Table of Contents

Exec Presidential Policy_Disclosure of Financial Interests and Management of COI_White to Carlson 1
---SNW-SC-COI-Research-APM-028 ................................................................. 1
---All Senate Comments COI APM-028 ............................................................ 3
---Shane White ............................................................................................... 23
---Sandra Graham ......................................................................................... 23
GC Final Response ....................................................................................... 24
CPB Final Response ..................................................................................... 25
COR Final Response ..................................................................................... 26
FWC Final Response ..................................................................................... 27
L&S Final Response ..................................................................................... 28
Exec 3-29-18 Joint Systemwide Review Cvr Ltr ........................................... 29
Exec DRAFT COI 700-U Policy ................................................................ 32
---I. POLICY SUMMARY ............................................................................... 32
---II. DEFINITIONS ......................................................................................... 33
---III. POLICY TEXT ..................................................................................... 34
---IV. COMPLIANCE / RESPONSIBILITIES ................................................ 37
---V. PROCEDURES ....................................................................................... 38
---VI. RELATED INFORMATION ................................................................. 38
---VII. FREQUENTLY ASKED QUESTIONS ................................................ 38
---VIII. REVISION HISTORY ............................................................... 38
Exec DRAFT 028-04-10 clean 3-29-18 ....................................................... 39
Exec DRAFT 028-04-10 redline 3-29-18 ....................................................... 44
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
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 LaBrriola, 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, 2017-19 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
UCORP Vice Chair

Jeffrey D. Richman
UCORP Chair

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

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
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 you 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 17, 2018

To: Sandra Graham, Chair
    Academic Senate

From: Julio Vergara, Chair
    Graduate Council


At its meeting on May 11, 2018, the Graduate Council reviewed and discussed the Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028. Members found the proposed policy to be straightforward and offered no additional comments.

Thank you for the opportunity to review and comment.
May 8, 2018

Sandra Graham
Chair, UCLA Academic Senate


Dear Professor Graham,

At its May 7, 2018 meeting, the Council on Planning and Budget (CPB) reviewed the Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028.

Members agreed with the proposed new policy and changes to APM – 028 and had no additional comments or concerns.

Thank you for the opportunity to review the proposed new policy. If you have any questions for us, please do not hesitate to contact me at cbakhos@humnet.ucla.edu or via the Council’s analyst, Elizabeth Feller, at efeller@senate.ucla.edu or x62470.

Sincerely,

Carol Bakhos, Chair
Council on Planning and Budget

Cc: Joseph Bristow, Vice Chair, Academic Senate
Susan Cochran, Past Chair, Academic Senate
Elizabeth Feller, Committee Analyst, Council on Planning and Budget
Linda Mohr, CAO, Academic Senate
Members of the Council on Planning and Budget
May 11, 2018

Sandra Graham
Chair, UCLA Academic Senate


Dear Professor Graham,

Thank you for providing the Council on Research (COR) with an opportunity to comment on the Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028. The proposed policy was reviewed at the May 2, 2018 COR meeting. We were joined by Vice Chancellor for Research Roger Wakimoto and Assistant Vice Chancellor for Research and Campus Compliance Coordinator Ann Pollack to discuss the proposed new policy and understand the rationale for its development. the new policy.

Members agree with the proposed new policy and the changes to APM – 028 and do not have any additional comments or concerns.

Thank you for the opportunity to review the proposed new policy. If you have any questions for us, please do not hesitate to contact me at lhavton@mednet.ucla.edu or via the Council’s analyst, Elizabeth Feller, at efeller@senate.ucla.edu or x62470.

Sincerely,

Leif Havton, Chair
Council on Research

cc:    Joseph Bristow, Vice Chair, Academic Senate
       Susan Cochran, Past Chair, Academic Senate
       Elizabeth Feller, Analyst, Council on Research
       Linda Mohr, Chief Administrative Officer, Academic Senate
       Members of the Council on Research
May 1, 2018

Professor Sandra Graham
Chair, UCLA Academic Senate


Dear Professor Graham,

The committee reviewed and discuss the proposed revisions to the policy on Disclosure of Financial Interest and the revised APM 028 via email. Members agreed with the revisions and had no additional comments. Thank you for the opportunity to review and comment.

Sincerely,

David Lopez
Chair, Committee on Faculty Welfare

cc: Members of the Committee on Faculty Welfare
   Linda Mohr, CAO, Academic Senate
   Valeria Dimas, Executive Assistant
   Annie Speights, Committee Analyst, Committee on Faculty Welfare
The College FEC appreciates the opportunity to comment on the proposed new Presidential Policy on Disclosure of Financial Interests and Management of Conflict of Interest in Private Sponsors of Research as well as the revisions to the Academic Personnel Manual 028 – Disclosure of Financial Interest in Private Sponsors of Research. We reviewed the drafts of the policies at our meeting on April 27, 2018. We were joined by Vice Chancellor Roger Wakimoto and Assistant Vice Chancellor Ann Pollock to provide a historical overview of the policy and the highlight the changes to the document.

