MINUTES
Wednesday, June 5, 2002
Room S118

PRESENT:  M. Weiner (Chair), R. Malone, D. Deen, D. Kitterman, M. Shultz, J. Levine, P. Benner

ABSENT:   H. Bourne, M. Schambelan, S. Cummings, D. Rennie, L. Sheiner

GUESTS:   Deanna Rutter, Administrator – Conflict of Interest Advisory Committee

The meeting of the Conflict of Interest Task Force was called to order by Chair Weiner on June 5, 2002 at 4:15 p.m. in room S30. A quorum was present.

Approval of Minutes

The Task Force unanimously approved the minutes of the meetings of March 1, April 2 and May 5, 2002.

Announcements from the Chair

No announcements.

Clinical Research and Current UCSF Conflict of Interest Policy

The Task Force discussed whether to recommend that the word “clinical” be removed from clause 11 of the UCSF Guidelines on Conflict of Interest. Clause 11 of the current guidelines reads:

“11. Faculty who have, or participate in, a sponsored clinical study shall not concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study. In addition, they shall not have any investment in, or serve in a decision making capacity for (such as service on the Board of Directors or management committee), or be an officer or employee of the company sponsoring the study.”

Several members of the Task Force supported the removal of the word “clinical” and noted that conflict of interest policies should be applied to all medical research, regardless of its nature.

Following extensive discussion, the Task Force agreed to postpone a decision on whether to approve this recommendation until the next meeting.
**Voting Mechanisms/Approval of Recommendations**

The Task Force discussed at length how to proceed towards the drafting of a final report. The Task Force recognized that a unanimous or majority decision on several issues is unlikely to occur and considered several options which would allow the Task Force to make strong recommendations to Dan Bikle, Chair of the Academic Senate and still express dissenting opinions.

The Task Force agreed on the following process which outlines the steps to be taken prior to drafting a final report:

- Individual Task Force members will submit motions for recommendations to be included in the final report to Senate Analyst E. Langdon-Gray by email no later than June 30, 2002.
- The Task Force will discuss motions at the July meeting of the Task Force.
- The Task Force will vote on motions by email ballot immediately after the July meeting.
- Chair Weiner and Senate Analyst E. Langdon-Gray will to draft a report of the Task Force in July, based on the motions approved in the ballot.
- The Task Force will review the draft report at the August meeting.
- The Task Force will approve the final report by email ballot before September 1, 2002.

**New Business**

Deanna Rutter, Administrator to the Conflict of Interest Advisory Committee, alerted the Task Force to three areas of potential conflict of interest, which are either not addressed or are addressed ambiguously in the UCSF Guidelines, and suggested that the Task Force might want to comment on these three areas:

1. **Gifts**: Sometimes a faculty member receives a substantial unrestricted gift in support of research and has financial ties to the donating entity (either consulting fees or ownership of stock). Should there be a restriction on the use of these gift funds? For instance, should none of the funds be used for that faculty member's compensation?

2. **Federally sponsored research**: UCSF has many federally funded clinical trials. Sometimes, the PI or a participant on a clinical study owns a company (or consults for the company) that owns or manufactures a drug or device that may be used, tested, evaluated, compared, or further developed under that federal research grant. This situation may become intensified with the opening of the facilities at Mission Bay. Although the current UCSF Guidelines do not specifically address this situation, the COI Advisory Committee has been recommending that the PI (or participant) not participate in any aspect of the clinical trial, including patient recruitment, enrollment, or data analysis/evaluation.

3. **State of California's financial disclosure form (Form 730-U)**: For privately sponsored research, the State of California requires that the principal investigator submit a financial disclosure form on which he/she discloses any financial interest in the sponsor of the research. No financial disclosure form is required from other participants in the research. This allows participants (other than the PI)
in a study to maintain a conflict of interest without being required to disclose the conflict. Federal law requires that all participants disclose related financial interests.

_The meeting adjourned at 5:50 p.m._

Senate Staff:
Elizabeth Langdon-Gray
Senate Analyst
476-1307
elangdon-gray@senate.ucsf.edu