

July 9, 2012

MOLLY THEODOSSY

Policy Coordinator
Office of the Provost/Executive Vice Chancellor

Re: Review of PPM 230-07, Public Health Service Regulations on Objectivity in Research

The Davis Division of the Academic Senate received your request to review PPM 230-07 on June 13, 2012. As communicated at that time, the Division was unable to perform a full review of the section by July 6, 2012. You were unable to provide an extension as the section was required in order to comply with new regulations. Given there was no other choice, the Division forwarded the request to the Committees on Planning and Budget, Faculty Welfare and Research as well as Graduate Council. The committees were unable to conduct a review of the section due to the absence of members during summer session. Below, I have included comments received from committee members.

We understand the requirement for the campus to comply with the new regulation. Regardless, compliance will create another administrative burden for those projects falling within its requirements as well as some campus administrative units. Therefore, as the Division has previously pointed out in writing and during discussions, the campus must not seek to achieve broad compliance. I have been assured verbally by Associate Vice Chancellor Kiel that the Office of Research does not wish to create an administrative burden for any group beyond those *required* to comply. I am trusting she will work within the Office of Research staff and with any and all affected administrative units, to minimize the work associated with compliance for PI's and administrative staff supporting research projects falling within the requirements.

Additionally, given the lack of consultation and notice, we call upon the Office of Research to use existing data to identify and communicate with those impacted by the new regulation. This outreach must occur well in advance of August 2012. We believe this advance notice will allow those impacted to assess workload and plan for successful compliance with the new requirements.

Two sections seem overly broad and one seems to be erroneously cross-referenced:

II.I. says----“A. Significant Financial Interest (SFI)—Anything of monetary value that meets the PHS thresholds (see Section III.C below) for reporting received by the Investigator (including the Investigator’s spouse or registered domestic partner, and dependent children for the following categories except travel) that reasonably appears to be related to or is in the same field of expertise as the Investigator’s Institutional Responsibilities. Examples of SFI include:

1. Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization; or salary received outside of the University of California.
2. Stock or stock options in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
3. Receipt of income from any organization other than the University of California for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from prior employers and other universities.
4. Travel reimbursements made to, or on behalf of, the Investigator, regardless of the amount, by a for-profit or nonprofit entity, excluding a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.”

For example, suppose I write a mystery novel and sell it on Amazon and thereby earn royalties. II.I.3 seems to say I have to report this. I don't see where the potential conflict of interest is.

The wording in 4. Travel reimbursements, also seems to be overly broad. Suppose I give a seminar at a foreign university and they pay my hotel bill for a night?

Section III. C. is incorrectly referred to above says-- rather than financial thresholds for reporting (\$5,000 per year, I believe)

“Disclosures by collaborators

1. Collaborators from other institutions, who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from UC Davis are expected to comply with the policies and procedures of the organization at which they are employed.
2. Subawards issued by UC Davis will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending UC Davis notification of their ability to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.
3. Collaborators, who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by UC Davis should be identified as Investigators by the UC Davis PI and must complete the UC Davis disclosure forms.
4. If, upon review, UC Davis determines that these SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to eliminate, reduce or manage the identified conflicts of interest.”

Sincerely,



Linda F. Bisson, Chair
Davis Division of the Academic Senate
Professor of Viticulture and Enology

c: Vice Chancellor-Research Lewin
Associate Vice Chancellor Kiel