The meeting of the Conflict of Interest Task Force was called to order by Chair Bikle on December 16, 2003 at 2:10 p.m. in room S22. A quorum was present.

Determining Our Areas of Agreement and Disagreement

Task Force members discussed areas of agreement and disagreement at length throughout the meeting. The extensive discussion which took place is summarized below.

Disclosure Thresholds

*UCSF Guidelines on Conflict of Interest Pertaining to Receiving / Disbursing Research Funds* (hereinafter UCSF Guidelines on Conflict of Interest) state that “Faculty who have, or participate in, a privately sponsored clinical study shall not concurrently receive any compensation from the sponsor…” (Clause 11)

The task force considered whether the financial disclosure threshold for non-federally funded clinical trials (i.e. the privately funded clinical trials of Clause 11) should be the same as the disclosure threshold for state-funded research as outlined in State law. Such a change would raise the threshold which currently stands at *any* income, investment or management position.

In a straw vote, three members of the task force voted in favor of applying the same threshold to both non-federal (i.e. privately funded) and state-funded trials. Five members voted in favor of maintaining the existing threshold.

Chair Bikle noted that the task force is therefore divided on this issue and that this division will be reflected in the final report of the task force.

Proposed Modifications of Current UCSF Guidelines on Conflict of Interest

Task Force member Lewis Sheiner prepared a document outlining *Proposed Modifications of Current UCSF Guidelines on Conflict of Interest* (attached) which was distributed prior to the
meeting. This document highlights known areas of potential disagreement among task force members in **bold**.

Task force members discussed each of these areas at length. A summary of the discussion of each area of potential disagreement follows (text in italics and bold refers to text from the attached document *Proposed Modifications of Current UCSF Guidelines on Conflict of Interest*):

1. **Researcher:**
   - **Scope of focus:** {All research} or {research involving human subjects only}
   - **Scope of roles:** PI’s, {Faculty} &/or {post-doc} &/or {grad student} &/or {professional student} &/or {staff} with direct involvement in {study design} &/or {execution} &/or {data gathering} &/or {data entry} &/or {data analysis}.

   **Scope of Focus** - Task Force members agreed that further discussion of proposed changes to the UCSF Guidelines on Conflict of Interest should pertain to all areas of research.

   **Scope of Roles** - Members differed in their views on which individuals involved in a research project should be required to make conflict of interest disclosures. Following extensive discussion, members agreed not to make recommendations on those roles which should be subject to disclosure requirements. Instead, they agreed that the onus of responsibility for disclosures should be placed on the Principal Investigator and that this individual should ensure that disclosures are made by all personnel who have independent responsibility for the design, conduct, and analysis of a research project. Furthermore, only UCSF personnel are required to make disclosures for review by UCSF. To this end, the task force will recommend that principal investigators submit two lists of personnel to UCSF Contracts and Grants at the time of grant submission:

   a. A list of “key personnel” as required by the National Institutes of Health (NIH)
   b. A list of UCSF personnel who have independent responsibility for the design, conduct, and analysis of research

   The second of these lists will go forward to the Chancellor’s Advisory Committee on Conflict of Interest (COIAC) for consideration along with the conflict of interest disclosure of the principal investigator. This procedure will be recommended for application to all research grants at UCSF; both involving human subjects and not.

2. **Significant:**
   - **Payments:** {of any amount} or {which, in the aggregate have in the prior calendar year exceeded the de minimis amount established in PHS regulation (presently $10,000), or are expected to exceed that amount in the next twelve months}.

   The task force agreed not to make recommendations regarding financial interest levels at which specific management strategies would be recommended by the COIAC. Instead, members agreed to recommend that COIAC should review each disclosure separately and recommend management strategies on a case-by-case basis.

   Task force members then considered whether to recommend that management strategy options available for recommendation by COIAC be as broad for research involving human subjects and research not involving human subjects. Currently, if a disclosure of a financial conflict of interest is made for research not involving human subjects, COIAC may recommend one of three options:

   a. acceptance of funding
b. acceptance of funding in conjunction with management of conflict
c. rejection of funding

If a disclosure of a financial conflict of interest is made for research involving human subjects, COIAC may recommend one of two options:

a. acceptance of funding pending elimination of conflict
b. rejection of funding

Three members of the task force opined that the breadth of management strategy options should be the same for both areas of research.

Four members of the task force opined that there should be fewer management strategy options for human subject research than for research not involving human subjects.

**Expert Witness Fees**

D. Rennie noted that investigators are not currently required to disclose to the COIAC fees received for services as an expert witness. Disclosure of these fees is currently made through departmental Compensation Plans.

The task force agreed to recommend that language be included in the UCSF Guidelines on Conflict Interest which requires investigators to disclose income received for expert witness services and to include disclosure of retainers received for these services.

**Remaining Areas of Potential Disagreement**

Task force members did not discuss remaining areas of potential disagreement as highlighted in the Proposed Modifications of Current UCSF Guidelines on Conflict of Interest, noting that the issues highlighted have already been resolved.

**New Business**

Task force members agreed on the following course of action to complete task force business in the new year:

- At the meeting of January 27, 2004, the task force will discuss General University Policy Regarding Academic Appointees – APM 028 – Disclosure of Financial Interest in Private Sponsors of Research
- In the new year the task force will begin to develop a final report which will outline not more than two sets of recommendations regarding possible changes to the UCSF Guidelines on Conflict of Interest
- This report will be distributed to faculty and discussed, along with current state and federal regulations, at town hall meetings open to all faculty
- The Academic Senate will put final recommendations before the faculty for vote by secret ballot

*The meeting adjourned at 3:53 p.m.*