Conflict of Commitment (COC) and Conflict of Interest (COI)

Presented by:

Rebecca L. Woolston
VCHS Academic Affairs Office
(619) 543-2937
rwoolston@ucsd.edu
and
Jennifer J. Ford
Director, Conflict of Interest
(858) 534-3335
jjford@ucsd.edu

April 26, 2018
Conflict of Commitment & Outside Professional Activities

APM 671/APM 025

Rebecca L. Woolston
Introduction

The University of California acknowledges the value of faculty engagement in outside professional activities. Accordingly, faculty members are permitted to engage in outside consulting and other activities in accordance with University policies.

Relevant Policies:

• Regent’s Standing Order 103.1(b)
• APM 671
• APM 025
Outside Professional Activities and Conflict of Commitment

- Outside Professional Activities (compensated or uncompensated) are defined as those activities which are within a faculty member’s area(s) of professional, academic expertise and that advance or communicate that expertise through interaction with industry, the community, or the public. (APM 671-4(a)/APM 025-4(a)).

- Under University policy, a Conflict of Commitment occurs when a commitment to external activities interferes with the successful performance of a faculty member’s University obligations.
Categories of Outside Professional Activities

University policy categorizes Outside Professional Activities into 3 categories based upon the degree to which the activity may interfere with the faculty member’s University duties.¹

Each category has varying requirements including disclosure and approval:

- Category I: Requires annual disclosure of activity and earnings + prior approval from the Compliance Advisory Group (CAG)
- Category II: Requires annual disclosure of activity and earnings
- Category III: No disclosure requirement nor prior approval required

¹ Based upon the faculty member’s appointing series and percentage of effort (see APM 671 and APM 025), Outside Professional Activities which may cause a Conflict of Commitment must be disclosed and/or approved.
Category I Activities

Activities which are most likely to create a Conflict of Commitment because they relate to the faculty member’s training and expertise and/or the activity requires a significant professional commitment, such as:

- Teaching/Research/Administration of a grant outside the University
- Employment outside the University
- Assuming a founding/co-founding role of a company
- Assuming an executive or managerial position outside of the University (excluding positions with professional societies)

Procedure:

- Complete a Prior Approval Form, requesting authorization to engage in the activity prior to commencing the outside activity.
- If authorized, disclose the activity on the “Report of Category I and II Compensated Outside Professional Activities” form for each fiscal year.

UC San Diego Health
Managing Conflicts of Commitment

Compliance Advisory Group: reviews, investigates, and advises on concerns related to compliance with University policy and/or state and federal laws for Health Sciences, including issues related to conflicts of interest and commitment

Membership (as of 3/1/18):

- Daniel Weissburg, JD, CHC – Chief Compliance and Privacy Officer for UC San Diego Health
- Douglas Ziedonis, MD – Associate Vice Chancellor for Health Sciences
- Andrew Ries, MD, MPH - Associate Vice Chancellor for Academic Affairs
- Vivian Reznik, MD, MPH - Associate Vice Chancellor for Faculty Affairs
- Janet Kamerman – Chief Human Resources Officer
- David Meier – Director, Audit & Management Advisory Services
- Angela McMahlill, Esq – Executive Director, Research Compliance & Integrity
- Andrew Walton, CLS, CHRC – Director, Research Compliance Program
- Kimberlee Eskierka – Director, UC San Diego Health Employee Advocacy
- Grace Kuo, PharmD, MPH, PhD, FCCP – Associate Dean for Academic Clinical Affairs, Skaggs School of Pharmacy and Pharmaceutical Sciences
- Sarah Suskauer, Esq – Associate Counsel for UC San Diego Health (is advisory to CAG)
GENERAL UNIVERSITY POLICY REGARDING ACADEMIC APPOINTEES
Conflict of Commitment and Outside Activities of Faculty Members

PRIOR APPROVAL FORM
FOR OUTSIDE ACTIVITIES (CATEGORY I)

Name:

Last First M.I.

Faculty Title:

Academic- or Fiscal-Year Appointment:

Department: College/School:

For each Category I outside professional activity in which you wish to engage in outside professional activities, answer the following questions. Attach separate sheets, if necessary.