The committee heard the report and had no further comments. As always, our membership appreciates the consultative process and welcomes the opportunity to participate in the discussion of important matters like this. You are welcome to contact me at tornell@econ.ucla.edu with questions. Mitsue Yokota, Academic Administrator, is also available to assist you and she can be reached at (310) 794-5665 or myokota@college.ucla.edu.

cc: Lucy Blackmar, Assistant Vice Provost, Undergraduate Education Initiatives
Valeria Dimas, Executive Assistant, Academic Senate
Linda Mohr, Chief Administrative Officer, Academic Senate
March 29, 2018

CHANCELLORS
LABORATORY DIRECTOR WITHERELL
ACADEMIC COUNCIL CHAIR WHITE
ANR VICE PRESIDENT HUMISTON


Dear Colleagues:


Effective July 22, 2015, the Fair Political Practices Commission (FPPC) revised its regulations regarding review of Statements of Economic Interests for Principal Investigators (also known as the Form 700-U). The revision removed the requirement to perform independent substantive review of Forms 700-U by campus conflict of interest committees. However, in subsequent conversations, the FPPC staff has indicated that the change was inadvertent, and the University is still expected to perform substantive reviews of Forms 700-U. Also, the UC Systemwide Provost and the Council of Vice Chancellors for Research have expressed their desire to continue to have a review process to mitigate risks associated with conflicts of interest possibly resulting in harm to the University and its researchers.

This new Policy provides the core parameters for continued compliance with the regulations issued by the FPPC, including a continuation of the University’s long-standing practice of performing a substantive review of Forms 700-U. The foregoing conversations indicate that UC has flexibility in how the substantive review is performed. Accordingly, this new Policy provides the UC campuses, Lawrence Berkeley National Laboratory, and the Division of Agriculture and Natural Resources greater flexibility in their local processes for reviewing the Forms 700-U.
March 29, 2018
Page 2

APM - 028, Disclosure of Financial Interest in Private Sponsors of Research

Also enclosed for Systemwide Review are proposed revisions to APM - 028, Disclosure of Financial Interest in Private Sponsors of Research. The rationale for the proposed revisions to APM - 028 is two-fold: (1) APM - 028 has not been substantively revised since 1984 and the referenced state and federal laws are outdated; and (2) the proposed new Presidential Policy applies to all University employees, not just academic appointees. As a result, the proposed APM revisions strike topics now covered by the new Presidential Policy. Thus, the new Presidential Policy will govern continued compliance with FPPC regulations and review of Forms 700-U for all University employees while revised APM - 028 will maintain additional important principles guiding the conduct of sponsored research for academic appointees.

Systemwide Review

Systemwide Review is a public review distributed to the Chancellors, the Director of Lawrence Berkeley National Laboratory, the Chair of the Academic Council, and the Vice President of Agriculture and Natural Resources, requesting that they inform the general University community, affected employees, and union membership about policy proposals. Systemwide Review also includes a mandatory, three-month full Senate review. Employees should be afforded the opportunity to review and comment on the draft policy, available online at https://www.ucop.edu/academic-personnel-programs/academic-personnel-policy/policies-under-review/index.html. Attached is a Model Communication which may be used to inform non-exclusively represented employees about these proposals. The Labor Relations Office at the Office of the President is responsible for informing the bargaining units representing union membership about policy proposals.

We would appreciate receiving your comments by June 27, 2018. Please submit your comments on the proposed new Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research to RPAC@ucop.edu. Please indicate “700-U Policy Comments” in the subject line. Please submit your comments on the proposed revisions to APM - 028 to ADV-VPCarlson-SA@ucop.edu.

Questions relating to the proposed new Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research may be directed to Timothy Miller at Timothy.Miller@ucop.edu or (510) 987-0647. Questions relating to the proposed revisions to APM - 028 may be directed to Kimberly Grant at Kimberly.Grant@ucop.edu or (510) 987-9499.

Sincerely,

Susan Carlson
Vice Provost
Academic Personnel and Programs

Sincerely,

Arthur Ellis
Vice President
Research and Graduate Studies
March 29, 2018
Page 3

Attachments:
2. Revised APM - 028, Disclosure of Financial Interest in Private Sponsors of Research (clean and redline copies)
3. Model Communication

cc: President Napolitano
Provost and Executive Vice President Brown
Executive Vice Chancellors/Provosts
Executive Vice President & Chief Financial Officer Brostrom
Executive Vice President, Chief Operating Officer & Chief of Staff Nava
Executive Vice President Stobo
Senior Vice President & Chief Compliance and Audit Officer Bustamante
Senior Vice President Gulbranson
Vice President & Chief Investment Officer Bachher
Vice President & General Counsel Robinson
Vice President Budil
Vice President Duckett
Vice President Holmes-Sullivan
Vice Provost Gullatt
Deputy General Counsel Woodall
Vice Chancellors/Vice Provosts of Academic Personnel/Academic Affairs
Vice Chancellors for Research
Academic Personnel Directors
Chief Policy Advisor & Executive Director Kao
Senior Counsel Auriti
Senior Counsel Morodomi
Executive Director Baxter
Executive Director Chester
Executive Director Peterson
Executive Director Streitz
Chief of Staff and Director Henderson
Director Grant
Director Lee
Director Myjer
Manager Donnelly
Manager Smith
Academic HR Manager Jordan
Human Resources Manager Crosson
Analyst Ha
Analyst Miller
Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

I. POLICY SUMMARY

This Policy describes the review process for disclosures of financial interests made on the State of California financial disclosure form entitled, *Statement of Economic*
Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

_Statement of Economic Interests for Principal Investigators_ (Form 700-U). The Policy sets forth the requirements for review of such disclosures by campuses, and other UC locations, and authorizes reviewers to make recommendations about how to manage, reduce, or eliminate conflicts of interest.

