

University of California
San Francisco



Office of Innovation, Technology & Alliances

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Re: UC Policy on Reimbursement for Audits
Date: 7/24/13

As requested, I write this letter in confirmation of UCSF policy requiring reimbursement of all costs associated with audits arising from our conduct of industry-sponsored clinical trials.

This reimbursement requirement is mandated under California Law and University of California Policy, which carries the force of California law, and is therefore non-negotiable. Specifically, University of California Policy and state law require that industry sponsors reimburse the University for all costs (direct or indirect) incurred by the University under extramural awards; including sponsored clinical trials. UCSF is thereby prohibited from forgiving or subsidizing the cost of FDA Audit's or Inspection's *initiated* by a clinical trial sponsor, as such audits and inspections are conducted in connection with the sponsor's regulatory filing, and therefore must be reimbursed by the sponsor. Accordingly, audits *unrelated* to sponsor's activities (such as any routine FDA inspections) would not require reimbursement by sponsor.

California Constitution

The California Constitution requires that UCSF charge a sponsor for all costs incurred. See Article XVI, Section 6 of the California Constitution which prohibits state entities from giving any type of gifts. Failure to recoup all costs incurred amounts to a gift of public funds, and is thus prohibited.

"The Legislature shall have no power to give or to lend, or to authorize the giving or lending, of the credit of the State, or of any county, city and county, city, township or other political corporation or subdivision of the State now existing, or that may be hereafter established, in aid of or to any person, association, or corporation, whether municipal or otherwise, or to pledge the credit thereof, in any manner whatever, for the payment of the liabilities of any individual, association, municipal or other corporation whatever; nor shall it have power to make any gift or authorize the making of any gift, of any public money or thing of value to any individual, municipal or other corporation whatever"

UC Regulation No. 4

The Regents of the University of California also require that UCSF charge a sponsor for costs incurred. See University of California Regulation No. 4 Academic Appointees Code: APM 020 which dictates that the University must recover the costs associated with research. This regulation states that:

For all tests and investigations made for agencies outside the University, a charge shall be made sufficient to cover all expenses, both direct and indirect.

UCSF cannot include exact audit costs, as this may vary depending on the requirements of the inspection. Specifically, only those costs incurred under extramural awards, thus only those audits related to the relevant clinical trial are covered. In the expenditure of extramural funds, the University follows the federal OMB Circular A-21 definition of reasonable costs as "the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made" (the "prudent person" test.) Where indefinite audit cost is a concern, sponsors are free to meet with UCSF to confer and mutually agree on the parameters of an audit or inspection.

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