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):

- Conflicts of commitment (COC)
- Conflict of resources (COR):
  - Involving the participation of undergraduate students, graduate students, post-doctoral researchers or other Dean of the Faculty appointees
  - Involving the use and allocation of equipment or space
- Financial conflict of interest (FCOI)

III. MEMBERSHIP

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

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

B. In addition to the ex officio members noted above, three 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 Associate Dean(s) of the Faculty, 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.

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 sponsored research - Exists when the Dean for Research reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored 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 professional research staff adversely impacts, or appears to impact, his or her capacity to meet University 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, post-doctoral researchers, and other Dean of Faculty appointees and/or the use of allocated space or equipment involves outside interests that may conflict with the mission of the University.

**V. PROCEDURES**

A. Annual Disclosure Form Review

1. All faculty and professional research staff submit an annual disclosure form via the COI Reporting System that discloses retrospectively over the previous year all actual or perceived conflicts of commitment (COC), financial conflicts of interest (FCOI), or conflicts of resources (COR).

2. Following annual disclosure submission deadlines, members of the office of the Dean of the Faculty (DOF) and Research Integrity and Assurance (RIA) meet to identify any potential significant conflicts and places them into the following categories:
   a. Conflicts disclosed but unlikely to reach thresholds of significance
b. Conflicts disclosed with potential to exceed thresholds of significance
3. Review of disclosures by Public Health Service (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 DFR, working with the relevant offices, as needed [DOF, DGS, and Dean of the
College (DOC)]. Management plans must be approved by the DFR and then
presented to the Panel.
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 researchers

1. All PHS-funded researchers must disclose significant financial interests (SFI)
(Appendix A) via the COI reporting system within 30 days of acquiring or
discovering the interest.
2. Upon receipt of a SFI disclosure, the DFR shall determine if the disclosed SFI meets
the definition of a FCOI as defined by the FCOI regulations (Appendix B). The
Dean may consult with other relevant persons to aid in the determination of
relatedness to, and potential impact of the SFI on, the researcher’s PHS-funded
research.
3. If the DFR determines that the SFI is a FCOI, 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 DFR. Approval authority for
management plans rests on the DFR.
4. The management plan will be reported to the relevant PHS funding agency in
accordance with the regulations.
5. The management plan will be reported to the Panel at the next regularly scheduled
meeting.

C. Disclosure and Review of conflicts of non-PHS Funded researchers

1. At any time during the year, including after the annual disclosure review process,
non-PHS funded researchers may bring to the attention of RIA any perceived or
potential conflicts of any type.
2. The DFR will determine if the disclosure represents a significant conflict of any
type. The Dean may consult with other relevant persons to aid in the determination.
3. If a significant conflict determination is made, a management plan may be developed
and implemented. The plan will be developed by RIA staff or by an ad-hoc
committee of Panel members appointed by the DFR. Approval authority for
management plans rests on the DFR.
4. The management plan will be reported to the Panel at the next regularly scheduled
meeting.
VI. RESPONSIBILITIES

A. Institution
1. Ensures the disclosure of SFI s by investigators during the annual disclosure. For PHS funded researchers, disclosure must occur within 30 days of acquiring or discovering that interest as defined by the FCOI regulations (Appendix A).
2. Ensures the disclosure of reimbursed or sponsored travel by PHS funded investigators as defined by the FCOI regulations (Appendix A).

B. COI in Research Panel
1. Reviews significant conflicts.
2. Reviews management plans developed by RIA personnel and endorsed by the DFR.
3. Reviews management plans previously approved by the DFR.
4. Develops policy recommendations on conflict of interest in research for consideration by the University Research Board (URB) or other appropriate University bodies.

C. Dean for Research
1. Appoints, in consultation with DOF, committee members to the Panel.
2. Makes determination about FCOI.

D. 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.
2. Ensures compliance with University policies regarding conflict of commitment.
3. Ensures compliance with University policies regarding the use of allocated space, equipment and personnel.
4. Provides expert advice to the Panel on matters related to COR.

E. Dean of the Graduate School
1. Provides expert advice to the Panel on matters related to conflict of resources involving graduate students.

F. Dean of the College
1. Provides expert advice to the Panel on matters related to conflict of resources involving undergraduate students.

G. Research Integrity and Assurance
1. Monitors the COI Reporting System and fields questions and concerns regarding the annual reporting process.
2. Administers and convenes the Panel meetings. Provides subject matter expertise for regulatory compliance.
3. Provides follow-up and support to action items resulting from Panel meeting.
4. Supports the DFR in FCOI determinations.
5. Assists the DFR in developing COI management plans as needed.
6. Ensures that all identified FCOIs related to PHS funded research are reported to the relevant funding agency in accordance with the FCOI regulations.
7. Verifies that all PHS funded investigators have completed the requisite training as required by the FCOI regulations and University policy.
8. Sends periodic reminders to PHS funded investigators about disclosure requirements in accordance with the FCOI regulations.

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.
APPENDIX A
CRITERIA FOR DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST

For PHS funded investigators

Pursuant to 42 CFR Part 50, 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. 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

For non-PHS funded investigators:

Criteria to be used to define significant financial interest as defined by grant and University policy are as follows:

i. Income (salary, royalties or other payments) from a single entity which when aggregated for the investigator or their spouse or dependent children exceeds $10,000 over twelve months; and/or

ii. An equity interest in a single entity held by the investigator, their spouse or dependent child when aggregated is in excess of $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or 5% ownership interest.
APPENDIX B
CRITERIA FOR DETERMINATION OF FINANCIAL CONFLICT OF INTEREST

For PHS funded investigators:

42 CFR Part 50, “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 PHS funded research. A SFI is related to an investigator’s PHS funded research when it can be reasonably determined that the SFI could reasonably affect the PHS 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 PHS-funded research.

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

For non-PHS funded investigators:

For all other funded researchers, 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 the funded research.