II. DEFINITIONS

A. **Designated Campus Reviewer (DCR)**

A Designated Campus Reviewer (DCR), or the DCR’s designee, is responsible for conducting preliminary reviews of financial interests disclosed on Forms 700-U. Consistent with this Policy, a DCR may either perform a substantive review and make a recommendation about how possible conflicts of interest can be eliminated, reduced, or managed, before the acceptance of the grant(s), contract(s), gift(s), or Material Transfer Agreement(s) (MTA) or refer the matter to the location’s Independent Substantive Review Committee (ISRC) for substantive review. A DCR is designated by the Chancellor of each UC campus, or in the case of the Lawrence Berkeley National Laboratory, the Director, or, in the case of the Division of Agriculture and Natural Resources, the Vice President.

B. **Filing Officer**

A person or persons designated by the Chancellor of each UC campus, or in the case of the Lawrence Berkeley National Laboratory, the Director, or, in the case of the Division of Agriculture and Natural Resources, the Vice President, to retain Forms 700-U submitted by Principal Investigators. The Filing Officer may be the DCR.

C. **Financial Interest**

As defined under the Fair Political Practices Regulations, a Financial Interest includes one or more of the following for the Principal Investigator, Principal Investigator’s spouse/registered domestic partner, and dependent children:

1. A business position with the sponsor or donor, such as a director, officer, partner, trustee, consultant, employee, or holding any position of management with the sponsor.
2. Investment or equity (ownership) interest in the sponsor or donor worth $2,000 or more.
3. Income or loan from the sponsor or donor aggregating $500 or more.
4. A gift from the sponsor or donor with a value of $50 or more.

---

1 The Fair Political Practices Commission publishes and periodically updates the Statement of Economic Interests for Principal Investigators, also known as the Form 700-U.
2 Cal. Code Regs., tit. 2, § 18755
Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

5. Payment for travel from the sponsor or donor with a value of $50 or more if a gift or $500 or more if income. Payments either in advance, as reimbursement, or in-kind are reportable.

D. Statement of Economic Interests for Principal Investigators (or Form 700-U)

A State of California financial disclosure form entitled, Statement of Economic Interests for Principal Investigators, is used to comply with the Fair Political Practices Regulations as it relates to the University of California and its Principal Investigators. The Form 700-U is a public record under Gov. Code Section 81008(a).

E. Independent Substantive Review Committee (ISRC)

A committee that performs a substantive review of research projects and makes recommendations to the Chancellor, Director, or Vice President of the UC Location or their designees regarding disclosed Financial Interests. The ISRC may make recommendations as to whether disclosed Financial Interests present a conflict of interest and, if so, about how possible conflicts of interest can be eliminated, reduced, or managed before the acceptance of the grant(s), contract(s), gift(s), or material transfer agreement(s) (MTA).

F. Principal Investigator (PI)

An employee of a UC Location who is eligible to submit a proposal for research support in accordance with UC Contract and Grant Manual Section 1-520 and as further implemented by local policies and procedures, and who is principally responsible for the conduct of the research (a Principal Investigator, Co-PI, or Multiple PI).

G. UC Location

UC campus, the Office of the President, the Lawrence Berkeley National Laboratory, and the Division of Agriculture and Natural Resources.

III. POLICY TEXT

A. Purpose, Scope and Application

The purpose of this Policy is to describe the process of receiving and reviewing disclosures of financial interests made on the State of California financial disclosure form entitled, Statement of Economic Interests for Principal Investigators (Form 700-U).
Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

This Policy applies to all UC Locations and requires that Principal Investigators use the Form 700-U to disclose whether or not they have a Financial Interest in the sponsor of research that is funded or supported in whole or in part (a) through a contract or grant with a non-governmental entity or (b) by a gift from a non-governmental entity which is designated by the gift donor for a specific research project, or a specific Principal Investigator, or a laboratory or research program headed by a Principal Investigator, or (c) through in-kind support provided under an MTA. This Policy also authorizes reviewers to make recommendations on how to manage, reduce, or eliminate a conflict of interest.

Forms 700-U and supplemental materials associated with Forms 700-U are open to public inspection.

B. Disclosure Requirement

1. Initial Disclosure

The initial Form 700-U must be submitted by PIs in accordance with the rules and procedures of the respective UC Location before final acceptance of a contract, grant, gift, or MTA. Each Form 700-U shall include any and all reportable business positions with and investments in the sponsor or donor as of the date that the award is made. Furthermore, each Form 700-U shall include reportable income, gifts, and travel payments received from the sponsor or donor within the 12 months prior to the date that the award is made.

