

Conflict of Interest in Research Panel

Charter

I. MISSION

The *Conflict of Interest in Research Panel* (Panel) promotes integrity in research by reviewing, identifying and managing disclosed conflicts of interest.

II. PURPOSE and SCOPE

In accordance with University policy and Federal regulations, the Panel reviews investigator disclosures and determines whether a conflict of interest exists. If a conflict of interest exists, a management plan is developed for handling the identified conflict.

The Panel reviews the following types of conflicts (see Section IV for definitions):

- Conflict of commitment (COC)
- Conflict of resources (COR):
 - Involving the participation of undergraduate students, graduate students, Academic Professionals and Librarians
 - Involving the use and allocation of equipment or space
- Financial conflict of interest (FCOI)

III. MEMBERSHIP

A. The following are *ex officio* voting members of the Panel:

- Dean for Research (DFR; Chair)
- Dean of the Faculty (DOF)
- Dean of the Graduate School
- Dean of the School of Engineering and Applied Science
- General Counsel
- Director, Office of Technology Licensing (OTL)
- Director, Research Integrity and Assurance (RIA)

B. In addition to the *ex officio* members noted above, a minimum of three voting tenured members of the Faculty, one from Division I or II, and two from Divisions III and/or IV are appointed to the panel by the Dean for Research in consultation with the Dean of the Faculty, for staggered, renewable, three year terms. The Panel may invite expert consultants to aid in the review of a given disclosure.

- C. A member from RIA serves as the Panel's secretary. The Assistant Dean(s) of the Faculty, the Dean of the College (DOC), the Director of the Office of Research and Project Administration (ORPA), the Senior Licensing Associate in OTL, and additional RIA staff sit with the Panel as needed as non-voting members.
- D. No member of the Panel may participate (except to provide information requested by the Panel) in the review or determination of a conflict of interest matter in which he/she has or expects to have a financial interest or any other conflict.

IV. DEFINITIONS

- A. Significant Financial Interest (SFI) – Anything of monetary value rising to the level of significance, as defined in Appendix A, including but not limited to salary; other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options, or other ownership interests); or intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
- B. Financial Conflict of Interest in research - Exists when the Chair or Panel reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of research.
- C. Conflict of Commitment (as defined by The Rules and Procedures of the Faculty of Princeton University) - Occurs when the commitment to external activities of a faculty member or member of the professional research staff adversely impacts, or appears to impact, his or her capacity to meet their Institutional responsibilities. This form of conflict is typically recognizable through a perceptible reduction of the individual's time, focus, and/or energy devoted to University activities.
- D. Conflict of Resources– Occurs when participation of undergraduate or graduate students, Academic Professionals and Librarians and/or the use of allocated space or equipment involves outside interests that may conflict with the mission of the University.
- E. Institutional Responsibilities – An Investigator's professional responsibilities on behalf of the University including, but not limited to research and teaching activities both within and outside the University.
- F. Investigator – A person that is a Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of funded research. An investigator may include Co-Principal Investigators, key personnel, independent investigators, students, Academic Professionals, collaborators or consultants.
- G. Management Plan – A document developed by RIA and approved by the Chair or Panel that outlines terms to address identified conflicts of interest. The terms of the management plan may include, but are not limited to, public disclosure of conflict of interest in

publications or presentations, informing other research team members regarding conflicts, or reducing or eliminating the conflict to ensure, to the extent possible, that the design, conduct and reporting of the research will be free from bias.

