their jurisdiction when it is in the best interest of the University. Approval by The Regents is required in all cases where the University assumes liability for a third party's actions. Unless an exception to the policy has been approved by the Chancellor, the University's medical malpractice insurance coverage will only cover clinical trial activity that is conducted under an agreement executed by an authorized representative of the University for such project.