Type of activity in which you will be involved:

Category I Activities

Executive/managerial role:_

Salaried employee:_

Outside teaching or research activity:_

Other potential conflict of commitment:_

General description of the business/agency/organization/group/individual:

Activities/products/services of entity described above:_

Nature of your relationship to entity named above (check all that apply):

Founder/co-founder:_

Owner:_

Board member:_

Salaried employee:_

Equity/royalty interest:_

Consultant:_

Owner:_

Stockholder/partnership interest:_

Other, please explain:_

Description of the nature of your participation in this activity, including, if you wish, possible beneficial outcomes to areas of research, industry, and public service:

Beginning/ending month/year you could be involved in this activity:_

Fiscal year(s) for which seeking approval:_ (Approvals are generally for one fiscal year but may be granted for a longer term not to exceed five years. Compliance reports must be submitted annually.)

Estimated number of days involvement during academic- or fiscal-year appointment:_ Will you be requesting a full- or part-time leave without pay while engaged in this activity?

Approval granted through fiscal year ending June 30,

Request denied:

Department Chair Date

Dean Date

Faculty Member Signature Date Chancellor or Chancellor’s Designee Date

Rev. 7/1/14
Compliance – Conflict of Commitment
Category I Prior Approval Requests

Candidate

Completes Category I Prior Approval form

Submit completed request to Compliance*

Compliance (CAG)

Preliminary evaluation of Prior Approval form and supplemental information**

CAG reviews Prior Approval request**

Notify candidate and department of recommendation

Department

Reviews and endorses Prior Approval form

* For policy advising, contact VCHS Academic Affairs (specific contacts: Rebecca Woolston (rwoolston@ucsd.edu) and Julia Partridge (jpartridge@ucsd.edu). Please contact your department admins for submission of Category I Prior Approval Requests.

**If additional information is needed, will refer back to candidate.

NOTE: Outside activities may also involve Conflict of Interest (COI) issues and/or Intellectual Property (IP) issues. Please contact the COI Office (http://blink.ucsd.edu/sponsor/coi/index.html) directly to discuss any potential COI issues associated with the outside activities. The COI Office can be reached via phone at (858) 534-6465 or via email at info-coi@ucsd.edu. Please contact the Office of Innovation and Commercialization (http://innovation.ucsd.edu) directly to discuss any potential IP issues associated with outside activities. The Office of Innovation and Commercialization can be reached via phone at (858) 534-5815 or via email at invent@ucsd.edu.

Prior approval request forms can be accessed at: http://academicaffairs.ucsd.edu/ files/aps/forms/pdf/PriorAppvICat1Activities_HSCP_Participants.pdf
Category II Activities

Short-term activities outside the scope of University employment, such as:

- Additional University-compensated teaching
- Consulting: 1) under the auspices of the University of California; 2) for for-profit entities; 3) for non-profit entities; 4) for non-profit health or education related organizations; 5) for government agencies
- Serving on a board of directors outside the University
- Providing or presenting a workshop for industry
- Providing outside consulting or compensated professional activities performed for entities such as the Los Alamos and Lawrence Livermore National Laboratories

All Category II activities must be disclosed on the “Report of Category I and II Compensated Outside Professional Activities” form for each fiscal year.
REPORT OF CATEGORY I AND II COMPENSATED OUTSIDE PROFESSIONAL ACTIVITIES
FOR THE FISCAL YEAR ENDING JUNE 30,

EXPLANATIONS FOR INFORMATION REQUESTED

Compensated Outside Activities: *Compensation* is defined broadly as all types of remuneration (including stock options) realized or having the potential to become realized for outside activity, excluding customary honoraria and reimbursement for reasonable travel expenses and per diem.

Fiscal-Year Faculty Appointment: A *Fiscal-Year Appointment* is an appointment in which the faculty member renders service to the University throughout the calendar year as opposed to the academic year (APM - 600-4-f). Fiscal-year faculty accrue vacation time in accordance with APM - 730.

Terms of Leave, if any: A faculty member may be permitted to go on full- or part-time leave in order to pursue certain compensated outside professional activities. If you were on such leave during any part of the pertinent fiscal year, provide information here about the percentage of time and inclusive months.

Category: For each activity, enter I or II.

Category I activities include: teaching, research, or administering a grant at an educational institution, trust, organization, government agency, or foundation outside of the University; employment outside the University; assuming a founding/co-founding role of a company; assuming an executive or managerial position outside of the University. You must receive prior approval to engage in Category I activities, which always count toward the 21-48-day limit and must be reported annually.

