August 3, 2018

SUSAN CARLSON, VICE PROVOST
ACADEMIC PERSONNEL


Dear Susan:

As you requested, the proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research, and revised APM 028 was distributed for systemwide review. All ten Academic Senate divisions and three systemwide committees (UCORP, UCAP, and UCPB) submitted comments. These comments were discussed at Academic Council’s June 27 and July 25, 2018 meetings and are attached for your reference. Council voted unanimously to support the policy and APM revisions on July 25.

First, I would like to acknowledge the three UCOP consultants who joined the July 25 Council meeting: Timothy Miller from the Office of Research and Graduate Studies, and Mark Morodomi and Ellen Auriti from the Office of General Counsel. Their information about the background and potential impact of the policy provided Council with much-needed clarity.

We understand that the policy is the University’s implementation of a state-mandated requirement originating from the Fair Political Practices Commission (FPPC). The policy describes requirements for making and reviewing disclosures of financial interest reported on the State of California form “Statement of Economic Interests for Principal Investigators” (Form 700-U), relative to grants, gifts, and income from private, non-government sponsors of research, including circumstances in which an independent “substantive review” of a disclosure of financial interest must be completed by the campus’s Designated Campus Reviewer (DCR) versus its Independent Substantive Review Committee (ISRC). In addition, proposed revisions to APM 028 update language about disclosures of financial interest in private sponsors of research to align with federal and state law, and detail principles to guide the conduct of sponsored research for academic appointees.
We understand that the policy establishes a process by which the University reviews disclosures of financial interest on form 700-U and decides whether to conduct a substantive review. In addition, we understand that the policy is not intended to increase the disclosure or review burden. In fact, the aim of the new policy is to be less restrictive than current practice, to give campuses greater flexibility in the conduct of their reviews, and to quicken turnaround by allowing more reviews to be conducted by qualified DCRS rather than ISRCs.

As you can see, the original comments from some Senate reviewers reflected some initial misunderstandings. Several reviewers expressed concern that the minimum disclosure thresholds for a gift ($50) or income ($500) on form 700-U are too low, and represent an unnecessarily onerous administrative burden. Council understands, however, that the disclosure thresholds for form 700-U are controlled by the state, are beyond UC’s control, and cannot be changed. We also understand that the Policy’s most significant new provision is to allow for disclosures below a specified threshold to be reviewed by the individual DCR, instead of the ISRC. UCOP, in consultation with campuses, set the minimum income threshold to mirror NSF’s COI policy threshold of $10,000, the highest among federal agencies. However, the Policy gives the campuses the flexibility to set a lower threshold. In addition, it allows a past decision about a substantially similar gift or income to exempt a second full committee review.

Once again, Council would like to express its support for these policy revisions. We also note that while the original comments reflected some misunderstandings, they also included helpful suggestions for improving the policy, which should be considered while the policy is being finalized.

Thank you for the opportunity to review and comment. Please do not hesitate to contact me if you have questions.

Sincerely,

Shane N. White, Chair
Academic Council

Encl.

Cc: Academic Council
   Research Policy Analyst Miller
   Senior Counsel Morodomi
   Senior Counsel Auriti
   Senate Director Baxter
   Senate Executive Directors
SHANE WHITE
Chair, Academic Council


Dear Shane,

On May 7, 2018, the Divisional Council (DIVCO) of the Berkeley Division discussed the proposal cited in the subject line, informed by commentary of our divisional committees on Faculty Welfare (FWEL) and Research (COR). Our discussion highlighted the following concerns.

DIVCO agreed with the points raised by COR primarily about the disclosure form 700-U:

Currently, the 700-U form requires faculty to disclose any gifts over $50, and the form needs to be signed in real ink (no electronic disclosure is allowed). We believe that this disclosure limit, set in the 1980’s, is far too low and may have the unintended effect of encouraging faculty to not report small gifts. In particular:

- The limit is incompatible with many cultural traditions. For example, when working with Asian companies, it is a sign of respect to offer a small gift, like a pen or bottle of Sake, whose value are not easily assessed. Similarly, it is common for companies in other countries to host faculty for dinner after research presentations.

