Conflict of Commitment & Conflict of Interest

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Conflict of Commitment & Outside Professional Activities

APM 671/APM 025
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

• Outside Professional Activities 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)).

• University policy categorizes Outside Professional Activities into 3 categories based upon the degree in which the activity may interfere with the faculty member’s University obligations. Each category has varying requirements including annual disclosure and prior approval.
Conflict of Commitment

- Under University policy, a Conflict of Commitment occurs when the commitment to external activities, whether professional or non-professional, compensated or uncompensated, interferes with the successful performance of the faculty member’s University obligations.

- Where an outside activity creates a Conflict of Commitment, there are certain steps that must be taken to ensure appropriate disclosure and approval.
Managing Conflicts

- **Compliance Advisory Group (CAG):** 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.
  - Any individual may request review of a potential problem, issue, or exceptional request
  - **Membership:**
    - Daniel Weissburg, JD, CHC – Chief Compliance and Privacy Officer for UC San Diego Health
    - Kimberly Gillespie, Esq. – Chief Counsel for UC San Diego Health
    - Sarah Suskauer, Esq. – Regulatory Counsel for UC San Diego Health
    - Janet Kamerman – Chief Human Resources Officer
    - Andrew Ries, MD, MPH - Associate Vice Chancellor for Academic Affairs
    - Vivian Reznik, MD, MPH - Associate Vice Chancellor for Faculty Affairs
    - Marianne Generales – Assistant Vice Chancellor for Research
    - David Meier – Director, Audit & Management Advisory Services
    - Kathleen Naughton, CHC, CPC, CCS-P – Compliance Program Advisor
    - Kimberlee Eskierka – Director, UC San Diego Health Employee Advocacy
    - Grace Kuo, Pharm.D., MPH, PhD, FCCP – Associate Dean for Academic Clinical Affairs, Skaggs School of Pharmacy
    - Angela McMahon – Director, Conflict of Interest UC San Diego
Managing Conflicts (cont’d)

• **COI Independent Review Committee (IRC):** provides independent substantive review of financial disclosures and serves as the principal advisory committee to the Chancellor for review and assessment of specific conflicts of interest.
  
  • Any individual may request review of a potential problem, issue, or exceptional request
  
  • Membership: full-time, tenured faculty members from major areas of UCSD appointed by the Chancellor.
  
  • Responsible for establishing and implementing management strategies to eliminate, manage, or reduce conflicts of interest
Categories of Outside Professional Activities

Based upon the faculty members appointing series and percentage of effort, Outside Professional Activities\(^1\) which may cause a Conflict of Commitment\(^2\) must be disclosed and/or approved.

Each category has varying requirements including disclosure and approval, as defined below:

- **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

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1 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 per APM 671-4(a).

2 Defined as occurring when a faculty member’s outside activities interfere with the faculty member’s professional obligations to the University per APM 671(b).
Category I Activities

Activities which are most likely to create a Conflict of Commitment because they relate to the training and expertise and/or the activity requires significant professional commitment.

- Examples:
  - Teaching/Research/Administration of a grant at an entity 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
Possible criteria for reviewing requests to engage in Category I activities:

1. Amount of time the activity would require.
2. Size of the company
3. Ability of the faculty member to separate his or her company work from his or her University work.
4. Ability of the faculty member to fully meet his or her University obligations of teaching, research, and public service.
5. Value to UCSD.
6. Uniqueness of the contribution the faculty member may make to the outside professional activity.
7. Benefit to society.
8. Ability of the campus to manage any associated conflicts of interest
Category I Activities (cont’d)

Possible **conditions for approval** of Category I activities:

1. Activities would be monitored by a faculty panel.
2. Periodic reports to his or her Department Chair and Dean.
3. Approval could be withdrawn at any time.
4. Limitations on service as dissertation or thesis adviser of graduate students.
5. Limitations on service as principal supervisor of postdoctoral scholars.
6. Disclosure of faculty member's association with the company.
7. Re-application for approval beyond initial scope.
8. Any inventions involving one or more UC employees would be disclosed to the University.
10. Approval could be given for a limited period of time.
11. Approval contingent on a reduction in the faculty member's appointment percentage or leave.
GENERAL UNIVERSITY POLICY REGARDING ACADEMIC APPOINTEES
Conflict of Commitment and Outside Activities of Faculty Members

PRIOR APPROVAL FORM
FOR OUTSIDE ACTIVITIES (CATEGORY I)

Name: Faculty Title:
Last First M.I. 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: Salaried employee: Consultant:
 Board member: Owner: Stockholder/partnership interest:
 Equity/royalty 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 Advisory Group

- Preliminary evaluation of Prior Approval form and supplemental information**
- Compliance Advisory Group reviews Prior Approval request**

Notify candidate and department of recommendation

Department

- Reviews and endorses Prior Approval form

* Contact Sarah Suskauer at ssuskauer@ucsd.edu
** 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 Technology Transfer Office [http://invent.ucsd.edu/invent/] directly to discuss any potential IP issues associated with outside activities. The Technology Transfer Office 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 course and scope of University employment.