2. Interim Disclosure

A Form 700-U must be filed within 30 days after funding is renewed and shall disclose any and all reportable business positions, investments, income, gifts, and travel payments held or received during the period between the date the initial statement was filed and the date the funding for the project was renewed.

C. Supplemental Forms and Information

UC Locations may create supplemental forms and require PIs to complete them to gather additional information to make informed decisions regarding assessment and management of any conflicts that may arise from Financial Interests disclosed by a PI. Forms on which supplemental information is gathered must bear appropriate privacy notices.

---

3 Reportable investments and business positions are described above in § II.C.1 & 2.
4 Reportable income, gifts, and travel payments are described above in § II.C.3-5.
D. Disclosure Retention

Submitted Forms 700-U shall be retained at the UC Location by the locally designated Filing Officer in accordance with applicable UC document retention and disposition schedules. See UC Records Retention Schedule.

E. Disclosure Review

When a Principal Investigator's Form 700-U indicates they have no Financial Interests (a "negative disclosure"), no further review is required.

When a Principal Investigator's Form 700-U indicates that a Financial Interest exists (a "positive disclosure"), a substantive review must be performed. Pursuant to this Policy and local procedures and practices, a DCR must assess whether the disclosure must be reviewed by the ISRC or whether the DCR may perform the substantive review.

1. Criteria for Required ISRC Reviews

If, during review of the Principal Investigator's Form 700-U, the DCR determines that any of the following circumstances exist, the ISRC shall perform a substantive review of the Form 700-U and related supplemental forms or information:

- 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.

2. ISRC Review Pursuant to Local Procedures and Practices

For positive disclosures that do not meet the thresholds listed above in Section E.1, each UC Location may adopt local procedures and practices designating whether the substantive review of the research project should be conducted by the DCR or ISRC. Each UC location may establish procedures and practices where the DCR has the flexibility to seek substantive review by the ISRC even if the disclosed financial interests do not warrant a mandatory ISRC substantive review as specified in Section E.1.
Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

3. Conduct of Reviews

The DCR and/or ISRC may seek additional information and/or consult with administrators, faculty, and others involved in the research and review process, and may also consult with or request Principal Investigators and department chairs to provide additional or supplemental information to make a fully informed recommendation. Individuals with competence in special areas may assist in the review process when expertise beyond, or in addition to, that available to the DCR or ISRC is needed.

DCRs or ISRCs should recommend to the Chancellor, Director, or Vice President of the UC Location as appropriate or their designees whether there are any conflicts of interest that must be managed, reduced or eliminated before support for the research project can be accepted by the campus.

4. Timeline of Reviews

Reviews must be completed and any identified conflicts of interest must be managed, reduced, or eliminated prior to the institution’s expenditure of contract, grant, or gift funds, or acceptance of MTAs associated with the financial disclosure.

IV. COMPLIANCE / RESPONSIBILITIES

A. Chancellors and the Chief Executive or Head of each UC Location

Each UC Location is responsible for implementing this Policy locally and developing procedures for conducting independent substantive review consistent with this policy. Each Chancellor, the LBNL Director and the ANR Vice President (or a designee) is responsible for establishing the ISRC, and for designating a Filing Officer(s) and/or DCR to receive Forms 700-U, and store them for record keeping. Filing Officers and DCRs do not need to be the same person.

Subject to the requirements of this Policy, each UC Location has the authority to determine how reviews shall be conducted including whether such reviews should be conducted by a DCR or by an ISRC.

B. Designated Campus Reviewers (DCRs) and Independent Substantive Review Committees (ISRCs)

DCRs and ISRCs are responsible, per local campus policies and procedures, for reviewing substantively the subject matter of the proposed research and assessing the

---

5 Cal. Gov’t Code § 81009(e)(f).
Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

Principal Investigator’s disclosed Financial Interest(s). In addition, they are responsible for communicating their assessment to the Chancellor, LBNL Director, or Vice President of ANR (or designee) along with a recommendation of whether support for research in the form of a contract, grant, gift, or MTA should be accepted and, if so, whether any modifications or conditions are required to manage identified conflicts of interest.

DCRs, their designees, and ISRC members should possess the academic, professional, and administrative competence and expertise necessary to review the subject matter of the proposed research and to assess the University and other public interests involved.

C. Principal Investigators

Principal Investigators are responsible for complying with this Policy, including the California Fair Political Practices Commission’s (FPPC) requirement to file Forms 700-U for research supported by non-governmental entities, and the policies and/or procedures adopted by their UC Location to implement this Policy.

V. PROCEDURES

UC Locations should develop local procedures to implement this policy.

