

Penn Medicine Policy: Conflict of Interest and Commitment COI Policy Effective 9/1/2022

POLICY

The University of Pennsylvania (Penn) and the Perelman School of Medicine and University of Pennsylvania Health System (Penn Medicine) have long recognized the value to the institution of the engagement of individual faculty in extramural activities, as long as these activities are fully consistent with the faculty member's institutional responsibilities. In light of Penn's foremost responsibility to ensure the integrity of clinical care, education and research, and to avoid conflict of interest in the conduct of these activities, Penn and Penn Medicine have developed conflict of interest and commitment as well as financial disclosure policies with which faculty are required to comply. An individual's failure to gain approval as required, to properly disclose all extramural activity as required or otherwise comply with regulations related to extramural activities may compromise the integrity of the School, Health System and University or may raise questions about whether individuals are fulfilling their commitments as a PSOM or Penn Medicine employee. As a result, failure to follow Penn's and Penn Medicine's conflict of interest and commitment policies may result in restrictions and/or sanctions imposed by Penn Medicine and/or Penn.

PURPOSE

The purpose of this policy is to:

- Describe the role of the Penn Medicine Conflict of Interest and Commitment Committee for Faculty (PM-COICC)
- Reinforce the requirement for annual extramural activities reporting and the consequences for noncompliance
- Reinforce the consulting arrangements policy

IMPI FMENTATION

Senior leadership, Department chairs, business administrators, and faculty members share responsibility for implementing this policy.

PROCEDURE

PENN MEDICINE CONFLICT OF INTEREST AND COMMITMENT COMMITTEE (PM-COICC)

The PM-COICC shall be composed of a small group of PSOM faculty with representation of the full spectrum of Penn's missions, and both clinical and basic science departments with the following major functions:

- Serve in an advisory role to Penn Medicine leadership for issues related to conflict of interest and commitment and extramural activities.
- Develop and update recommendations for PSOM conflict of interest and commitment policies and practices including standard expectations for journal disclosures, disclosure slides for talks, board roles, consulting agreements, and outside financial interests as they may relate to employment activities.
- Participate in reviews of individual cases when questions arise regarding proper disclosure or appropriateness of activities and, where appropriate, make recommendations for consideration by the Dean.

ANNUAL EXTRAMURAL ACTIVITIES REPORTING

All full time PSOM faculty members are required to complete an Annual Extramural Reporting Form http://my.med.upenn.edu/ The reporting requirement only covers outside work (paid or unpaid) in the area of expertise for which the faculty member is employed by Penn Medicine. Examples of extramural activity include, but are not limited to roles as:

- a consultant or other role on behalf of a corporation, business or industry.
- a consultant to a private foundation or professional or trade association.
- a voluntary paid expert witness in any civil or criminal case.
- an editor or an editorial board member for professional journals.
- a member of a scientific advisory board.
- a member of a professional society board.
- a faculty member invited to speak at a non-Penn/CHOP CME event or course, excluding those invitations from academic institutions.

Faculty will be given adequate time to complete their Annual Extramural Reporting Form. Failure to comply will result in the following:

- List of non-compliant faculty will be sent to department chairs or their designees for local communication with expectation to complete within 4 weeks.
- Non-compliant faculty will receive notification from the Dean's office advising them to complete
 within next 30 days or no new engagements will be reviewed or approved until extramural
 reporting is complete.
- Department chairs will be notified by the Office of COI that no new extramural engagements will be reviewed or approved until extramural reporting is completed for persistently non-compliant faculty.

• Continuously noncompliant faculty will be referred to PM-COICC who will review the case and may choose amongst the recommendations below to make to the Dean.

CONSULTING ARRANGEMENTS POLICY

All proposed faculty consulting agreements need to be reviewed by the PSOM Office of Conflict of Interest and the department chair or their designee for written approval <u>prior</u> to entering into any agreement to ensure (ie make certain) that (1) the financial terms, time commitments, and contractual obligations do not give rise to a conflict of interest or commitment, and (2) all appropriate disclosures are made in a timely fashion. The purpose of this review is to make sure that the agreement is consistent with University policies – in particular: conflict of interest, conflict of commitment, intellectual property, confidentiality, and the use of the University's name and property. Because of the obvious potential for a conflict, it is critical to establish full transparency of this information, including the amount of consulting income, particularly in those instances where a faculty member is engaged in clinical research. These items must be reported both to the department Chair and to the IRB for any relevant protocol when requesting approval, and reported in the annual extramural reporting review form from the School. The Dean will approve consulting arrangements for Department Chairs and Vice Deans after review by the Office of Conflict of Interest.

Faculty who fail to obtain prior permission for extramural consulting activities as detailed above will be referred to the PM-COICC. On an annual basis, PM-COICC will receive anonymous summaries of the disclosures to assess general compliance and processes. This annual review will include a focus upon faculty with the highest levels of annual extramural earnings and/or aggregate annual consulting time to determine if a concern exists regarding a conflict of interest or commitment. PM-COICC may ask the Chair and/or the faculty member to respond to the committee either in writing or in person to clarify the activity(ies).

Continuously noncompliant faculty will be referred to PM-COICC who will review the case and may choose amongst the recommendations below to make to the Dean.

POSSIBLE RECOMMENDATIONS FROM PM-COICC FOR CONTINUOUSLY NONCOMPLIANT FACULTY

- Require the faculty member to modify or terminate a current consulting relationship
- Limit consulting relationships
- Suspend current or future consulting relationships
- Withhold of incentive payouts
- Suspend eligibility for annual merit increases

Relevant resources:

Penn Medicine Conflict of Interest Faculty Advisory Committee Charter

<u>Policies and Procedures and the Consulting and Outside Activities Policies and Procedures of the</u> University of Pennsylvania

| Consulting arrangements memo | |
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| Guidelines for Interactions of Healthcare Professionals and Industry | |
| Extramural Activity Reporting Process FAQ | |
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