

Guidelines for Cases in Which a Researcher is Consulting for and Receiving Research Funding or a Gift from the Same Entity

Document Summary:

This document establishes guidelines for investigators who are consulting AND receiving research funds or a gift from the same entity. Compensated consulting that rises to a level of significance defined below as a Significant Financial Interest (SFI), and receiving research funds from the same entity should be disclosed as an SFI on the Annual Disclosure form in Part G: Significant Financial Interests Relating to Your Research or Teaching Activities. Once disclosed, the information will be evaluated on a case by case basis by the Dean for Research (DFR) or the Conflict of Interest in Research Panel (COIR Panel), to determine whether the SFI constitutes a financial conflict of interest (FCOI). If the DFR or the COIR Panel determines that the SFI is an FCOI, there are three possible outcomes: 1) a management plan is implemented; 2) aspects of the relationship between the investigator and the entity are eliminated; or 3) the funding may be denied.

Scope:

This guideline applies to all Dean of the Faculty (DOF) appointees, regardless of funding source, who meet the monetary threshold for significant financial interest (SFI) received from consulting practices as defined below and are also receiving research funds from the same entity.

Regulatory Background:

Princeton University follows the Public Health Service (PHS) Federal Regulation 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research" to define monetary thresholds used to identify SFI in cases where such interests relate to an individual's institutional responsibilities.*

Princeton University's Rules and Procedures of the Faculty state: "The risk of conflict of interest, or serious appearance of conflict, can arise when a University investigator (or his/her spouse or dependent children) has an SFI in an external enterprise engaged in activities closely related to the investigator's line of University research. It is the policy of the University to require faculty to complete an annual disclosure form designed to identify any potential conflicts of interest arising from SFIs so that they may be appropriately managed. **

Responsibilities:

Institution: Ensures the submission of disclosures of SFIs by all DOF appointees (Faculty, Academic Professionals, and Professional Librarians) during the annual disclosure period, and reviews the disclosures for potential conflicts of interest (COI).

Investigator: Complies with Federal regulations and Princeton Policy on conflict of interest by submitting an annual disclosure form that includes SFI disclosures related to his/her institutional responsibilities. PHS-funded investigators must disclose annually, and in addition within 30 days of acquiring a new SFI that is related to their institutional responsibilities.

Chair of the COIR Panel and the COIR Panel: The Chair of the COIR Panel is the Dean for Research (DFR). The DFR reviews SFIs that are related to institutional responsibilities and makes determinations of Financial Conflict of Interest (FCOI) or defers this determination to the COIR Panel.

Departmental Chairs: Ensure that annual disclosure forms are returned in a timely manner. In addition to the Panel review of annual disclosures, Department Chairs should review annual disclosure forms submitted by their department members and address any conflict of interest concerns with Research Integrity and Assurance (RIA). In addition to the general review of the form, Department Chairs should also review the use of space, equipment, students and Academic Professionals when the use relates to any SFI. Finally, the Department Chair consults, if necessary, with the Dean of the Faculty (DOF) and/or RIA on any special circumstances regarding consulting and the potential for COI. ***

Definitions:

Consulting - Professional activity related to the person's field or discipline, where a fee-for-service or equivalent relationship with a third party exists. When consulting, a person agrees to use his or her professional capabilities to further the agenda of a third party, in return for an immediate or prospective gain.

Significant Financial Interest (SFI) – In general, this refers to a financial interest for a DOF appointee (and/or his or her spouse or dependent children) that is related to his/her institutional responsibilities. If the monetary value received by the individual exceeds \$5,000 over a period of a year, and/or the person receives any ownership interest (stocks or stock options) from a privately held entity, and/or the person receives any ownership interest (stocks or stock options) from a publicly-traded entity that is worth over \$5,000, this is deemed significant. In the context of this document, if the above monetary thresholds are met and result from consulting activities and, in addition, the entity for which the DOF appointee consults also funds his/her research activities either through a research award or a gift, then the consulting activity and the research funding should be disclosed as an SFI on the annual disclosure form. For PHS-funded individuals, the SFI must be reported within 30 days of acquiring it.

Institutional Responsibilities – A DOF appointee's responsibilities on behalf of the University including, but not limited to, research and teaching activities both within and outside the University.

Financial Conflict of Interest (FCOI) - Exists when the DFR or the COIR Panel reasonably determine that an SFI related to a DOF appointee's research activities could directly and significantly affect the design, conduct, or reporting of research.

The existence of a financial conflict of interest does not imply wrongdoing and does not mean that a researcher may not retain his or her financial interest nor undertake the affected research. Often Princeton can work with the person to manage a financial conflict of interest or the appearance of a conflict so that the research can continue in a way that minimizes the possibility of bias in, and preserves the objectivity of, the research. Proper management of a conflict depends on full and prompt disclosure.