VI. RELATED INFORMATION


VII. FREQUENTLY ASKED QUESTIONS

Not applicable

VIII. REVISION HISTORY

This policy supersedes RPAC Guidance Memo 17-03 and is intended to establish the terms of that Guidance Memo as policy.
GUIDELINES FOR DISCLOSURE AND REVIEW
OF PRINCIPAL INVESTIGATOR’S FINANCIAL INTEREST
IN PRIVATE SPONSORS OF RESEARCH

These Guidelines Implement the University Policy on Disclosure of
Financial Interest in Private Sponsors of Research

I. Rationale

University research is currently reviewed according to the principles specified below and according to other well-established policies guiding the conduct of sponsored research, including the principle that researchers must be free to pursue knowledge and that this freedom, which is essential to the research process, must not lightly be abridged. The proposed review is supplemental to this process and takes advantage of the expertise and structure of the existing system. While it is normally the case that a principal investigator takes responsibility for the central issues raised in these guidelines, when a principal investigator has a financial interest of the sort defined in the University Conflict of Interest Code requiring disclosure, it is possible that his or her judgment may appear to be affected by potential financial gain rather than by the pursuit of knowledge. Therefore, it is proper that the principal investigator, the University community, and the public be assured that the principles central to the research process are followed.

II. Principles

A. Traditional conflict of interest situations should continue to be avoided

In the conventional sense, conflict of interest refers to situations in which employees may have the opportunity to influence the University’s business decisions in ways that could lead to personal gain or give advantage to associates or entities in which employees have an interest. Principal investigators, like all UC employees, are expected to continue to separate their University and private interests in accordance with existing University policies and State law.
B. **Research is appropriate to the University**

The research must be appropriate to the mission of the University, i.e., promising significant contributions to scholarship and knowledge and, when possible, providing appropriate opportunities for students. The suitability of the research would be judged according to the standards of the discipline and should be guided by the principles and policies of University Regulation 4, Special Services to Individuals and Organizations (APM - 020).

C. **The teaching and research environment is open**

The teaching and research environment should continue to promote the free exchange of ideas, information, and materials among students and faculty in all of their forums—classrooms, laboratories, meetings, and anywhere in the University. Selection of students for participation in the research project should not be inappropriately influenced by the interest of the sponsoring entity.

D. **Freedom to publish and to disseminate research results is preserved**

Consistent with current University policies, there should be no limits placed on the freedom to publish, except for short periods of delay that permit a sponsor to comment or to permit filing of patent applications.

E. **Licensing agreements require thorough review**

If the principal investigator has a financial interest in the sponsoring entity, justification for granting of an exclusive license to the sponsoring entity will require careful review to ensure that the best interests of the public and the University are served. This review should be coordinated with the Patent Administrator for consideration in negotiations concerning patent rights.

F. **University facilities and resources are used appropriately**

As is currently the policy, University resources—supplies, equipment, and facilities, as well as staff time—must not be used for the benefit of the outside entity without proper compensation.
III. Procedures for conduct of committee review

Review committees should be guided by the following practices and apply them as appropriate.

A. Assure adherence to relevant University policies, guidelines, and regulations

These policies are identified, summarized, and paraphrased in the Business & Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest.

B. Consider, to the extent possible, the nature and extent of the financial interest in the relationship of the principal investigator to the sponsoring entity

In addition, to the extent possible, the potential financial effects of the research both on the sponsor and on the principal investigator should be considered.

C. Give special consideration to:

1. Conditions of research agreements which involve:
   a. The testing of a sponsor’s products or inventions;
   b. Research conducted in the sponsor’s facilities;
   c. Research performed jointly with an employee or agent of the sponsor; or
   d. Research involving the provision of proprietary information from the sponsor.

2. The relationship between the principal investigator and the sponsor when the principal investigator has:
   a. A significant ownership interest in the sponsor;
   b. The opportunity to receive substantial financial benefits from the sponsor (e.g. bonuses, stock options); or
   c. A long term or ongoing consulting relationship with the sponsor.
D. **Obtain additional information from the Principal Investigator when necessary**

Since committees may find it useful to get more information from the principal investigator than is covered in the Statement of Economic Interests, Form 700-U, a sample form is provided (entitled the Principal Investigator’s Addendum to Statement of Economic Interest) which includes possible questions and also advice to the principal investigator about the purpose of the request and its legal status.

In the event that such a sample form, or the like, is utilized, it must contain a privacy statement.

E. **Apply the principles set forth in II above:**

Some questions which might be considered when appropriate are:

1. Do the facts and circumstances suggest that the principal investigator’s financial involvement with the sponsoring entity will in any way affect or impair the conduct of the research in accordance with the applicable University policies and the highest professional standards?

2. How will the interests of the University be maintained in consideration of the principal investigator’s interest in the sponsor?

3. Will the research project lead to the advancement of knowledge rather than to routine testing of primary benefit to the sponsor?

4. How will this research project contribute to the University’s mission of teaching, research, and public service?

5. Do the potential public benefits to be gained from undertaking this research outweigh any potential erosion of academic freedom, collegiality, or public trust?

6. Are the best interests of the University and the public served by granting an exclusive license to the sponsor?
F. **Make a recommendation providing the necessary documentation and indicating:**

- Acceptance of the gift or grant.
- Non-acceptance of the gift or grant.
- Modification, specifying what modifications need to be made, or what conditions need to be imposed.

The UC Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research can be found at [insert link].
028.0—Policy

The University of California policy on disclosure of financial interest in private sponsors of research (revised April 26, 1984, with technical updates made on April 29, 2010) is set forth in the following pages.

