MINUTES
Meeting of May 7, 2002
Room S30

PRESENT: M. Weiner (Chair), R. Malone, D. Deen, D. Kitterman, L. Sheiner, H. Bourne, M. Shultz, S. Cummings, D. Rennie, J. Levine

ABSENT: H. Bourne, M. Schambelan, P. Benner

GUESTS: Deanna Rutter, Administrator – Conflict of Interest Advisory Committee
John Klimek, Director – Contracts and Grants
Tamara Maimon, Director – UCSF Academic Senate

The meeting of the Conflict of Interest Task Force was called to order by Chair Weiner on May 7, 2002 at 10:10 a.m. in room S30. A quorum was present.

Approval of Minutes

The minutes of the meeting of March 1 and April 2, 2002 were distributed to the task force. Members will forward suggested changes and additions to Senate Analyst, Elizabeth Langdon-Gray prior to the next meeting.

Announcements from the Chair

No announcements.

Presentation by Deanna Rutter, Administrator – Conflict of Interest Advisory Committee

D. Rutter provided task force members with an overview of federal and state laws, and University and campus guidelines that regulate conflict of interest issues at UCSF. Details of these laws and guidelines can be found at http://www.ucsf.edu/ora/coiac/index.htm. She noted that UCSF guidelines can be changed only within the parameters defined by federal and state law.

D. Rutter noted that disclosures of potential financial conflicts of interests have more than doubled at all University of California campuses in the last two years. At UCSF, more than 7000 disclosures are made each year. Of these, 3% result in a positive identification of a financial conflict of interest. The number of disclosures made each year may further increase with the introduction of new
guidelines by the Office of Human Research Protections (OHRP) (http://ohrp.osophs.dhhs.gov/) which may remove financial thresholds from conflict of interest policies.

D. Rutter recognized a need to streamline disclosure procedures at UCSF and simplify disclosure forms. She further recognized the need to develop and distribute a faculty guide to conflict of interest policies and guidelines at UCSF.

Clinical Research and Current UCSF Conflict of Interest Policy

Darlene Rosenzweig-Kitterman distributed a Proposal to Implement the AAMC Recommendations at UCSF (attached) for discussion and review. Proposed implementation would modify clause 11 of current USCF Guidelines on Conflict of Interest (http://www.ucsf.edu/ora/coiac/coiac_policy.htm), which currently 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.”

The Task Force identified three alternatives in the incorporation of AAMC recommendations in UCSF guidelines:

1. Recommend that UCSF add a rebuttable presumption to the text of clause 11 of the UCSF Guidelines on Conflict of Interest, to read:

   “11. Faculty who have, or participate in, a sponsored clinical study shall not have a significant financial interest in the sponsor unless compelling circumstances\(^{1}\) can be demonstrated to the COIAC that the financially interested faculty member should be permitted to conduct the research. Significant Financial Interests in Research include the following interests of the faculty (and his or her spouse and dependent children), or of any foundation or entity controlled or directed by the individual or his or her spouse:
   
   • Consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, or “in kind” compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that 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.
   • Equity interests, including stock options, of any amount in a non-publicly-traded financially interested company (or entitlement to the same).
   • Royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work.

\(^{1}\)Compelling circumstances include circumstances that relate to the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, the degree of risk to the human subjects involved that is inherent in the research protocol, and the extent to which the interest is amenable to effective oversight and management.
• Any non-royalty payments or entitlements to payments in connection with the research that are not
directly related to the reasonable costs of the research (as specified in the research agreement
between the sponsor and the institution). This includes any bonus or milestone payments to the
investigators in excess of reasonable costs incurred, whether such payments are received from a
financially interested company or from the institution.
• Service as an officer, director, or in any other fiduciary role for a financially interested company,
whether or not remuneration is received for such service.

Exceptions. Significant financial interests in research do not include the following:
• Interests of any amount in publicly traded, diversified mutual funds.
• Stock in a publicly-traded company that (when valued in reference to current public prices) meets
the de minimis criteria established in PHS financial disclosure regulations (presently, an interest
that does not exceed $10,000 in value and does not represent more than a 5% ownership interest in
any single entity).
• Stock options in a publicly-traded company that (when valued using accepted valuation methods)
meet the de minimis criteria established in PHS financial disclosure regulations (presently, an
interest that does not exceed $10,000 in value and does not represent more than a 5% ownership
interest in any single entity).
• Payments to the institution, or via the institution to the individual, that are directly related to
reasonable costs incurred in the conduct of research as specified in the research agreement(s)
between the sponsor and the institution.
   Salary and other payments for services from the institution.”

2. Recommend that UCSF incorporate AAMC definition of a significant financial interest into
current UCSF guidelines as an absolute prohibition with no rebuttable presumption. Clause 11
would then read:

“11. Faculty who have, or participate in, a sponsored clinical study shall not have a significant financial
interest in the sponsor. Significant Financial Interests in Research include the following interests of the
faculty (and his or her spouse and dependent children), or of any foundation or entity controlled or
directed by the individual or his or her spouse:
• Consulting fees, honoraria (including honoraria from a third party, if the original source is a
financially interested company), gifts or other emoluments, or “in kind” compensation from a
financially interested company (or entitlement to the same), whether for consulting, lecturing, travel,
service on an advisory board, or for any other purpose not directly related to the reasonable costs of
conducting the research (as specified in the research agreement), that 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.
• Equity interests, including stock options, of any amount in a non-publicly-traded
financially interested company (or entitlement to the same).
• Equity interests (or entitlement to the same) in a publicly-traded financially interested company that
exceed the defined de minimis amount (see exceptions below).
• Royalty income or the right to receive future royalties under a patent license or copyright, where the
research is directly related to the licensed technology or work.
• Any non-royalty payments or entitlements to payments in connection with the research that are not
directly related to the reasonable costs of the research (as specified in the research agreement
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• Payments to the institution, or via the institution to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution.
• Salary and other payments for services from the institution.”

3. Recommend that clause 11 be left unchanged.

The Task Force discussed issues surrounding proposed changes to clause 11 at length. Members recognized the need for collaboration between UCSF clinical researchers and outside industry and the need to avoid conflicts of interest. Members differed in their approach to the difficulties inherent within the interaction of these two competing goals. Some members advocated the incorporation of a rebuttable presumption as a means to allow researchers extensive involvement in all phases of clinical research with outside industry. Other members advocated a more restrictive policy whereby the potential for actual or possible conflicts of interest would be eliminated.

Chair Weiner recognized that despite constructive discussion, a unanimous or majority decision on the proposed modifications to clause 11 is unlikely at the current time. Discussion of the proposed modifications will continue at the next meeting of the task force.

The meeting adjourned at 12:00 p.m.

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