MINUTES
Tuesday, September 30, 2002
Room S118


ABSENT: P. Benner, V. Lingappa, D. Rennie, M. Schambelan

GUEST: Lisa Bero, PhD

The meeting of the Conflict of Interest Task Force was called to order by Chair Bikle on September 30, 2003 at 2:06 p.m. in room S118. A quorum was present.

Announcements from the Chair and Introductions

Chair Bikle thanked Mike Weiner, MD for his service as Chair of the Task Force during 2002 – 2003 and thanked all members of the task force for their continued service. Members of the Task Force introduced themselves, stating their name, department, and reasons for serving on the task force.

Determination of Process to Obtain Final Task Force Report

Chair Bikle noted that the task force was constituted to provide recommendations first to the Academic Senate and then to the chancellor. He went on to outline a proposed process for the continuation of the work of the task force so that these recommendations may be formalized:

1. Two proposals of recommendations will be developed – reflecting the differences of opinion held by members of the task force – and will be accompanied by position papers;

2. These proposals and supporting materials will be presented and discussed at town hall meetings open to all UCSF faculty;

3. Following town hall meetings, ballots will distributed to UCSF faculty so that faculty may vote on recommendations to be finalized;

4. Finalized recommendations will be conveyed to Academic Senate Chair Leonard Zegans and UCSF Chancellor Michael Bishop.
This proposed process was discussed at length. It will be further considered during discussion prior to and during the October meeting of the task force.

**Special Guest: Lisa Bero, Chair, Chancellor’s Advisory Committee on Conflict of Interest (COIAC)**

Dr. Bero gave the Task Force an overview of the role of the Chancellor’s Advisory Committee on Conflict of Interest and briefly summarized recent national debate regarding conflict of interest. She highlighted the following points, several of which were made in response to questions from task force members:

- There is a great deal of misinformation surrounding conflict of interest among faculty both at UCSF and other institutions. Many universities have been recently evaluating their clinical trials and conflict of interest policies.
- The COIAC interprets compensation referred to in the UCSF Guidelines on Conflict of Interest (11. Faculty who have, or participate in, a privately 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,) as income.
- There is not a clear distinction between travel reimbursement for faculty and compensation/income.

Each of these points gave rise to extensive discussion. This discussion was focused to identify areas of debate on which task force members broadly agree and areas of debate on which members do not agree. Statements of areas of agreement and disagreement are summarized as follows:

**Areas of Agreement**

1. Broad definition of what activities/interests would constitute a conflict of interest.

2. There is widespread lack of knowledge surrounding conflict of interest among faculty, specifically regarding UCFS policy and its application.

3. There is a need for clarification of policy and new policy to address specific loopholes or oversights.

4. If COIAC currently informally implements an appeal process for investigators, this process should be codified within UCSF guidelines.

**Areas of Disagreement**

1. Whether faculty conducting clinical research should be subject to different regulations than faculty conducting basic research.

2. Financial thresholds of financial interest which may constitute a conflict of interest or should be prohibited.
3. The potential for research to benefit a researcher financially, regardless of funding source.

4. The time limit of the effectiveness of the Conflict of Guidelines (should these guidelines apply only during the length of a grant award, or post-award also?)

5. Scope of application of guidelines beyond the principal investigator.

6. Whether a distinction exists between exempt and non-exempt sponsors.

7. Whether a rebuttable presumption of a conflict of interest should be included within UCSF guidelines.

Following extensive discussion of these points, task force members agreed that further clarification of current application of UCSF Guidelines on Conflict of Interest by COIAC is needed. The following questions will therefore be submitted to COIAC Staff Deanna Rutter and COIAC Chair Lisa Bero for consideration prior to the next meeting of the task force:

1. How are the following issues handled?
   a. compensation. In particular does this include reimbursement for travel expenses for consultations/advisory board meetings that are not otherwise covered by the project budget?
   b. stock: Is there a $ limit here? How would this be handled if the stock were included in a portfolio run by a mutual fund?
   c. honoraria. Is there a $ limit here? Would this include honoraria for writing articles or giving talks for a privately sponsored symposium or CME event?
   e. compensation plan as recipient: ie. If the compensation, honorarium etc were put into the compensation plan, would this make it exempt from COI policy rules?

2. What policies exist governing conflict of interest other than the UCSF Guidelines on Conflict of Interest and how are they interpreted and applied? In particular we want to know how UC (State) and Federal guidelines impact on UCSF policy. Please provide specifics.

3. Define participation in research. Here we want to know who all are covered by the COI policy for any given project. Is it only the PI; are CoIs included; are consultants, collaborators, advisory board members included?

4. Do the UCSF Guidelines apply only to contracted research? What about faculty who serve on advisory boards, consultation groups for privately sponsored research but are not directly involved with a contracted research project? Specifically what situations require notification of the COIAC?

5. What is the screening process of disclosures by staff and by the full COIAC? Review for us the step by step process by which a potential COI situation is identified, and how it then is handled.

6. What are the penalties for violation of the Guidelines?

7. What is the appeal process if any?

8. Is a “de minimus” level of financial compensation ever allowed?
9. To what extent are faculty working on patient based research projects treated differently from faculty working on non patient based research regarding conflict of interest issues? To what extent do the same rules apply, and where do the rules differ?

Chair Bikle asked that D. Deen further consider areas of debate which may need further discussion and clarification by the task force and that L. Sheiner summarize areas of further areas of debate on which task force members have already reached agreement.

The meeting adjourned at 4:01 p.m.

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