028.10—Guidelines

The University of California guidelines on disclosure of financial interest in private sponsors of research are set forth in the following pages.
I. Policy on Disclosure of Financial Interest in Private Sponsors of Research

A principal investigator must disclose whether or not he or she has a direct or indirect financial interest in the sponsor of research which is funded or supported in whole or in part—
(a) through a contract or grant with a non-governmental entity or (b) by a gift from
a non-governmental entity which is earmarked by the donor for a specific research project or a specific principal investigator. Disclosure statements must be filed (a) before final acceptance of such a contract, grant, or gift; and (b) when funding is renewed. The
Statements will be open to public inspection. When disclosure indicates that a financial interest exists, an independent substantive review of the disclosure statement and of the research project must take place prior to acceptance of the contract, grant, or gift.

Department chairs must disqualify themselves from approving a research proposal for a project which is funded in whole or in part by a non-governmental entity in which they have a financial interest.

This policy is consistent with California Code of Regulations, Title 2, Section 18702.4(c).

II. Definitions

A. “Financial Interest.” A “financial interest” in the sponsor of research means:

1. A direct or indirect investment in the sponsor worth $2,000 or more;*  
2. A position as director, officer, partner, trustee, employee of or any other position of management in the sponsor;  

*An “investment” is defined by Government Code Section 2034, and includes any financial interest in or security issued by a business entity, including but not limited to common stock, preferred stock, rights, warrants, options, debt instruments and any partnership or other ownership interest.
3. Income from the sponsor, including consulting income, aggregating $500 or more in value, received by or promised to the principal investigator within 12 months prior to the time the award is made. (For the purposes of this policy, “income” is further defined as in California Government Code Section 82030.)

4. A gift or gifts provided to, received by, or promised to, the principal investigator within 12 months prior to the time the award is made which, when aggregated, meet or exceed the gift limit in the Political Reform Act, California Government Code Section 89503, as adjusted biennially on January 1 of every odd-numbered year based on a Consumer Price Index escalator, California Code of Regulations, Title 2, Section 18940.2.²

B. “Indirect Investment” or “Indirect Financial Interest.” A principal investigator has an “indirect investment” or “indirect financial interest” in a sponsor if:

1. His or her spouse, registered domestic partner, or dependent child has a financial interest in the sponsor;

2. The principal investigator, his or her spouse, registered domestic partner, or dependent child own directly, indirectly, or beneficially a 10 percent interest or greater in any business entity or trust which has a financial interest in the sponsor of the research.

C. “Equity (Ownership) Interest.” For the purposes of this policy, an “equity (ownership) interest” shall be an investment of $2,000 or more in the sponsor by the principal investigator, his or her spouse, registered domestic partner, or dependent children.

D. “Gift.” As defined by the Fair Political Practices Commission Form 700-U, also known as the Statement of Economic Interests for Principal Investigators, a gift is anything of value for which you have not provided equal or greater consideration to the donor.

²As of January 1, 2009, the gift limit was $420. California Code of Regulations, Title 2, Section 18940.2.
III. Disclosure Requirement

When a principal investigator has disclosed a financial interest in a sponsor of research, the required financial disclosure statement on Fair Political Practices Commission Form 700-U shall contain:¹

A. Disclosure of Income

1. The name and address of the sponsor, a general description of the business activity, if any, of the sponsor, and the amount of research funding;

2. A statement whether the aggregate value of income from the sponsor, or in the case of a loan, the highest amount owed to the sponsor, was at least $500 but did not exceed $1,000, whether it was in excess of $1,000 but was not greater than $10,000, whether it was in excess of $10,000 but was not greater than $100,000, or whether it was greater than $100,000;

3. In the case of a gift of $50 or more, a description of and the amount of the gift and the date received; and

4. In the case of a loan, the annual interest rate and the security, if any, given for the loan.

B. Disclosure of Equity or Ownership Interest and Disclosure of Position in Sponsor

When an investment or equity (ownership) interest is required to be disclosed, or when the principal investigator is a director, officer, partner, trustee, employee, or holds any position of management, the disclosure statement shall contain:

1. A statement of the principal business activity of the sponsor;

2. A statement whether the fair market value of the investment or interest exceeds $2,000 but does not exceed $10,000, whether it exceeds $10,000, but does not exceed $100,000, whether it exceeds $100,000 but was not greater than $1,000,000, or whether it exceeds $1,000,000; and

3. The position held in the entity by the principal investigator.

¹The Fair Political Practices Commission publishes and periodically updates the Form 700-U, also known as the Statement of Economic Interests for Principal Investigators. A current copy of the form may be found at: http://www.fppc.ca.gov/index.php?id=500.
IV. Independent Substantive Review Committees

When disclosure indicates that a financial interest exists, an independent substantive review of the disclosure statement and research project shall take place before a contract, grant, or gift is accepted. Chancellors, the Lawrence Berkeley National Laboratory Director, and the Vice President—Agriculture and Natural Resources, after consultation with appropriate academic and administrative groups, shall develop a procedure for independent substantive review including the designation or establishment of a committee to conduct the review.