Category II activities include: additional University-compensated teaching, including teaching pursuant to APM – 662. Additional Compensation: Additional Teaching, for UNEX courses and programs, other continuing education programs run by the University, and self-supporting UC degree programs; consulting under the auspices of the University of California; consulting or testifying as an expert or professional witness; consulting for for-profit entities; consulting for non-profit entities; consulting for non-profit health or education-related organizations; consulting for government agencies; serving on a board of directors outside of the University whether compensated or uncompensated; providing or presenting a workshop for industry; providing outside consulting or compensated professional activities performed for entities such as the Los Alamos and Lawrence Livermore National Laboratories; other income-generating activities specified in approved Implementing Procedures. Category II activities are counted within the 21-48-day limit and must be reported annually.

Number of Days: A full-time faculty member may engage in outside professional activities 21-48 days depending on the terms of the Department/School Implementing Procedures.

Enter the approximate number of days you worked on this activity during your period of active service to the University. For compensated outside professional activities a *Day* is defined using common sense and customary practice. This definition may vary by campus and/or discipline. A School or Departmental Implementing Procedure may include a more specific definition of a day. For additional teaching activities, the general rule is that every six contact or “podium” hours spent with students equals one day. See APM - 662 for further information.

Role: Use one or more of the following terms to describe your relationship to the entity identified in the last column: Founder/co-founder, owner, board member, consultant, recipient of equity or royalty interest, stockholder or partnership interest, salaried employee, or other (explain).

Compensation Dollars in Thousands: If income earned for the activity did not exceed the annual threshold, check the box in the left column. If income earned exceeded the annual threshold, enter the amount earned in the right column.

7/1/14
## ANNUAL HEALTH SCIENCES COMPENSATION PLAN REPORTING FORM
### FOR CATEGORY I & II COMPENSATED OUTSIDE PROFESSIONAL ACTIVITIES

**Fiscal Year Ending June 30,**

In accordance with APM - 671, all Compensation Plan participants are required to complete this form not later than 7/1/14.

<table>
<thead>
<tr>
<th>Category I or II</th>
<th># of Days</th>
<th>Name of Outside Entity</th>
<th>Description of Services Provided</th>
<th>Role (e.g., consultant, speaker, employee, shareholder)</th>
<th>Compensation Dollars in Thousands</th>
<th>Check left column if income earned did not exceed the threshold of $</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Income earned did not exceed the threshold $ □ $
Income earned exceeded threshold $ □ $

<table>
<thead>
<tr>
<th>Income earned did not exceed the threshold</th>
<th>Income earned exceeded threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

I did not engage in Category I or II activities during the reporting period. Total income earned did not exceed the earnings threshold.

I certify that I have complied with the provisions of the University of California Health Sciences Compensation Plan, the School of Health Sciences Compensation Plan Implementation Procedures, and any departmental guidelines for the Plan regarding limitations on the retention of earnings, and time spent in Outside Professional Activities.

Faculty Member Signature Date

The department chair's signature affirms the form was received and reviewed. Corrective actions should be implemented for time reports (days) that are above the annual limit and for unapproved Category I activities.

Department Chair Signature Date

Total # Days: Total income earned $ □ $

Note: Information disclosed herein is a public record under the California Public Records Act.

7/1/14
Category III Activities

Activities within the course and scope of University employment and unlikely to raise conflict of commitment issues.

• Examples:
  • Serving on government or professional panels or committees or as an officer or board member of a professional or scholarly society
  • Reviewing manuscripts or acting in an editorial capacity
  • Attending and presenting talks at university/academic colloquia and conferences
  • Developing scholarly or creative works

There is no disclosure requirement or prior approval required.
Time and Earning Limitations

University policies place limitations on the time a faculty member spends on Outside Activities and the earnings derived from those activities.

- **Time Limits:** May not exceed 48 days annually
- **Earnings:** Maximum annual earnings from outside activities is up to $40,000 or 40% of the fiscal-year base salary scale (scale 0), whichever is greater

- **Procedures:**
  - Earnings up to the approved threshold may be directly retained by the HSCP member, but must be disclosed.
  - Earnings above the approved threshold must be deposited to the HS Compensation Plan.
Additional Considerations

- **Good Standing:**
  - Per APM 671/APM 025, a UCSD faculty member is only authorized to engage in Outside Professional Activities when in Good Standing.