- The policy is internally inconsistent. If faculty charge something (e.g. a flight) to their sponsored account from a company, that would be acceptable under the policy but if the sponsor pays for it directly, the policy requires reporting.

- Many other organizations have much higher limits. For example, we believe that LBNL’s [Lawrence Berkeley National Laboratory’s] limit for reporting is $5,000.

- It is rather unrealistic to think that a faculty member will sell their integrity for $50.
We suggest that the limit be increased to something much more substantial [such as $5,000] in order to reduce administrative burdens and focus on only real potential conflicts of interest. Especially in this environment of austerity, getting rid of unnecessary disclosures would be a good start.

We share FWEL’s concern about the “Timeline of Reviews” (page 6 of revised APM – 028):

… a deadline as short as two weeks or as long as a month should be explicitly listed in the policy and related guidelines. There was consensus that it is critical for UC Berkeley grant applicants, who are often already facing tight external deadlines, not be further handicapped by a protracted review period.

Sincerely,

Lisa Alvarez-Cohen
Chair, Berkeley Division of the Academic Senate
Fred and Claire Sauer Professor
Department of Civil and Environmental Engineering

Cc: Terrence Hendershott and Caroline Kane, Co-chairs, Committee on Faculty Welfare
    Stuart Bale, Chair, Committee on Research
    Sumali Tuchrello, Senate Analyst, Committee on Faculty Welfare
    Deborah Dobin, Senate Analyst, Committee on Research
June 20, 2018

Shane White  
Chair, Academic Council


Dear Shane:

The proposed new Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research, as well as proposed revisions to APM-028 (Disclosure of Financial Interest in Private Sponsors of Research), were forwarded to all standing committees of the Davis Division of the Academic Senate. Three committees responded: Academic Freedom and Responsibility (CAFR), Academic Personnel Oversight (CAP), and Research (COR).

Overall, COR supports the policies but recommends clarifying the following areas: first, if there are any situations in which the new policy would apply to state or federal funding; second, the composition of Independent Substantive Review Committees (ISRC) and training provided to their members; third, additional guidelines on what it means for conflicts of interest to be “managed, reduced or eliminated” by Designated Campus Reviewers or ISRCs; and fourth, what assurances, if any, will be made that “additional review will be completed in a timely manner, so as not to interfere with the likelihood of receiving the grant/contract and without infringing on academic freedom? Who will decide if research is appropriate to the mission of the university?”

CAFR thinks the policy is not explicit enough as to what constitutes a conflict of interest with private sponsors of research. As CAFR notes, “Several members believe that as currently framed, travel reimbursements from a private university for presenting research might count as a conflict, which seemed surely unintended, but if it were the case would be a significant curb on academic freedom.” Thus, CAFR recommends clarifying what constitutes a conflict of interest.

The Davis Division appreciates the opportunity to comment.
Sincerely,

Rachael E. Goodhue
Chair, Davis Division of the Academic Senate
Professor and Chair, Agricultural and Resource Economics

Enclosed: Davis Division Committee Responses

c: Edwin M. Arevalo, Executive Director, Davis Division of the Academic Senate
Hilary Baxter, Executive Director, Systemwide Academic Senate
Michael LaBriola, Principal Policy Analyst, Systemwide Academic Senate
June 11, 2018

Shane White, Academic Council
1111 Franklin Street, 12th Floor
Oakland, CA 94607-5200


Dear Shane,

At its meeting of June 5, 2018, the Irvine Division Senate Cabinet reviewed the proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and the revised APM - 028, Disclosure of Financial Interest in Private Sponsors of Research. The proposed new presidential policy describes the review process for disclosures of financial interests made on the “Statement of Economic Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research” form and the requirements for review of such disclosures by the campuses. The proposed revisions to APM - 028 detail important principles guiding the conduct of sponsored research for academic appointees.