Guidelines:

Consulting and receiving research funds from the same entity should be disclosed as a Significant Financial Interest (SFI) on the Annual Disclosure form in Part G: Significant Financial Interests Relating to Your Research or Teaching Activities.

Members of the University who pursue external consulting must take care that the agreements that define these activities are not in conflict with the provisions of Princeton's patent policy, its obligations under any sponsored grant or contract, or any other policies of the University.** Financial gain must be incidental to the research: the prospect of such gain cannot be allowed to govern the selection and conduct of research projects.

FCOI Determination:

Each SFI disclosure is handled on a case-by-case basis. Once the relationship is disclosed as an SFI (in this case when the consulting remuneration threshold is met and is from an entity that is also funding the research via awards or gifts) the following criteria will be used to determine whether the SFI rises to the level of an FCOI:

- Whether the research is of a basic or fundamental nature.
- Whether the research could have a significant impact on a company's business or financial outlook.
- Whether one of the goals of the research is to validate or invalidate a particular approach or methodology that could affect the value of the company.
- The magnitude of the consulting fees.
- Whether the funded research from the company that the DOF appointee is consulting for is related to the appointee's federally funded research.
- Whether the entity that the DOF appointee is consulting for licenses Princeton's intellectual property derived from the DOF appointee's research.
- Whether the DOF appointee also has equity interest in the company that he/she is consulting for.
- Whether the DOF appointee who is consulting for, and being funded by, the entity also has other connections or interrelationships with the entity (i.e. Material Transfer Agreements, visitors from the entity, family members with equity interest in the entity, use of Princeton University space or equipment by the entity).

- Whether the DOF appointee holds a managerial position (e.g., CEO, Director, President or VP) at the entity for which they consult and from which he/she receives research funding.

After evaluating the information provided by the DOF appointee in light of the criteria above, if the determination of an FCOI is made, possible options for mitigation may include: (1) implement a management plan to mitigate the potential for conflict or bias; or (2) eliminate aspects of the interrelationship; or 3) the funding may be denied.

Other considerations:

In the case when a DOF appointee is consulting and receiving funding from the same entity, consulting agreements with the entity should carefully delineate and separate university responsibilities from consulting responsibilities. Specifically, the scope of the consulting services should be distinguished from the scope of research commitments at Princeton University.

When a DOF appointee is consulting for and being funded by the same entity, he/she may not use University resources or personnel, including students, academic professionals, facilities and equipment for consulting-related activities, except in a purely incidental way. In conducting research funded by an entity for whom the DOF appointee also consults, the same rules concerning the use of University resources apply as they would for any other research activity. In particular, inappropriate use of University resources includes the following:

- A faculty member assigning tasks to students, staff, or postdoctoral scholars for purposes of potential or real financial gain to the faculty member and/or his or her spouse or dependent children rather than the advancement of the scholarly field or the students' educational needs.
- Involvement of the faculty member's students or staff in his or her outside consulting or business activities without prior review and approval by the Department Chair.
- Granting the external entities with whom one consults and receives funding or gifts access to Princeton University resources, personnel or services for purposes outside the University's missions.

Intellectual property (IP) resulting from a DOF appointee's research, including any research done in collaboration with the entity for which a DOF appointee is consulting and from which he/she is receiving funding, is to be disclosed to Princeton's Office of Technology Licensing (OTL) as required by the University's Patent Policy and contractual obligations. The IP will be pursued in accordance with University Patent Policy.****

Princeton is under no obligation to license any intellectual property resulting from a DOF appointee's research to the entity that a DOF appointee is consulting for and being funded by, unless there is a previously approved research agreement that specifies the licensing terms of the intellectual property.

The University must retain full rights concerning the timing and content of publications, including publications resulting from any research done in collaboration with the entity for which a DOF appointee is consulting and from which he/she is receiving funding.

A DOF appointee may not publish articles or other forms of scholarly communication under their own names in the course of their outside professional activities that are written in whole or material part by employees of the outside entity (i.e., "ghost written"). This is of particular relevance in cases where the DOF appointee receives funding and consults for the same company.

All significant consulting contracts (e.g. if the monetary value received by the individual exceeds \$5,000 over a period of a year, and/or the person receives any ownership interest (stocks or stock options) from a privately held entity, and/or the person receives any ownership interest (stocks or stock options) from a publicly-traded entity that is worth over \$5,000) that are put into place with an entity that is also funding or gifting a DOF appointee's research should be reported to the COIR Panel for review and possible mitigation.

References:

*[Public Health Service Federal Regulation 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research"](#)

**[Rules and Procedures of the Faculty, Chapter 5:1 – Conflicts of Interest in Research](#)

***[Guidebook for Department Chairs and Managers, Outside Professional Activities and Conflicts of Interest](#)

****[Princeton University Patent Policy](#)