V. PROCEDURES

A. Annual Disclosure Form Review

1. All Faculty, Academic Professionals and Librarians submit an annual disclosure form via the COI Reporting System that discloses retrospectively over the previous year (from Jan 1 until Dec 31) all actual or perceived conflicts of commitment (COC), financial conflicts of interest (FCOI), or conflicts of resources (COR). Faculty, Academic Professionals and Librarians will be divided into the following categories: Public Health Service (PHS) funded (e.g., NIH); Non-PHS federally funded (e.g. NSF, DOE, DOD); and all others (e.g., Funded by Foundation, Industry, Private Source, or State of New Jersey, Corporate and Foundation Gifts, and those that are non-funded).
2. Following annual disclosure submission deadlines, members of the office of the Dean of the Faculty (DOF) and Research Integrity and Assurance (RIA) collaborate to identify any potential significant conflicts and places them into the following categories:
 - a. **GROUP A** consists of disclosures of those individuals with SFIs, which RIA/DOF has designated as not representing a real or potential FCOI.
 - b. **GROUP B** consists of disclosures in which activities/associations were reported that potentially represent a real or perceived FCOI, or for which RIA/DOF recommends a closer examination by the Panel.
 - c. **GROUP C** consists of disclosure of COI issues that have arisen during the year and separate from the annual COI disclosure process.
 - d. **GROUP D** consists of COI disclosure issues that do not relate to FCOI but rather to resources (e.g., use of students, equipment or space).
 - e. **GROUP E** consists of SFI disclosures for non-PHS federally funded and all other individuals that may pose a FCOI.
3. Review of disclosures by PHS funded researchers will be given priority so as to comply with the 60-day review and determination requirement.
4. For those disclosures that represent a significant conflict of any type, a management plan may be developed by RIA staff or a committee of Panel members appointed by the Chair, working with the relevant offices, as needed (DOF, Dean of the Graduate School, and DOC). Management plans must be approved by the Chair and then presented to the Panel. Management plans are reviewed annually.
5. DOF will report at the next convened Panel meeting on communications or actions related to COC.

B. Review and determination of Significant Financial Interest (SFI) disclosures submitted by PHS funded Faculty, Academic Professionals, and Librarians

1. All PHS funded Faculty, Academic Professionals, and Librarians must disclose SFI(s) (Appendix A) via the COI reporting system annually and within 30 days of acquiring or discovering the interest.
2. Upon receipt of an SFI disclosure, RIA may set up a meeting with the PI to further understand the nature of the SFI. RIA will create a report summarizing the meeting and make a recommendation to the Chair on whether or not the SFI is an FCOI, and whether a management plan is needed (refer to Appendix B).
3. Ultimately, the Chair or Panel determines if the disclosed SFI meets the definition of an FCOI as defined by the FCOI criteria (Appendix B). The Chair may make the determination individually, consult a subject matter expert (SME) or send the matter to the Panel for deliberation and determination. In the event of time sensitivity, the Chair maintains the right to make the determination of FCOI without seeking input from the Panel.
4. If the Chair (or Panel) determines that an FCOI (or COC or COR) exists, a management plan will be developed and implemented. The plan will be developed by RIA staff, or by an ad-hoc committee of Panel members appointed by the Chair. Approval authority for management plans rests with the Chair.
5. All PHS funded identified FCOI(s) are reported through the Electronic Research Administration (eRA) Commons web based system.
6. The management plan will be reported to the Panel at the next regularly scheduled meeting.
7. For those PHS funded investigators that are determined to have an FCOI, Princeton is required, if requested to make public a disclosure of such information including the name of the investigator, the conflicted entity, and the amount of the financial interest through either a website or by written request. Princeton University will respond in writing on a case-by-case basis to requests for this information and will not maintain a website to report such interests. Affected investigators will be notified in advance of the release of this information in response to any such requests.

C. Review and determination of Significant Financial Interest (SFI) disclosures submitted by non-PHS federally funded and all other Faculty, Academic Professionals and Librarians

1. All non-PHS federally funded and all other Faculty, Academic Professionals and Librarians must disclose SFI(s) (Appendix A) via the COI reporting system annually. At any time during the year, including after the annual disclosure review process, non-PHS federally funded and all other Faculty, Academic Professionals and Librarians may bring to the attention of RIA any perceived or potential conflicts of any type.
2. Upon receipt of an SFI disclosure, RIA may set up a meeting with the PI to further understand the nature of the SFI. RIA will create a report summarizing the meeting and make a recommendation to the Chair on whether or not the SFI is an FCOI, and whether a management plan is needed (refer to Appendix B).

3. Ultimately, the Chair or Panel determines if the disclosed SFI meets the definition of an FCOI as defined by the FCOI criteria (Appendix B). The Chair may make the determination individually, consult a subject matter expert (SME) or send the matter to the Panel for deliberation and determination. In the event of time sensitivity, the Chair maintains the right to make the determination of FCOI without seeking input from the Panel.
4. If the Chair (or Panel) determines that an FCOI (or COC or COR) exists, a management plan will be developed and implemented. The plan will be developed by RIA staff, or by an ad-hoc committee of Panel members appointed by the Chair. Approval authority for management plans rests with the Chair.
5. In the event that Princeton University cannot satisfactorily manage an NSF funded FCOI management plan, RIA must contact the NSF's Office of General Counsel.
6. The management plan will be reported to the Panel at the next regularly scheduled meeting.

