CONFLICT OF INTEREST TASK FORCE

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PROPOSAL FOR MODIFICATION OF UCSF CONFLICT OF INTEREST GUIDELINES

Most clinical trials of new drugs and devices are sponsored by industry. These clinical trials are an important part of the foundation of clinical practice and public health and can be a source of significant advances in medical science. At the crucial interface between innovation and development, researchers from academic medicine often play a critical role by conducting the early translational research that gives rise to new products, and by testing these products for safety and efficacy. However, industry sponsorship may generate pressure to produce research results and reports that are favorable to the marketing of drugs and devices. Academic investigators can increase the objectivity and quality of this research by assuming leadership roles in the design, conduct and dissemination of research results.

To avoid potential (or perceived) bias in the course of conducting research in collaboration with industry, UCSF as well as many other institutions have developed guidelines that are intended to prevent the influence of financial pressure and incentives from industry sponsors. We believe that the current UCSF guidelines, which prohibit clinical investigators from receiving any compensation (even for time or travel expenses) outside the conduct of a study and thus prohibit concomitantly designing and conducting research in collaboration with industry, have served to discourage the formation of the principled partnership between industry and academia that is essential if we are to preserve medical progress and to continue to improve the health of our citizenry. Recognizing the need to develop such partnerships, the American Association of Medical Colleges (AAMC) convened a Task Force on Financial Conflicts of Interest in Clinical Research, which published its recommendations in December 2001 (http://www.aamc.org/members/coitf/start.htm). We propose that UCSF adopt the AAMC recommendations, which have been widely endorsed by academic medical centers throughout the country.

In addition, in May 2004, HHS published its final guidance “Financial Relationships and Interests in Research Involving Human Subjects” (http://ohrp.osophs.dhhs.gov/humansubjects/finalguid/finalguid.pdf). This guidance, which does not conflict with and is less proscriptive than the AAMC’s recommendations, provides parameters to manage necessary potential financial conflicts of interest and only specifies prohibition of financial payments that are “significant”.

The abiding principle in the AAMC guidelines is that an institution should regard all significant financial interests in human subjects research as potentially problematic and, therefore, as requiring close scrutiny. Examples of significant financial interests include:

- Consulting fees, honoraria, and gifts from a financially interested company that exceed the de minimis amount established in the PHS regulations (currently $10,000 per year).
- Equity interests, including stock options, of any amount in a non-publicly-traded financially interested company
- Payments that are not directly related to the reasonable costs of the research, including any bonus or milestone payments to the investigators
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.

To provide such scrutiny, we propose that the Chancellor’s Advisory Committee on Conflict of Interest be permitted to use the same options (approve, manage, deny) to regulate financial ties above the state disclosure limit (currently $500) for human research as it does for non-human research. Current UCSF policy stipulates that no financial ties to a sponsor of human research be permitted by an investigator during the course of the investigation, leaving the Chancellor’s Advisory Committee on Conflict of Interest with no option but to deny the research support while such financial ties exist regardless of the level or type of financial tie involved. As in the AAMC guidelines, this committee could establish the rebuttable presumption that an individual who holds a significant financial interest in research involving human subjects may not conduct such research. The intent is not to suggest that every financial interest jeopardizes the welfare of human subjects or the integrity of research, but rather to ensure that institutions systematically review any financial interest that might give rise to the perception of a conflict of interest, and further, that they limit the conduct of human subjects research by financially interested individuals to those situations in which the circumstances are compelling. The presumption against significant financial interests in human subjects research should apply whether the research is funded by a public agency, a non-profit entity, or a commercial sponsor, and wherever the research may be carried out. In the event of compelling circumstances, an individual holding significant financial interests in human subjects research may be permitted to conduct the research. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. Finally, we believe that whatever the decision of the Academic Senate on this matter, it should apply equally to all types of research (basic as well as clinical) conducted on the campus.