- Examples:
  - 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 the board of directors outside of 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
  - Other income-generating activities

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.
## 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

<table>
<thead>
<tr>
<th>Faculty Member Name (Print)</th>
<th>Academic Title</th>
<th>Department</th>
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<table>
<thead>
<tr>
<th>Category</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>
</tr>
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<tbody>
<tr>
<td>I or II</td>
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- **Check left column if income earned did not exceed the threshold of $**  
- **Check right column if income earned exceeded the threshold of $**

**Income earned did not exceed the threshold**  
**Income earned exceeded the threshold**

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<thead>
<tr>
<th>Income earned did not exceed the threshold</th>
<th>Income earned exceeded the threshold</th>
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- **I did not engage in Category I or II activities during the reporting period**
- **Total income earned did not exceed the earnings threshold**

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

**Department Chair Signature**

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- **Faculty Member Signature**  
- **Date**

**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 my departmental guidelines for the Plan regarding limitations on the retention of earnings, and time spent in Outside Professional Activities.**

**Total # Days**  
**Total income earned**

<table>
<thead>
<tr>
<th>Total # Days</th>
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N.B. - Information disclosed herein is a public record under the California Public Records Act.
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 nor 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% if the fiscal year base salary scale (scale 0)**, whichever is greater

  - **Procedures:**
    - Earnings up to the approved threshold **may be directly retained** by the physician (either faculty or staff), but must be disclosed.
    - Earnings above the approved threshold must be deposited to the HS Compensation Plan.
Disclosure Requirements

<table>
<thead>
<tr>
<th>POPULATION/ELIGIBILITY</th>
<th>CONTROLLING POLICY</th>
<th>DISCLOSURE REQUIREMENTS</th>
<th>TIME AND EARNINGS LIMITATIONS</th>
</tr>
</thead>
</table>
| All faculty members who participate in the HS Compensation Plan (HSCP) | APM 671: Conflict of Commitment and Outside Activities of HSCP Participants. | • Category I Activity: Annual disclosure on the “Report of Category I and II Compensated Outside Professional Activities” form for each fiscal year including description of activity and earnings derived from activity; AND prior approval by the Chancellor’s designee  
• Category II Activity: Annual disclosure on the “Report of Category I and II Compensated Outside Professional Activities” form for each fiscal year including description of activity and earnings derived from activity  
• Category III Activity: No disclosure requirement nor prior approval required | • Time Limits: Time devoted to outside professional activities, either compensated or un compensated, may not exceed 48 days annually.  
• Earnings: Maximum annual earnings from outside activities is up to $40,000 or 40% if the fiscal year base salary scale (scale 0), whichever is greater  
  o Earnings up to the approved threshold may be directly retained by the physician (either faculty or staff), but must be disclosed in accordance with annual reporting requirements  
  o Earnings above the approved threshold, with the exception of income from Category III activities, must be deposited to the HSCP, and is thus subject to the established Department and/or School assessment policies. |
| All faculty members who do not participate in the HSCP but are appointed at 50% time or higher | APM 025: Conflict of Commitment and Outside Activities of Faculty Members | Same as above. | Same as above.  
(Notes: earnings above threshold will be run through the University for payment/distribution to the faculty member). |
| All MSP Staff Physicians with appointment at greater than 50% effort | Compensation Plan for UCSD Staff Physicians  
MSP Contract for Staff Physicians at 51% or more | Same as above. | Same as above.  
(Notes: earnings above threshold will be run through the University for payment/distribution to the physician). |
| All faculty members who do not participate in the HSCP and appointed at less than 50% time | N/A | Disclosure of outside activities is not required on an annual basis nor is obtaining prior approval for the outside activities. | N/A |
| MSP Staff Physicians at 50% time or less | Compensation Plan for UCSD Staff Physicians  
MSP Contract for Staff Physicians at 51% or more  
PPSM -82: Conflict of Interest | Disclosure of outside activities is not required on an annual basis nor is obtaining prior approval for the outside activities. However, the staff physician is responsible for compliance with the staff Conflict of Interest policy (PPSM-82), which regulates activities which create a conflict of interest between the employee’s assigned University functions and any other interest or obligation. Disclosure of gifts and/or financial conflicts of interest are required under the policy. | N/A |

