



September 29, 2004

REPORT OF THE ACADEMIC SENATE TASK FORCE ON CONFLICT OF INTEREST

Daniel Bikle, MD, PhD – Chair

Process

The Academic Senate Task Force on Conflict of Interest (TF-COI) was appointed by then Academic Senate Chair Daniel Bikle in September, 2001 with Professor Michael Weiner as Chair to evaluate current UCSF guidelines governing conflict of interest. These guidelines are attached as [Appendix 1](#). The Charge to the TF-COI is attached as [Appendix 2](#). The initial membership list is attached as [Appendix 3](#).

The TF-COI reviewed 10 recent articles in the New England Journal of Medicine and Journal of the American Medical Association regarding conflict of interest issues, conflict of interest guidelines produced by the Association of American Medical Colleges and National Institutes of Health, federal regulations governing conflict of interest in federally funded research, conflict of interest policies from our comparison 8 universities, an additional 13 other universities, and the current University of California and University of California, San Francisco policies. The list of specific articles and policies reviewed is attached as [Appendix 4](#).

In September, 2003 Professor Bikle took over the Chair from Professor Weiner, who remained on the TF-COI. Professors Steve Cummings, Darlene Rosenzweig Kitterman and Vishwanath Lingappa were replaced on the TF-COI by Professor Lisa Bero and Deanna Ruth Rutter, Chair and COI Officer, respectively, for the Chancellors Advisory Committee on Conflict of Interest (COIAC). Because of this additional expertise, the TF-COI gained a better understanding of the differences in regulations governing federally and non federally supported research, and where UCSF policy differed from federal regulations and state law. The highlights of these differences are found in a table attached as [Appendix 5](#).

The TF-COI then focused on current UCSF policy and practices governing financial conflict of interests, determining areas where consensus could and could not be achieved. Those areas in which consensus was achieved are found below as specific recommendations. The major area of disagreement concerned the manner by which a declared financial conflict of interest involving the sponsor of a privately supported clinical research project should be handled. Current UCSF policy prohibits all financial ties between the private sponsor of a clinical research project and the UCSF investigator during the time the project is being executed. In research not involving a private sponsor of a clinical project, the COIAC reviews declared financial ties and recommends to the Executive Vice Chancellor (under delegation from the Chancellor) whether funding for the research project should be approved, managed, or denied given the financial ties.

The TF-COI was divided as to whether to retain current UCSF policy, extend current UCSF policy to include basic as well as clinical non-federally supported research, or modify UCSF policy to enable the COIAC to review all disclosed financial conflicts of interest. Therefore, we decided to put the matter to a vote of the faculty following an educational effort to increase faculty awareness of the existing regulations and policies. This effort was initiated with consultation by Chair Bikle with the Deans and by Chair Bikle

and Professor Bero with the newly appointed Executive Vice Chancellor. The ballot was developed to probe two questions:

1. Should the current UCSF policy, which permits no personal financial ties between private sponsors and researchers conducting studies involving human subjects be made less stringent as follows: allow the Chancellor’s Advisory Committee on Conflict of Interest to use the same options (approve, manage, deny) to regulate financial ties above the State disclosure limit (current \$500) for both human and nonhuman research?

If the faculty person voted no on the above, the second question appeared.

2. If you voted “no” to changing current UCSF policy regarding financial ties and human research, should this same policy also apply to non-human research?

Prior to the vote, members of the TF-COI developed position papers either advocating for a change in UCSF policy or arguing to maintain existing policy. These were posted on the Senate Website along with illustrative examples of cases involving financial conflicts of interests and how they might be handled under existing regulations and policies. These position papers and illustrative cases are attached as [appendices 5](#) and [6](#). In addition a town hall meeting of the faculty was held on June 15 during which the existing regulations and policies governing financial conflicts of interest on this campus were reviewed by Professor Bero, pro and con arguments for modifying existing UCSF policy were presented by Professors Weiner and Malone, respectively, and questions from the audience were discussed by a panel comprised of these and other TF-COI members.

Results of Faculty Voting

The faculty vote was as follows:

Question 1: Changing current UCSF policy to enable all declared financial conflicts of interests to be reviewed by COIAC was strongly supported by the faculty with a vote of 293 for and 148 against.

Question 2: Of those who voted to retain current UCSF policy (i.e. voted ‘no’ on question 1) the overwhelming majority voted to extend such policy to non-human research with a vote of 112 for and 36 against.

Therefore, we conclude that a large majority of the faculty want a consistent policy that treats all non federally supported forms of research the same, and, in particular, that declared financial ties between sponsor and investigator be reviewed by COIAC rather than proscribed outright.

Consensus Recommendations

Although the TF-COI was divided with respect to COIAC review of non-federally supported clinical research, the TF-COI achieved consensus on a number of other issues which we are recommending as changes or clarifications of existing UCSF policy.

1. *Clarification of the individuals associated with a project who need to disclose a potential financial conflict of interest.* Federal regulations and state law differ. For example, California Form 700-U requires disclosure only from the principal investigator. Federal regulations state that for all federally funded projects all UCSF participants “who have independent responsibility for the design,

conduct or reporting of the research”, as specified by the PI, are subject to disclosure regulations. The TF-COI wants it made clear to all faculty and staff that this list may not be the same as “key personnel” which frequently includes non independent investigators (e.g. postdoctoral fellows, graduate students, technicians) or collaborators with or without salary whose role is restricted. The PI needs to ensure that the list of individuals who will be required to submit a disclosure form includes only those who meet the definition of “participant”. Definitions of “key personnel” and “participant” can be found in the COIAC website under the FAQ section, which is attached as [Appendix 8](#).

2. *Travel reimbursements.* Ambiguity exists as to whether reimbursement for travel from the sponsor which is not otherwise budgeted in the project should be considered income with respect to disclosure thresholds. State law requires that such travel reimbursement be disclosed in question #3F on Form 700-U, and that a faculty member make a determination as to whether the travel reimbursement is “gift” or “income” per the instructions that accompany Form 700-U. However, current UCSF practice by COIAC does not consider travel reimbursements as income for purposes of UCSF Guideline #11. UCSF policy needs to state clearly that although reimbursement for such travel needs to be declared, it does not by itself constitute a proscribed conflict of interest. However, the TF-COI recognizes that there may be levels of travel reimbursement that exceed what is required to perform ones professional activities, and such reimbursement should be subject to review by the COIAC. Clarification of this issue is included in the FAQ section of the COIAC, attached as [Appendix 8](#).
3. *Professional witness fees.* The TF-COI recommends that UCSF policy clearly state that professional witness fees from the private sponsor of a project are considered income, and need to be declared by the investigator.
4. *Increase staff support for the COIAC.* The TF-COI recognizes the large amount of effort expended by the faculty and staff of the COIAC. Therefore, we recommend that staffing of this Committee be increased to meet the demand. If all disclosures of financial ties are to be reviewed by COIAC including those from investigators doing non-federally supported clinical research, this demand will increase.

Appendices

[Appendix 1:](#) UCSF Guidelines on Conflict of Interest

[Appendix 2:](#) Charge to the UCSF Academic Senate Task Force on Conflict of Interest

[Appendix 3:](#) Membership of the UCSF Task Force on Conflict of Interest

[Appendix 4:](#) Documents Reviewed by the UCSF Task Force on Conflict of Interest

[Appendix 5:](#) Summary of Conflict of Interest Rules Governing UCSF Faculty

[Appendix 6:](#) Position Papers of the UCSF Task Force on Conflict of Interest

[Appendix 7:](#) Illustrative Cases of Conflicts of Interest

[Appendix 8:](#) Frequently Asked Questions