- **Intellectual Property**
  - Outside Professional Activities may also raise issues related to the ownership of Intellectual Property. For more information on these issues or to request consultation on a potential arrangement, please contact UCSD’s Office of Innovation and Commercialization at (858) 534-5815 or invent@ucsd.edu.

- **Conflicts of Interest**
  - Outside Professional Activities may also raise issues related to conflicts of interest. For more information on conflicts of interest or to request consultation on a potential issue, please contact the Conflict of Interest Office at (858) 534-6465 or info-coi@ucsd.edu.
UC San Diego Health

Conflict of Interest

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY
Conflict of Interest

Jennifer J. Ford
What is a “Conflict of Interest” (COI)?

A Conflict of Interest occurs when:

(1) an employee has a significant financial interest in a company that is providing funding for the employee’s research or other University activity; or

(2) the employee’s research might directly and significantly affect the significant financial interest of an employee responsible for the conduct of a research project.
What are the risks of a potential Conflict of Interest?

- **Appearance of bias** in the design, conduct or reporting of research
- Appearance of impropriety
- Compromise integrity
- Conflict of time commitment and effort
- Failure to recognize the UC *intellectual property* and interests
- Improper channeling of funds
- **Misuse** of UC facilities, resources, funds and personnel
- Violations can be costly
COI: Applicable Laws and Policies

- **Anti-Kickback Statute**: illegal to accept bribes
- **Stark Law**: prohibit physician self-referral
- **False Claims Act**: defraud governmental programs
- **CA Public Records Act**: record disclosure and public upon request
- **University Policy**
  - UC Policy for **Sponsored Research**: stipulates that an Investigator (any UC employee responsible for the design, conduct, or reporting of a sponsored project at UC) may be required to disclose significant personal financial interests related to that project.
What is Subject to COI Disclosure?
Research or Other Related Activities

**Sponsored Research** (Basic, Applied, Animal, Human)
- Federal:
  - NIH and NSF
  - Other agencies who have adopted the federal requirements (including sub-awards)
- Non-Federal
  - Non-Profit
  - For-Profit

**Other Related Activities**
- Gifts
- Lab Service Agreements (LSA)
- Institutional Service/Consulting Agreements (ISA/ICA)
- Material Transfer Agreements (MTA)
- Unfunded research activities involving human subjects
## For Research and Other Related Activities
### Which Form to Submit for COI Disclosure?

<table>
<thead>
<tr>
<th>Funding Entity</th>
<th>Common Sponsors</th>
<th>Types of Activities</th>
<th>Initial Disclosure Form</th>
<th>Additional Disclosure (if mark yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS)</td>
<td>NIH or those that have adopted FCOI</td>
<td>Research, Center, Career, Fellowships, Training</td>
<td>PHS Form</td>
<td>Supplement</td>
</tr>
<tr>
<td>Federal Non-PHS*</td>
<td>NSF or those that have adopted</td>
<td>Research, Career, Fellowships, Training</td>
<td>9510</td>
<td>Addendum</td>
</tr>
<tr>
<td>Non-Federal*</td>
<td>Non-Profit For-Profit</td>
<td>Research, Gifts, Services, MTA, UCOP programs</td>
<td>700U</td>
<td>Addendum</td>
</tr>
<tr>
<td>Unfunded Projects Clinical Research</td>
<td>Internal unrestricted</td>
<td>Clinical Research</td>
<td>700U</td>
<td>Addendum</td>
</tr>
</tbody>
</table>

There are different COI financial disclosure thresholds and forms required for different sponsors

*There are sponsors exempt from the disclosure requirement: all non-profit, tax-exempt educational institutions, and those on the list (on COI Website)
What Constitutes a Potential COI?

- Income/Payments: Salaries, Consulting, Honoraria, etc.
- Position: Founder, Partner, Board of Directors, Scientific Advisory Board, Employee, etc.
- Ownership Interest: Stocks, Bonds, Stock Options
- Gifts
- Loans
- Travel Reimbursement/Payments
- Intellectual Property

Applies to the Employee, Spouse, Registered Domestic Partner, Dependent Children
For Research and Other Related Activities
What to Interests to Disclose?