VI. RESPONSIBILITIES

A. Institution

1. Ensures the submission of disclosure of SFIs by PHS funded, non-PHS federally funded and all other Faculty, Academic Professionals, and Librarians during the annual disclosure period. For PHS funded investigators, disclosure must occur annually and within 30 days of acquiring or discovering that interest as defined by the SFI criteria (Appendix A).
2. Ensures the disclosure of reimbursed or sponsored travel by PHS funded investigators as defined by the SFI criteria (Appendix A).
3. Maintains an-up-to date written and enforced policy on FCOI.
4. Informs each PHS funded investigator of the University's policy on FCOI, outlining the investigators responsibilities for disclosure and training.
5. Designates an institutional official (IO) to review disclosures of significant financial interest. The Institution has designated the DFR as the IO.

B. Investigator (PHS funded, non-PHS federally funded and all other Faculty, Academic Professionals, and Librarians)

1. Comply with Federal regulations and Princeton Policy on conflict of interest by submitting an annual disclosure form that includes SFI disclosures related to their institutional responsibilities according to the criteria contained in Appendix A.
2. PHS funded investigators must disclose annually and within 30 days of acquiring a new SFI that is related to their institutional responsibilities, and they must disclose reimbursed or sponsored travel (See Appendix A).
3. PHS funded investigators must perform mandatory conflict of interest training prior to engaging in PHS funded research and every four years thereafter.

4. PHS funded and non-PHS federally funded investigators must determine and identify in the grant application, progress report, or any other report submitted to a funding agency, any person regardless of title or position who is responsible for the design, conduct and reporting of the PHS and non-PHS federally funded research and if that investigator is PHS funded, he/she must perform mandatory conflict of interest training prior to engaging in PHS funded research and every four years thereafter.
- C. Conflict of Interest in Research Panel
1. Reviews significant conflicts.
 2. Makes determinations of FCOI.
 3. Reviews management plans developed by RIA and approved by the Chair.
 4. Reviews existing management plans annually.
 5. Develops policy recommendations on conflict of interest in research for consideration by the University Research Board (URB) or other appropriate University bodies.
- D. Panel Chair/IO
1. Appoints, in consultation with DOF, committee members to the Panel.
 2. Makes determinations of FCOI.
 3. Approves Management Plans.
- E. Dean of the Faculty
1. Initiates annual COI disclosure request to ensure that appointees disclose conflicts of interest issues that may have arisen during the previous year (from Jan 1 through Dec 31).
 2. Follows-up on individuals who have not submitted their annual disclosure form.
 3. Ensures compliance with University policies regarding conflict of commitment.
 4. Ensures compliance with University policies regarding the use professional researchers.
 5. Provides expert advice to the Panel on matters related to COR and COC.
- F. Dean of the Graduate School
1. Provides expert advice to the Panel on matters related to conflict of resources involving graduate students.
- G. Dean of the College
1. Provides expert advice to the Panel on matters related to conflict of resources involving undergraduate students.
- H. Research Integrity and Assurance
1. Monitors the COI Reporting System and fields questions and concerns regarding the annual reporting process.
 2. Follows-up on individuals who have not submitted their annual disclosure form.
 3. Ensures compliance with University policies regarding the use of allocated space, and equipment.
 4. Administers and convenes the Panel meetings. Provides subject matter expertise for COI regulatory compliance.

5. Provides follow-up and support to action items resulting from Panel meeting.
6. Supports the Chair in FCOI determinations.
7. Assists the Chair in developing COI management plans as needed.
8. Ensures that all identified FCOIs related to PHS funded research are reported to the relevant funding agency in accordance with the Federal FCOI regulations.
9. Verifies that all PHS funded investigators have completed the requisite training as required by the Federal FCOI regulations and University policy.
10. Sends periodic reminders to PHS funded investigators about disclosure requirements in accordance with the Federal FCOI regulations.
11. Initiates and develops appointment letters for those tenured faculty that sit on the Panel as voting members but are not *ex-officio* members.