The committees shall review disclosure statements and relevant features of the research project and on the basis of the review recommend to the Chancellor, the Lawrence Berkeley National Laboratory Director, or the Vice President—Agriculture and Natural Resources whether funding for the research project should be accepted and, if so, whether any modifications or conditions are needed. The committees shall be sufficiently qualified through the experience of their members to promote respect for their advice.

The committees should possess the academic, professional, and administrative competence and expertise necessary to review the subject matter of the proposed research and to assess the University and other public interests involved. The committee may include graduate students and one or more qualified members not affiliated with the University. The committee may consult with administrators, faculty, and others involved in the research and review process and the academic discipline in question. It may also consult with or request principal investigators and department chairs to provide information in order to make a fully informed recommendation. It may also invite individuals with competence in special areas to assist in the review process which require expertise beyond, or in addition to, that available to the committee. The committee review should occur as early as possible in the overall review process to assure that commitments are not inadvertently made to the sponsors. The committee shall, in its written documentation of the review, address each of the principles set forth in the Guidelines. The basis for the recommendation should be clearly established in the documentation of the review.

V. Implementation

Chancellors, the Lawrence Berkeley National Laboratory Director, and the Vice President—Agriculture and Natural Resources shall implement this policy. They must provide the committees with appropriate administrative support, assure that technical advice on conflict of interest matters is provided, and assure that appropriate documents related to this policy are available to the public, as required by law.
The Provost and Executive Vice President—Academic Affairs has responsibility for assuring compliance with applicable State law, this policy, and related University policies. The Provost and Executive Vice President—Academic Affairs is responsible for developing and issuing implementing guidelines for this policy. The Provost and Executive Vice President—Academic Affairs serves as the liaison on these matters with the Fair Political Practices Commission and with the campuses, the Lawrence Berkeley National Laboratory Director, and the Vice President—Agriculture and Natural Resources.
I. Rationale

University research is currently reviewed according to the principles specified below and according to other well-established policies guiding the conduct of sponsored research, including the principle that researchers must be free to pursue knowledge and that this freedom, which is essential to the research process, must not lightly be abridged. The proposed review is supplemental to this process and takes advantage of the expertise and structure of the existing system. While it is normally the case that a principal investigator takes responsibility for the central issues raised in these guidelines, when a principal investigator has a financial interest of the sort defined in the University Conflict of Interest Code requiring disclosure, it is possible that his or her judgment may appear to be affected by potential financial gain rather than by the pursuit of knowledge. Therefore, it is proper that the principal investigator, the University community, and the public be assured that the principles central to the research process are followed.

II. Principles

A. Traditional conflict of interest situations should continue to be avoided

In the conventional sense, conflict of interest refers to situations in which employees may have the opportunity to influence the University’s business decisions in ways that could lead to personal gain or give advantage to associates or entities in which employees have an interest. Principal investigators, like all UC employees, are expected to continue to separate their University and private interests in accordance with existing University policies and State law.
B. Research is appropriate to the University

The research must be appropriate to the mission of the University, i.e., promising significant contributions to scholarship and knowledge and, when possible, providing appropriate opportunities for students. The suitability of the research would be judged according to the standards of the discipline and should be guided by the principles and policies of University Regulation 4, Special Services to Individuals and Organizations (APM - 020).

C. The teaching and research environment is open

The teaching and research environment should continue to promote the free exchange of ideas, information, and materials among students and faculty in all of their forums—classrooms, laboratories, meetings, and anywhere in the University. Selection of students for participation in the research project should not be inappropriately influenced by the interest of the sponsoring entity.

D. Freedom to publish and to disseminate research results is preserved

Consistent with current University policies, there should be no limits placed on the freedom to publish, except for short periods of delay that permit a sponsor to comment or to permit filing of patent applications.

E. Licensing agreements require thorough review

If the principal investigator has a financial interest in the sponsoring entity, justification for granting of an exclusive license to the sponsoring entity will require careful review to ensure that the best interests of the public and the University are served. This review should be coordinated with the Patent Administrator for consideration in negotiations concerning patent rights.

F. University facilities and resources are used appropriately

As is currently the policy, University resources—supplies, equipment, and facilities, as well as staff time—must not be used for the benefit of the outside entity without proper compensation.
III. Procedures for conduct of committee review

Review committees should be guided by the following practices and apply them as appropriate.

A. Assure adherence to relevant University policies, guidelines, and regulations

These policies are identified; summarized, and paraphrased in the Business & Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest.

B. Consider, to the extent possible, the nature and extent of the financial interest in the relationship of the principal investigator to the sponsoring entity

In addition, to the extent possible, the potential financial effects of the research both on the sponsor and on the principal investigator should be considered.

C. Give special consideration to:

1. Conditions of research agreements which involve:
   a. The testing of a sponsor’s products or inventions;
   b. Research conducted in the sponsor’s facilities;
   c. Research performed jointly with an employee or agent of the sponsor; or
   d. Research involving the provision of proprietary information from the sponsor.