<table>
<thead>
<tr>
<th>1) Who is the Sponsor?</th>
<th>2) Which Disclosure Form?</th>
<th>3) What to Disclose?</th>
<th>4) Who decides if the research and the interests are related?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS) (i.e. NIH and those who have adopted PHS)</td>
<td>PHS</td>
<td>Disclose all interests related to the discloser’s Institutional Responsibilities*</td>
<td>Institution</td>
</tr>
<tr>
<td>Federal Non-PHS (i.e. NSF, CIRM and UC Programs)</td>
<td>9510</td>
<td>Disclose any interests related to the work to be conducted under the proposed project</td>
<td>Discloser</td>
</tr>
<tr>
<td>Non-Federal (For-Profit or Non-Profit)**</td>
<td>700U</td>
<td>Disclose any interests with the sponsor(s)</td>
<td>Institution</td>
</tr>
</tbody>
</table>

*Reasonably appears to be related to or is in the same field of expertise as your Institutional Responsibilities.

** Includes research and other related activities (gifts, service agreements, MTAs, unfunded projects, etc.)
COC, COI and Other Financial Interests

• **Disclosure Forms:**
  • Research and Other Related Activities:
    • PHS
    • Non-PHS (9510)
    • Non-Federal (700U)
  • Annual disclosure of outside professional activities ([APM 025 / APM 671](#))
  • Prior Approval for Category I activities (Faculty)

• **Offices to Submit Disclosures:**
  • Conflict of Interest (COI) Office
  • Compliance Advisory Group
  • Health System Pharmacy & Therapeutics (P&T) committee
  • Patients -- via the consent form for anesthesia, surgery and other procedures
  • Purchasing and Procurement Offices
  • Office of Innovation and Commercialization (Intellectual Property)
  • CME event learners (disclose partial support from industry)
  • Publications (disclose partial support from industry of other grants)
Conclusion
## Conflict of Commitment (COC) and Conflict of Interest (COI)

<table>
<thead>
<tr>
<th></th>
<th>Conflict of Commitment</th>
<th>Conflict of Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policies</strong></td>
<td>APM 025 / APM 671</td>
<td>UCSD PPM 200-13, APM 028, OP PHS and NSF*</td>
</tr>
<tr>
<td><strong>Disclosure Forms</strong></td>
<td>Category I (prior approval) and II</td>
<td>Dependent on outside funding entity**</td>
</tr>
<tr>
<td><strong>Timing</strong></td>
<td>Category I: Prior to Engagement Category II: Annually</td>
<td>Proposal and/or award stages and then dependent on funding</td>
</tr>
<tr>
<td><strong>Responsible Offices</strong></td>
<td>VCHS Academic Affairs</td>
<td>Conflict of Interest Office</td>
</tr>
</tbody>
</table>

**Similarity: Engagement with outside activities**

* There are many COI policies, see [http://blink.ucsd.edu/sponsor/coi/policies.html](http://blink.ucsd.edu/sponsor/coi/policies.html)

** Disclosure may be required for internal funding when Human Subjects are involved

UC San Diego Health
## Resources

<table>
<thead>
<tr>
<th>UC San Diego Health Compliance Program</th>
<th><a href="http://healthsciences.ucsd.edu/compliance/Pages/default.aspx">http://healthsciences.ucsd.edu/compliance/Pages/default.aspx</a></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(858) 657-7487</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:hscomply@ucsd.edu">hscomply@ucsd.edu</a></td>
</tr>
<tr>
<td>UC San Diego Conflict of Interest Office</td>
<td><a href="http://coi.ucsd.edu">http://coi.ucsd.edu</a></td>
</tr>
<tr>
<td></td>
<td>(858) 534-6465</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:info-coi@ucsd.edu">info-coi@ucsd.edu</a></td>
</tr>
<tr>
<td>UC San Diego Office of Innovation and Commercialization</td>
<td><a href="http://innovation.ucsd.edu">http://innovation.ucsd.edu</a></td>
</tr>
<tr>
<td></td>
<td>(858) 534-5815</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:Invent@ucsd.edu">Invent@ucsd.edu</a></td>
</tr>
<tr>
<td>UC San Diego VCHS Academic Affairs</td>
<td><a href="https://healthsciences.ucsd.edu/vchs/faculty-academics/academic-affairs/Pages/default.aspx">https://healthsciences.ucsd.edu/vchs/faculty-academics/academic-affairs/Pages/default.aspx</a></td>
</tr>
<tr>
<td></td>
<td>Specific contacts: Rebecca Woolston, Julia Partridge, AVC Andrew Ries, AVC Robert Ross</td>
</tr>
</tbody>
</table>