VI. MEETINGS

- A. *Meetings.* The Panel shall meet as frequently as it determines, but not less than twice annually.
- B. *Quorum, Votes and Committee Actions.* Quorum is one half of the committee membership plus one and is required at the Panel meetings to conduct business. For all committee actions, motions will be made and seconded and votes will be called for on such motions. Votes will be decided by a simple majority of those present. A quorum must be present (in person or through telephone or video conferencing) to take action. At the end of the meeting, a call for dissenting opinions will be made for the record.
- C. *Agenda, Minutes and Reports.* The Chair of the Panel, with assistance from RIA staff, shall be responsible for setting the agendas for each meeting. The agenda and information concerning the business to be conducted at each Panel meeting shall, to the extent practicable, be communicated to members sufficiently in advance of each meeting to permit meaningful review. RIA personnel will take minutes or other records of meetings and activities.
- D. *Resources.* The Panel has the authority to retain outside advisors, such as scientific consultants or other experts, as it deems appropriate; and to approve the fees and expenses of such advisors. Financial support for these types of activities will be provided by the Dean for Research.

VII. REFERENCES:

- A. Federal Regulations: Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought [Title 42 CFR Part 50, Subpart F](#)
- B. Federal Regulations: [Responsible Prospective Contractors Title 45 CFR Part 94](#)
- C. Federal Regulations: [NSF Policy \(Chapter V Grantee Standards \(NSF 05-131 subpart 510\)\)](#)

APPENDIX A
CRITERIA FOR DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST

For Public Health Service (PHS) funded, Non-PHS federally funded, and all other Faculty, Academic Professionals and Librarians:

Pursuant to Princeton Policy and Public Health Service Federal Regulation 42 CFR Part 50, Subpart F, criteria to be used to define significant financial interests are as follows:

- i. Any current or pending ownership interests (including shares, partnership stake, derivative interests such as stock options) in a privately-held entity held by the investigator or his/her spouse or dependent children related to the investigator's institutional responsibilities;
- ii. Any current or pending ownership interests of \$5,000 or more (including shares, partnership stake or derivative interests such as stock options) in a publicly-traded entity held by the investigator or his/her spouse or dependent children related to the investigator's institutional responsibilities;
- iii. Any income amounting to \$5,000 or more per year per company/organization including payment for services, consulting fees, honoraria, licensing or royalty income or any other financial interest in a single company/organization that amount to \$5,000 or more cumulatively received by the investigator or his/her spouse or dependent children related to the investigator's institutional responsibilities; and/or
- iv. For PHS funded investigators only: Any reimbursed or sponsored travel that amounts to \$5,000 from a single entity over the period of the previous year related to the investigator's institutional responsibilities.

APPENDIX B
CRITERIA FOR DETERMINATION OF FINANCIAL CONFLICT OF INTEREST

For Public Health Service (PHS) funded and Non-PHS federally funded Faculty,
Academic Professionals and Librarians:

Princeton Policy and Public Health Service Federal Regulation 42 CFR Part 50, Subpart F “Promoting Objectivity in Research” was enacted to establish reasonable standards that provide a reasonable expectation that the design, conduct and reporting of PHS funded research will be free from bias resulting from investigator financial conflict of interest.

The criteria to be used to determine when a significant financial interest (SFI) is a financial conflict of interest (FCOI) are as follows:

- i. The SFI is related to the investigator’s funded research. An SFI is related to an investigator’s funded research when it can be reasonably determined that that the SFI could reasonably affect the funded research or is in an entity whose financial interest could be affected by the research; and
- ii. A reasonable determination is made that the SFI could directly and significantly affect the design, conduct or reporting of the funded research.

In accordance with Federal regulation, information regarding PHS funded FCOIs shall also be made available within five (5) business days to any request made by the public.

For all other Faculty, Academic Professionals and Librarians:

For all other Faculty, Academic Professionals and Librarians, the criteria used to determine when a significant financial interest is a financial conflict of interest is when a reasonable determination is made that the SFI could directly and significantly affect the design, conduct of reporting of research or interfere with one’s institutional responsibilities.