2. The relationship between the principal investigator and the sponsor when the principal investigator has:
   a. A significant ownership interest in the sponsor;
   b. The opportunity to receive substantial financial benefits from the sponsor (e.g. bonuses, stock options); or
   c. A long term or ongoing consulting relationship with the sponsor.
D. **Obtain additional information from the Principal Investigator when necessary**

Since committees may find it useful to get more information from the principal investigator than is covered in the Statement of Economic Interests, Form 700-U, a sample form is provided (entitled the Principal Investigator’s Addendum to Statement of Economic Interest) which includes possible questions and also advice to the principal investigator about the purpose of the request and its legal status.

In the event that such a sample form, or the like, is utilized, it must contain a privacy statement.

E. **Apply the principles set forth in II above:**

Some questions which might be considered when appropriate are:

1. Do the facts and circumstances suggest that the principal investigator’s financial involvement with the sponsoring entity will in any way affect or impair the conduct of the research in accordance with the applicable University policies and the highest professional standards?

2. How will the interests of the University be maintained in consideration of the principal investigator’s interest in the sponsor?

3. Will the research project lead to the advancement of knowledge rather than to routine testing of primary benefit to the sponsor?

4. How will this research project contribute to the University’s mission of teaching, research, and public service?

5. Do the potential public benefits to be gained from undertaking this research outweigh any potential erosion of academic freedom, collegiality, or public trust?

6. Are the best interests of the University and the public served by granting an exclusive license to the sponsor?
F. Make a recommendation providing the necessary documentation and indicating:

- Acceptance of the gift or grant.
- Non-acceptance of the gift or grant.
- Modification, specifying what modifications need to be made, or what conditions need to be imposed.

The UC Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research can be found at [insert link].
Attachment to Guidelines

Sample Form

PRINCIPAL INVESTIGATOR’S
ADDENDUM TO STATEMENT OF ECONOMIC INTEREST

Campus

Principal Investigator _____________________________________________________________

_________________________________ NAME

DATE

Research Project ________________________________________________________________

Proposed Sponsor ______________________________________________________________

Introduction

(Include here information about the research process on the campus for review of disclosures of financial interest; reasons additional information is needed; and any other relevant information.)

Request for Information (recommended questions)

1. ____________________________________________________ Describe the nature of your financial interest in the sponsor, such as your responsibilities as a director, officer, partner, trustee, employee, consultant, ownership interest including actual or promised options or convertible securities or loans, and the relationship between that interest or position and this research project. Please indicate if there are any written agreements between you and the sponsor.

2. ____________________________________________________ Describe to the extent possible the potential financial effect of this project on the sponsor.

3. Explain if you separately, or along with your spouse, registered domestic partner, or dependent children, own 10% or more of the entity sponsoring this research project.
4. Describe your role in the research program of the sponsoring entity.

5. Describe in some detail if the research project involves:
   a. testing;
   b. licensing or other approval of any product or device by a governmental agency; or
   c. development of any product or other device of potential economic value to the sponsor.

6. Explain how the research will lead to the extension of knowledge, to an increased effectiveness in teaching, or will provide a public service.

7. Provide funding information about the project:
   a. Is the sponsor funding the full cost of the project?
   b. If other funding sources are involved in this research project, please indicate who they are and the dollar value of their support.
   c. Will the University be contributing to this project, either by supporting faculty or other salaries, or by directly providing supplies, equipment, or facilities?

8. Describe any participation of the sponsor in deciding the direction of the research, once begun.

9. Describe the role of students in the research project.

10. Indicate whether selection of topics for students will be restricted by commercial considerations.

11. Describe how the terms of your relationship with the sponsor could affect the free exchange of ideas, information, and materials among students and faculty.
12. Describe how the terms of your relationship with the sponsor could affect publication or other dissemination of research results by faculty or students involved in the project.

13. Indicate whether the contract, grant, or gift funding this research will require the ______ granting of an exclusive license to the sponsor.

14. Indicate whether the sponsor will be providing any proprietary data for use on the ______ project.

15. Indicate whether possession of proprietary data will require controls on access to the research data. Please describe any such requirements.

(Please include any additional information that may be of use to the committee in reviewing the proposal, including any background documentation about the development of the project, related research interests, negotiations or other correspondence with the sponsor, and a proposed budget if one has not already been submitted.)

____________________________________
SIGNATURE

____________________________________
DATE
The State of California Information Practices Act of 1977 (effective July 1, 1978) requires the University to provide the following information to individuals who are asked to supply information about themselves: The principal purpose for requesting the above information is to accomplish the independent and substantive review of positive financial disclosures as required by the Policy on Disclosure of Financial Interest in Private Sponsors of Research (Revised April 29, 2010). University policy and State law authorize maintenance of this information. Submission of this information is mandatory. The consequences of not providing all or any part of the requested information could be nonacceptance of your award from the proposed sponsor. The information is a public record under University policy and State law. Individuals have the right to review their own records in accordance with Academic Personnel Manual, Section 160. Information about this records policy may be obtained from the campus or Office of the President—Office of Academic Affairs. The officials responsible for maintaining the information collected on this form are the (appropriate campus officer) and the Provost and Executive Vice President—Academic Affairs.

---

¹ This statement must be included in the form.