Based on discussions within UC Irvine’s Council on Faculty Welfare, Council on Research, Computing, and Libraries, and the Senate Cabinet, the Irvine Division supports the proposal and offer the following suggestions to improve clarity and implementation:

- We recommend the inclusion of language in Section II of APM 028 that student participation in a research project covered by this policy be consistent with the educational mission of the University and an appropriate use of the student’s time.

- We recommend that Section III of APM 028 note that the “committee” is the Independent Substantive Review Committee as described in the Presidential Policy. Further, we recommend that Section III of APM 028 state that the review process and the role of the Independent Substantive Review Committee is described in the Presidential Policy.

- We recommend elucidation of the differences between Bulletin G-39 and the Presidential Policy.

- We recommend the establishment of both an oversight group to harmonize the implementation of the policy across all campuses as well as a mechanism for addressing and responding to disagreements about the application of the policy.
The Irvine Division appreciates the opportunity to comment.

Sincerely,

Maria Pantelia, Chair
Academic Senate, Irvine Division

C: Linda Cohen, Chair-Elect, Academic Senate, Irvine Division
   Hilary Baxter, Executive Director, Academic Senate
   Laura Gnesda, Analyst, Academic Senate, Irvine Division
   Natalie Schonfeld, Executive Director, Academic Senate, Irvine Division
June 13, 2018

Shane White
Chair, Academic Council


Dear Shane,

The Executive Board of the UCLA Academic Senate discussed the Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028 at its meeting on May 31, 2018. The Executive Board solicited comments from several standing committees of the Senate, as well as the Faculty Executive Committees.

The Executive Board members had no additional comment. All responses are attached.

As always, the Executive Board appreciates the opportunity to opine. Please feel free to contact me should have any questions.

Sincerely,

Sandra Graham
Chair, UCLA Academic Senate

cc: Hilary Baxter, Executive Director, Systemwide Academic Senate
    Susan Cochran, Immediate Past Chair, UCLA Academic Senate
    Joseph Bristow, Vice Chair/Chair-Elect, UCLA Academic Senate
    Michael LaBriola, Principal Policy Analyst, Systemwide Academic Senate
    Linda Mohr, Chief Administrative Officer, UCLA Academic Senate
MAY 10, 2018

SHANE WHITE, CHAIR, ACADEMIC COUNCIL

RE: PROPOSED PRESIDENTIAL POLICY ON DISCLOSURE OF FINANCIAL INTERESTS AND MANAGEMENT OF COI IN PRIVATE SPONSORS OF RESEARCH AND REVISED APM – 028

The proposed *Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research* and associated revisions to APM-028 were distributed to the standing committees of the Merced Division of the Academic Senate and the school executive committees. Comments were received from the Committee on Research. These are enclosed. The remaining committees appreciated the opportunity to opine, but had no comment.

At its May 8, 2018 meeting, Divisional Council discussed CoR’s comments, and ultimately endorsed their transmittal to you in full on behalf of the Division.

We thank you for the opportunity to opine.

Sincerely,

Susan Amussen, Chair
Division Council

CC: Divisional Council
   Hilary Baxter, Executive Director, Systemwide Academic Senate
   Laura Martin, Executive Director, Merced Senate Office
   Senate Office

Encl (2)
May 1, 2018

To: Susan Amussen, Chair, Division Council

From: David C. Noelle, Chair, Committee on Research (COR)


At its April 17 and May 1, 2018 meetings, the Committee on Research (COR) reviewed the Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and the associated proposed revisions to APM 028.

COR endorses the policy, but the Committee recommends that the systemwide Academic Senate clearly communicate to faculty the impact that these procedures will have if a faculty member makes a positive disclosure of financial interests.