1. For Health Sciences faculty not in the HSCP, APM 025 would control, however, reporting requirements remain the same.
2. Requires review by the Health Sciences Compliance Advisory Group (CAG) with approval authority from the Health Sciences Associate Vice Chancellor of Academic Affairs.
3. Faculty not in the HSCP and appointed at less than 50% time are not subject to the annual reporting and prior approval requirements per APM 025-14.
4. All MSP Staff Physicians with an appointment greater than 50% are subject to the same restrictions and reporting obligations applied to external earnings of faculty who participate in the HSCP.
5. See language from Endnote iii – reiterated in MSP Contract Section D.
6. All MSP Staff Physicians with an appointment greater than 50% are subject to the same restrictions and reporting obligations applied to external earnings of faculty who participate in the HSCP.
7. See language from Endnote iii – reiterated in MSP Contract Section D.
Additional Considerations

• Good Standing
  • Per APM 671/APM 025, UCSD faculty members are only authorized to engage in Outside Professional Activities where he or she is deemed to be in Good Standing.

• 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.

• 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 Technology Transfer Office at (858) 534-5815 or invent@ucsd.edu.
Conflict of Interest
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 impropriety
- Compromise integrity
- Conflict of time commitment and effort
- Failure to recognize the UC *intellectual property* & interests
- Improper channeling of funds
- **Misuse** of UC facilities, resources, funds and personnel
- Violations can be costly
How do Conflicts Arise?

1. You have a **material financial interest** (personal or private);

2. You **participate in**, influence, or make the **decision**, in your official duties / responsibilities as a UC employee; and

3. The decision is going to **materially effect** your financial interest.

- **All three components are required to have a conflict under the California PRA laws.**

*PRA = California Political Reform Act*
Examples of Potential Conflicts

- Anti-Kickback Statute
- Stark Law
- False Claims Act
- California PRA
- University Policy
  - UC Policy for Sponsored Research: “Disclosure of Financial Interests & Management of Conflict of Interest Related to Sponsored Projects”, 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 types of decisions are exempt from PRA Conflict of Interest Rules?

<table>
<thead>
<tr>
<th>These activities are not violations of PRA:</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching Decisions</td>
<td>Selecting texts or other educational materials</td>
</tr>
</tbody>
</table>
| Patient Care Decisions                      | A doctor’s decisions with respect to a specific patient’s course of treatment  
|                                             | □ Disclose financial interests to the patient (consent form)  
|                                             | □ UCSD Health policy MCP 750.2, Clinical COI |
| Personal Study / Research                   | Personal decision to pursue course of study or research  
|                                             | □ Other UC rules apply to disclosure of financial interests for research |

PRA = California Political Reform Act

UCSD Health policy site, http://mcpolicy.ucsd.edu  
Consent for Surgery or Special Procedure, http://forms.ucsd.edu
# What are ways to mitigate a Conflict of Interest?

<table>
<thead>
<tr>
<th>Disclose &amp; Recuse</th>
<th>Disclose the conflict: Failure to do so may be considered a crime in some circumstances.</th>
</tr>
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<tbody>
<tr>
<td>Recuse: Abstain from purchasing &amp; formulary decisions; and avoid making, participating in, or influencing business decisions.</td>
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</table>
| Remove the Financial Interest                         | - Sell stock on the public market
- Promptly return unused gift
- Donate unused gift to the University (e.g., put fruit basket in public area for enjoyment of staff & public) |
How to Disclose COI & Other Financial Interests

• **Disclosure Forms:**
  - Research grants and clinical trials: 700-U form
  - Clinical service agreements: 700-U form
  - Annual disclosure of outside professional activities (APM 025 / APM 671)
  - Prior Approval for Category I activities (Academic Faculty)

• **Disclosure to Others:**
  - Conflict of Interest Office
  - Health System Pharmacy & Therapeutics (P&T) committee
  - Patients -- via the consent form for anesthesia, surgery and other procedures
  - Purchasing and Procurement Offices
  - Intellectual Property & Technology Transfer
  - CME event learners (disclose partial support from industry)
  - Publications (disclose partial support from industry of other grants)
Conclusion
# 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>
</table>
|                                      | (858) 657-7487  
hscomply@ucsd.edu                                                                 |
| UC San Diego Conflict of Interest Office | [http://healthsciences.ucsd.edu/compliance/Pages/default.aspx](http://healthsciences.ucsd.edu/compliance/Pages/default.aspx) |
|                                      | (858) 534-6465  
Info-coi@ucsd.edu                                                                 |
| UC San Diego Technology Transfer Office | [http://invent.ucsd.edu/invent/](http://invent.ucsd.edu/invent/) |
|                                      | (858) 534-5815  
Invent@ucsd.edu                                                                 |