

## Gina Anderson

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**From:** Gina Anderson  
**Sent:** Wednesday, June 13, 2012 5:25 PM  
**To:** Kathryn Olmsted; 'Ann Orel'; andre knoesen; Stuart Hill  
**Cc:** Linda Bisson  
**Subject:** TIME SENSITIVE: PPM Review Request; Due 7/6/12  
**Attachments:** 230-07.docx

**Importance:** High

All, The Division has received the enclosed proposed revision to policy. We were forewarned it was forthcoming and is being generated by federal regulation changes. I have been told there was insufficient time to provide a draft in advance of spring quarter ending and there is an inability to hold off until fall quarter when the Division can conduct a full review. Chair Bisson is asking if you will individual review and submit comments. We realize it may not be possible to contact your committees as many of the faculty have left or are in the process of leaving for the summer. However, the draft is too important for the Division to forego review altogether.

If you are willing to submit comments to me before June 30, I will work with the Chair to develop a response. The response will include a statement regarding the poor timing and lack of ability to fully consult. If you believe it would be easier to meet as a group and discuss, let me know and we will schedule a meeting instead.

Best,  
Gina

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**From:** Molly M. Theodossy  
**Sent:** Wednesday, June 13, 2012 10:29 AM  
**To:** Gina Anderson; Steven Drown; Lynette Temple; Sandi Glithero; Cindy M Kiel; Yvonne Sundahl; JeffGibeling; Jeremiah J Maher; Leslyn Kraus  
**Subject:** PPM Review Request; Due 7/6/12

### **Policy and Procedure Manual Review Request**

**Date:** June 13, 2012

**Response requested by:** July 6, 2012

**To:** Internal Audit  
G. Anderson, Academic Senate/Academic Federation  
S. Drown/L. Temple, Campus Counsel  
J. Gibeling, Graduate Studies  
S. Glithero, Academic Affairs  
C. Kiel, Office of Research  
Y. Sundahl, UCDHS Policy

**Section:** 230-07, Public Health Service Regulations on Objectivity in Research

**Purpose:** Implements the Public Health Services (PHS) regulations on promoting objectivity in research.

A draft of the section is attached for your review. Please review the draft, entering your edits and comments in the attached file.

Return the edited file directly to me, via email, by the response date indicated above. In your return email, indicate any additional individuals in your office who have reviewed the draft.

**No response by the deadline above will be interpreted as your concurrence with the proposed manual section.**

Reviewers' comments and suggestions will be compiled, and I will work with the policy/process originator to resolve any issues. Once the comments are reconciled, I will prepare a final draft for approval by the originator, the department head and the appropriate vice chancellor or vice provost prior to publication.

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# UC Davis Policy and Procedure Manual

## Chapter 230, Sponsored Programs

### Section 05, Public Health Service Regulations on Objectivity in Research

Date: Draft 6/13/12

Supersedes: New

Responsible Department: Office of Research

Source Document: [University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Programs](#); [Academic Personnel Manual Section APM-028, Disclosure of Financial Interest in Private Sponsors of Research](#)

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#### I. Purpose

- A. This Policy implements the 2011 Public Health Services (PHS) regulations on Promoting Objectivity in Research and is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS or after August 24, 2012.
- B. PHS Research Activities that are ongoing as of August 24, 2012, will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension.
- C. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct or reporting of a PHS Research Activity.
- D. The Policy is applicable to all research activities supported by PHS and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research.

#### II. Definitions

- A. Conflict of Interest Committee (COIC)—A UC Davis faculty committee charged with determining if Significant Financial Interests that are related to the proposed research constitute financial conflicts of interest. The CIC is appointed by the Chancellor and is advisory to the Vice Chancellor—Research.
- B. Designated Official(s)—Campus official(s) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in a PHS Research Activity.
- C. Financial Conflict(s) of Interest (FCOI)—A Significant Financial Interest that is related to the PHS funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS-funded research activity.
- D. Institutional Responsibilities—Teaching/education, research, outreach, clinical service, and University and public service, on behalf of the University of California which are in the course and scope of the Investigator's UC appointment/employment.
- E. Investigator—Any individual who shares responsibility for the design, conduct or reporting of the results of a sponsored project with the Principal Investigator. This includes, but is not limited to Key Personnel named on a proposal budget.

- F. Key Personnel—A PHS research Project Director, Principal Investigator and any other personnel considered essential to work performance and identified as Key Personnel in the contract or grant proposal.
- G. PHS Research Activity(ies)—Any award for which research funding is available from PHS including research contracts, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards and conference grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.
- H. Principal Investigator (PI)—An Investigator (normally an academic appointee) who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.
- I. Significant Financial Interest (SFI)—Anything of monetary value that meets the PHS thresholds (see Section III.C below) for reporting received by the Investigator (including the Investigator's spouse or registered domestic partner, and dependent children for the following categories except travel) that reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities. Examples of SFI include:
  - 1. Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization; or salary received outside of the University of California.
  - 2. Stock or stock options in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
  - 3. Receipt of income from any organization other than the University of California for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from prior employers and other universities.
  - 4. Travel reimbursements made to, or on behalf of, the Investigator, regardless of the amount, by a for-profit or nonprofit entity, excluding a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.