We appreciate the opportunity to provide comments.

cc: COR members
    Senate Office
June 20, 2018

Shane White, Chair, Academic Council
1111 Franklin Street, 12th Floor
Oakland, CA 94607-5200


Dear Shane:

Attached you will find the full complement of the UCR Division’s feedback on the Proposed Presidential Policy on Disclosure of Financial Interests and COI, APM 028. The Division’s Executive Council met on June 11, 2018 and did not wish to add additional comments to the larger body of committee responses. You will see that the standing committees unanimously support the proposal and have generally not offered significant responses to its existing text.

Peace,

Dylan Rodríguez
Professor of Media & Cultural Studies and Chair of the Riverside Division

CC: Hilary Baxter, Executive Director of the Academic Senate
    Cherysa Cortez, Executive Director of UCR Academic Senate Office
June 14, 2018

Professor Shane White
Chair, Academic Senate
University of California
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

SUBJECT: Proposed Presidential Policy on Conflict of Interest and APM 028 Revision

Dear Shane:

The proposed revision to the Presidential Policy on Conflict of Interest and the revision to APM 028 were circulated to standing Senate committees for review, and were discussed at the San Diego Divisional Senate Council’s meeting on June 11, 2018. The San Diego Divisional Senate Council unanimously endorsed the proposed policy and revisions. Additional comments and suggestions are summarized below.

Reviewers noted that Section III.E.1 of the proposed policy specifies the threshold for triggering a substantive review by the Independent Substantive Review Committee is $10,000 in disclosed financial interests. It was not clear how the threshold amount was determined, and it was pointed out that some federal agencies, such as the National Institute of Health, have lower thresholds. Some reviewers commented that it would be preferable to have the same threshold as federal agencies.

Sincerely,

Farrell Ackerman, Chair
Academic Senate, San Diego Division

Enclosures

cc: H. Baxter    R. Horwitz    R. Rodriguez
June 19, 2018

To: Shane White, Chair
   Academic Council

From: Henning Bohn, Chair
      Academic Senate


The Council on Planning and Budget (CPB), Council on Faculty Welfare, Academic Freedom and Awards (CFW), and Committee on Research Policy and Procedures (CRPP) were asked to review the proposed policy and APM revision on behalf of the Santa Barbara Division. CPB and CFW chose not to opine.

CRPP’s discussion of this issue included consultation with Timothy Sherwood, UCSB’s Associate Vice Chancellor for Research. He noted that the proposed policy and proposed revisions to APM – 028 would not change the Office of Research’s current practices when reviewing these types of conflicts of interest. It was unclear to the Committee how potential conflict of interests for textbook writers would fit into this new policy, and they would like that to be clarified. Ultimately, CRPP unanimously supported the proposed policy and the proposed revisions to APM – 028.
June 14, 2018

SHANE N. WHITE
Chair, UC Academic Council


Dear Shane,

The Santa Cruz Division has reviewed and discussed the proposed Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research and proposed revisions to associated policy in APM-028. Responses were received from the Committees on Affirmative Action and Diversity (CAAD), Academic Personnel (CAP), Planning and Budget (CPB), and Research (COR). Overall, committees are supportive of the proposed policies, but they suggest some minor changes:

CAP raised the concern that the threshold for the reporting requirement is too low. The footnote on page 2 of the draft Presidential Policy suggests that the $50 reporting requirement comes from California Code regulations title 2 Section 1875. However, members agreed that if there is any flexibility, it would be beneficial to remove this undue burden so that resources could be focused on larger gifts with more pressing review requirements. CAP also recommends that the policy clarify whether there is a need to report travel reimbursements associated with normal academic activities for non-profit, academic funding agencies (e.g., review panels, university consortia, etc.).

COR recommends that APM-028 be periodically reviewed to ensure that it remains in compliance with current state and federal laws.

The Santa Cruz Division appreciates the opportunity to comment on this proposed amendment and hopes that the Academic Council will find its feedback helpful.

Sincerely,

Ólőf Einarsdóttir, Chair
Academic Senate
Santa Cruz Division

cc: CAAD Chair Greenberg
    CAP Chair Freccero
    CPB Chair Walsh
    COR Chair Milutinović
June 25, 2018

Shane White, PhD  
Chair, Academic Council  
Systemwide Academic Senate  
University of California Office of the President  
1111 Franklin St., 12th Floor  
Oakland, CA 94607-5200


Dear Shane:

The San Francisco Division of the Academic Senate recently reviewed the draft Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028. This proposed policy would define circumstances in which the substantive review of a disclosure of financial interests must be completed by the Independent Substantive Review Committee (ISRC), as opposed to a Designated Campus Reviewer (DCR). At UCSF, the ISRC is synonymous with the UCSF Conflict of Interest Advisory Committee (COIAC), which is a review committee under the auspices of the Administration.

The UCSF Committee on Research (COR) reviewed the policy and considered input from the UCSF Associate Director of Ethics and Compliance and the UCSF COI Manager. COR expressed concerns that the proposed policy would increase the number of disclosures submitted to the ISRC, which may lead to increased delays in the setup of extramural awards. COR asked UCOP to provide justification for the specific circumstances enumerated in the policy that would require substantive review by the ISRC. Finally, COR advised that the policy should enable the DCR, in consultation with the Chair of the ISRC, to determine whether a particular disclosure should be submitted to the ISRC for substantive review.

Thank you for the opportunity to provide comment.

Sincerely,

David Teitel, MD, Chair  
UCSF Academic Senate

Encl. (1)  
CC: Stuart Gansky, Chair, UCSF COR  
Hilary Baxter, Executive Director, UC Academic Senate
June 20, 2018

David Teitel, Chair
UCSF Academic Senate


Dear Chair Teitel:

UCSF Academic Senate Committee on Research (COR) has reviewed a proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research (proposed policy) and Revised APM - 028. COR considered input from the UCSF Associate Director of Ethics Compliance as well as the UCSF COI Manager.

The current policy (APM – 028) and the proposed policy both require disclosure of financial interests in two instances: an initial disclosure before a sponsored research agreement is accepted and an interim disclosure after renewal of sponsored research funding. However, in cases of a project renewal, the current policy does not specify a filing deadline for the interim disclosure. In contrast, the proposed policy states that the interim disclosure must be filed within 30 days after funding is renewed. This revision is consistent with the regulations of the Fair Political Practices Commission. In addition, it would clarify expectations and establish a reasonable timeframe for PIs to submit interim disclosures of financial interests.

All disclosures indicating a financial interest exists must undergo substantive review. The current policy provides that each campus “shall develop a procedure for independent substantive review including the designation or establishment of a committee to conduct the review.” However, it does not specify the circumstances when a substantive review either can be conducted by a Designated Campus Reviewer (DCR) or must be conducted by an Independent Substantive Review Committee (ISRC). In contrast, the proposed policy states that if “the DCR determines any of the following circumstances exists, the ISRC shall perform a substantive review:”

- The PI has received income, gifts, loans, or travel reimbursement from the sponsor or donor that, alone or when aggregated, equals or exceeds $10,000 during the previous twelve months.
- The PI holds an equity interest in the sponsor or donor that equals or exceeds $10,000.
- The PI holds a position as director, officer, partner, trustee, consultant, employee, or any position of management with the sponsor or donor.
At UCSF, under the current policy, disclosures of financial interest are first triaged by an appropriate administrator as well as the Chair of the UCSF Conflict of Interest Advisory Committee (COIAC). After a preliminary review, it may be determined necessary and appropriate to submit the disclosure to the COIAC to consider whether there are any conflicts of interest that must be managed, reduced or eliminated before support for the research project can be accepted. However, at UCSF, the determination whether a disclosure should be reviewed by the ISCR (COIAC) is based on a full assessment of the details in disclosure and the research, as opposed to either a monetary threshold or the existence of a position held with the sponsor or donor. In fact, there have been cases at UCSF in which either the financial interest exceeded $10,000 or the PI held a position with the sponsor or donor and yet the appropriate administrator, in consultation with the Chair of COIAC, triaged the conflict of interest without seeking the advice of the full ISRC (COIAC).