### III. Policy

- A. The PHS regulations on Objectivity in Research are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of PHS Research Activities will be free from bias resulting from any Investigator's Financial Conflicts of Interest.
- B. Each institution applying for or receiving research support from PHS must comply with the regulations by putting in place a procedure to ensure that:

1. Investigators complete a training/education program on Financial Conflicts of Interest, the responsibilities to disclose, and the PHS regulations:
  - a. Before engaging in PHS Research Activities and at least every four years thereafter while receiving PHS research funding, and
  - b. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.
2. Investigators disclose SFI at the following times:
  - a. Initial disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity before the application for funding is submitted.
  - b. UC Davis Investigators who are engaged in PHS Research Activities have an ongoing responsibility to update their disclosures throughout the period of PHS support:
    - 1) Within thirty (30) days of acquiring or discovering any new SFI; and
    - 2) At least annually.
  - c. New Investigators must complete a disclosure of SFI before joining an ongoing PHS Research Activity.
3. Investigators disclose to UC Davis SFI that meet the following PHS thresholds:
  - a. For a publicly traded entity
    - 1) Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior twelve months and the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.
    - 2) Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles.
  - b. For a non-publicly traded entity
    - 1) Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior twelve months that exceeds \$5,000, or any equity interest, including, but not limited to stock, stock options, or ownership interest in the entity.
    - 2) Investigators are not required to disclose:

- (i) payments made by The Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University of California; or
    - (ii) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education
  - c. Intellectual property rights and interests
    - 1) Income from each organization that exceeds \$5,000 during the twelve months preceding disclosure of such rights and interests.
    - 2) SFIs do not include royalties received from The Regents of the University of California related to patents or copyrights.
  - d. Travel
    - 1) Reimbursements of any amount received during the prior twelve months made to, or the value of travel paid on behalf of, the Investigator by a for-profit or non-profit organization.
    - 2) Faculty may also report future Travel Reimbursements anticipated in the upcoming twelve months to avoid multiple disclosures of this information throughout the year.
    - 3) Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.
- C. Disclosures by collaborators
  - 1. Collaborators from other institutions, who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from UC Davis are expected to comply with the policies and procedures of the organization at which they are employed.
  - 2. Subawards issued by UC Davis will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending UC Davis notification of their ability to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.
  - 3. Collaborators, who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by UC Davis should be identified as Investigators by the UC Davis PI and must complete the UC Davis disclosure forms.
  - 4. If, upon review, UC Davis determines that these SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to eliminate, reduce or manage the identified conflicts of interest.

#### IV. Reviews and Reporting

- A. With each PHS proposal, progress report, incremental funding, or extension, all Investigators who have disclosed any SFI will be asked to provide additional information about the SFI that they previously disclosed. This information will be used by UC Davis to conduct a preliminary review in order to reasonably determine whether any of an Investigator's SFI could:
  - 1. Could be affected by the PHS Research Activity; or
  - 2. Is in an entity whose financial interest could be affected by the research.
  - 3. If after review it is determined that a SFI is related to the proposed PHS Research Activity, there will be a second review conducted by the CIC or a Designated Official to determine whether the SFI(s) reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS Research Activity and thereby constitute a FCOI that may need to be eliminated, reduced or managed.
- B. In accordance with the PHS regulations, plans put into place to manage identified FCOI will be monitored for compliance until the completion of the PHS Research Activity. Each management plan will specify the way in which that will be accomplished.
- C. Initial reports of FCOI must be made to PHS prior to UC DAVIS's expenditure of any funds provided under a PHS Research Activity. When identified conflicts of interest are eliminated before research funds are expended, UC Davis is not required to submit a report to PHS.
- D. Additional FCOI reports must be submitted to PHS under the following circumstances:
  - 1. Throughout the lifetime of an award when progress reports are submitted, or at the time that an award is extended (either through extension notification or an NIH prior approval request).When during the course of an ongoing PHS Research Activity a FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
  - 2. Within 60 days of determining that a FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS Research Activity.
  - 3. Within 60 days of determining that a FCOI exists for an Investigator who joins an ongoing PHS Research Activity.
- E. When during the course of an ongoing PHS Research Activity, UC Davis identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Official will review the SFI within 60 days to determine whether it is related to PHS Research Activities and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.
- F. Whenever an FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose a SFI that was later determined to be a FCOI, or UC DAVIS's failure to review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, UC Davis must within 120 days of the determination of non-compliance complete a retrospective review of the Investigator's activities and the PHS Research Activities.

1. The purpose of this retrospective review is to determine if the ongoing PHS Research Activity was biased in its design, conduct or reporting.
2. Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that UC Davis will take to manage the identified FCOI.
3. If bias was found during the retrospective review, UC Davis will promptly notify PHS and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines UC DAVIS's plans to eliminate or mitigate the effect of the bias.

#### **V. Records Access and Retention**

- A. UC Davis is required to respond within 5 business days to any request for information about SFIs held by Key Personnel when UC Davis has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs. Under the California Public Records Act, information provided on disclosure forms may be made available to the public upon request.
- B. Records of financial disclosures, Designated Official's determinations, CIC recommendations, and University action regarding management of a conflict of interest will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer.
- C. Records relating to unfunded projects need not be retained.

#### **VI. Sanctions**

- A. Failure by an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline pursuant to APM-016 or other applicable employee or student disciplinary policies.
- B. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause.
- C. Agreements with subrecipient organizations may be terminated for cause if that organization fails to comply with its obligations under the PHS regulations.
- D. Federal regulations may require reports to the federal sponsor of any violations of federal regulations and University policy.

#### **VII. References and Related Policies**

- A. Public Health Service (PHS) "Objectivity in Research," Code of Federal Regulations (42 CFR Part 50, Subpart F and 45 CFR Part 94).
- B. California Public Records Act (Government Code § 6250 et seq.).
- C. UC Office of the President:
  1. University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects.

2. Business & Finance Bulletin, RMP-1, University Records Management Program.
  3. Business & Finance Bulletin, RMP-2, Records Retention and Disposition.
  4. Memo on Administrative Records Relating to Research: Retention Disposition and Requirements.
- D. UC Davis PPM Section 230-05, Individual Conflicts of Interest Involving Research.