The proposed policy would impact UCSF by increasing the number of disclosures submitted to the ISRC (COIAC). This expected increased workload may also lead to increased delays in all extramural award setup, which is already sometimes delayed while awaiting ISRC (COIAC) review of annual PI attestations in the COI-SMART online system.

In reviewing the proposed policy, we seek to understand the rationale for specifying the circumstances that require substantive review by the ISRC (COIAC). The state guideline uses a $500 threshold, so is the justification for the $10,000 threshold using the federal guideline?

We respectfully advise that the policy should enable the Designated Campus Reviewer, in consultation with the Chair of the ISRC (COIAC), to determine whether a disclosure of financial interest should be submitted to the ISRC (COIAC) for substantive review.

COR appreciates this opportunity to provide input with regard to the proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM - 028.

Sincerely,

Stuart Gansky, DrPH
Chair, Committee on Research
UCSF Academic Senate
2017-2018
SHANE WHITE
CHAIR, ACADEMIC COUNCIL


Dear Shane,


1. UCORP recognizes the critical importance of adhering to State policies, guidelines, and regulations and specifically recognizes this effort to keep University policies, guidelines, and regulations up to date. For this reason, we recommend that the document be revisited in the future to ensure its relevance and effectiveness.

2. UCORP also believes it is equally important to keep University policies, guidelines, and regulations clear to help ensure compliance. Accordingly, we note that some parts of the text are unclear, for example, the section on reportable payments for travel (II.C.5). We assume that the reporting limits are mandated but note that $50 for gifts and $500 income are significantly different but a matter of semantics. There is no specific timeline related to the receipt and or duration of reportable events, but we assume that it is annual, as per the “700” form.

3. Members of the committee noted that there is inconsistent intent between sections of the policy whereby it is indicated that the documents are meant to apply to all employees. The text itself specifically targets PIs and PI-dependents, and there was significant concern that this text makes PIs responsible for all employees, all co-investigators, and all participants. This seems different from the intent stated in the preamble.
4. UCORP noted that the amounts for reporting purposes are very low ($50), and noticed that a 200-fold greater amount automatically triggers review ($10,000). While these amounts might be mandated, we would recommend increasing the threshold of a reportable gift above $50.

5. Finally, members of UCORP expressed concern that there are no guidelines to describe or develop mechanisms that would enable independent appeal of local decisions and that there are no mechanisms for post-implementation review to ensure uniform implementation across all campuses.

Sincerely,

Andrew Baird                Jeffrey D. Richman
UCORP Vice Chair            UCORP Chair

cc: Robert May, Academic Council Vice Chair
    Hilary Baxter, Academic Senate Executive Director
    UCORP members
May 23, 2018

RE: PROPOSED PRESIDENTIAL POLICY ON DISCLOSURE OF FINANCIAL INTERESTS AND MANAGEMENT OF COI IN PRIVATE SPONSORS OF RESEARCH AND REVISED APM – 028

Dear Shane,

UCAP reviewed the proposed revisions to Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028 during our meeting on May 9, 2018. UCAP has no objections to the proposed Presidential Policy and the proposed revisions to APM 028.

UCAP appreciates the opportunity to comment on this matter.

Sincerely,

Michelle Yeh, Chair
UCAP
SHANE WHITE, CHAIR
ACADEMIC COUNCIL

RE: Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM 028

Dear Shane,

At its June 3 meeting, the University Committee on Planning and Budget (UCPB) discussed the Proposed Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research, and the proposed revisions to APM 028. UCPB has no objection to the proposed policy or the revisions to APM 028.

Sincerely,

Joshua Schimel, Chair
UCPB

Encl.

cc: UCPB
    Executive Director Baxter