



## Conflict of Interest in Research PROCESS AND PROCEDURES

### I. DEFINITIONS

For specific definitions to capitalized terms (*e.g.*, Investigator, SFI, FCOI), please see the [COI in Research Policy](#). This Process and Procedures guidance is consistent with the [Rules and Procedures of the Faculty](#) and does not supersede the *Rules and Procedures of the Faculty*.

### II. DISTRIBUTION OF RESPONSIBILITIES

- A. Conflict of Interest in Research Panel (and subcommittees thereof)
  - 1. Reviews significant conflicts and unique COI related matters.
  - 2. At the request of the DFR, makes determinations, either by full committee or Subcommittee review of potential FCOIs/COIs and other financial interests, as to whether a Management Plan (MP) is needed.
  - 3. Monitors Investigator compliance to existing management plans at least annually.
  - 4. Develops policy recommendations on conflict of interest in research and related topics for consideration by other appropriate University bodies.
- B. Corporate Engagements and Foundation Relations (CEFR)
  - 1. Reviews incoming research gifts from companies and foundations.
  - 2. Confirms with RIA or via COI Reporting System that the recipient does not have an interest in the company or foundation.
  - 3. Ensures RIA has up to date information on gift portfolio for COI disclosure form review.
- C. Dean for Research (DFR)
  - 1. Chairs COIR Panel
  - 2. Appoints committee members to the COIR Panel, in consultation with the Dean of the Faculty
  - 3. Addresses appeals by Investigators regarding the need for a management plan.
- D. Office of Research and Project Administration (ORPA)
  - 1. Reviews Investigator status on proposals and ongoing sponsored projects, and ensures that appropriate proposal/project personnel at Princeton have submitted a timely COI disclosure or updated form (minimally within the last year), and that COI training for appropriate Investigators (such as on PHS/DOE projects) is current (within the last 4 years).



2. Determines and documents, in collaboration with RIA, whether appropriate Investigators at subrecipients are subject to subrecipient COI policies. If this is not the case, ORPA will ensure such personnel disclose and receive training through RIA/Princeton.
    - i. Collaborates with ODOF, the Graduate School, HR and other units to confirm status of project individuals, including appointment details and funding sources where appropriate
    - ii. Collaborates with RIA, who will work with the Investigator, or subrecipient, to ensure that a complete, accurate and timely COI disclosure or updated form is on file and, where appropriate, training is current.
    - iii. Compares internal disclosures in the COI Reporting System to disclosures made to funding agencies (e.g., biosketches and current and pending support documents) in proposals and progress reports, and reconciles these as appropriate in collaboration with the project personnel, academic unit, RIA, ODOF, etc.
  3. Prior to proposal submission, checks and enforces that timely FCOI/COI disclosures have been made where appropriate, and any other proposal-stage FCOI/COI requirement (i.e., in the solicitation) has been followed.
  4. Prior to award set-up, checks and enforces that timely disclosures as well as FCOI/COI determinations have been made where appropriate and, if necessary, a management plan has been implemented. Award set-ups may be delayed until compliance has been verified.
- E. Office of the Dean of the Faculty (ODOF)
1. Collaborates with ODFR to initiate annual COI disclosure request to ensure that appointees complete annual COI disclosure form and monitors completion compliance with department administration assistance.
  2. Administers compliance with University policies regarding conflict of commitment, conflict of resources, and other institutional requirements beyond those of research sponsors.
- F. ODOF Appointees – provide up-to-date information via COI Reporting System to RIA and the COIR Panel and respond to inquiries from ODFR in a timely manner.
- G. Department Chairs and Managers
1. Support ODOF and ODFR efforts to ensure that members of their department have submitted the annual COI forms in a timeframe determined by the ODOF and ODFR.



2. Collaborate with individual Investigators to ensure complete, accurate, and timely disclosures and advise ODOF and ODFR as those offices seek to ensure compliance with University and sponsor requirements.
  3. Make appropriate/relevant information in the COI Reporting System available to additional department staff with a bona fide need to know (i.e., grants managers or faculty assistants preparing and maintaining biosketches and current and pending documents for researchers).
- H. Office of Technology Licensing (OTL) – provides Princeton start-up information and ongoing licensing and other institutional agreements with start-ups to RIA and other relevant offices on a regular basis.
- I. Research Integrity and Assurance
1. Serves in a consulting role throughout the year for any Investigator to discuss any issues related to COIs, potential COI, and other financial interests, including those that may be newly acquired through the development of a new startup company, consulting positions, or positions/appointments at other academic institutions.
  2. Provides educational resources on COI regulations, policies and processes via website updates, departmental outreach and annual updates.
  3. Reviews all forms and compares disclosures of SFIs and other potential conflicts of interest with research awards, research funding, and other information available.
  4. Monitors the COI Reporting System and answers questions and concerns regarding the annual reporting process.
  5. Supports the ODOF with form completion compliance.
  6. Administers the COIR Panel or Panel Subcommittee meetings. Provides subject matter expertise for COI compliance.
    - a. Provides follow-up and support to action items resulting from COIR Panel meetings.
    - b. Supports the Chair and Panel in FCOI determinations and in developing MPs as needed.
  7. Develops and distributes appointment letters for those tenured faculty that sit on the Panel as voting members but are not *ex-officio* members.
  8. Ensures that all identified FCOIs (including under PHS, or DOE-funded research) are reported as appropriate to the relevant funding agency in accordance with agency requirements and the federal FCOI regulations.
  9. Verifies that all federally funded investigators are current with the requisite training as required by the federal FCOI regulations and University policy.
  10. Sends reminders to PHS/DOE funded investigators about disclosure requirements in accordance with the federal FCOI regulations.



11. Works with ORPA to address COI-related transactional requirements and other compliance-related needs, including review of SFIs, FCOI determinations and MPs issued if needed, prior to the expenditure of funds.
12. Collaborates with appropriate Princeton administrative offices (e.g., ODOF, ORPA) to review and, if necessary, revise the questions for Investigators in the COI Reporting System each year prior to the annual disclosure period.

### III. PROCEDURES

#### A. Disclosure Review and Management Process

1. All ODOF-appointees and any other Investigators must submit either an annual disclosure or an updated disclosure as required by the [COI in Research Policy](#).
2. Forms in which individuals make no disclosure (i.e., non-disclosures) are automatically routed through the COI Reporting System and are closed without further review.
3. The disclosure form in the COI Reporting System (form) collects information beyond what is necessary to meet federal requirements. This additional information is utilized by other administrative departments to meet University policies and other research sponsor requirements. RIA triages the disclosure forms with disclosures and routes questions or specific determinations to the appropriate department.
4. RIA prioritizes review of submitted disclosure forms utilizing a risk-based methodology (e.g., PHS or DOE-funded researchers given priority) and compares sponsored program/nonfunded agreement (ORPA/PeopleSoft) and gift (CEFR/Salesforce) information for the individual to review for relatedness. RIA may also cross reference disclosure information from researchers with other sources of information. RIA engages ODOF and OGC throughout the FCOI determination and management process
5. RIA screens all forms in which individuals made a disclosure (i.e., positive disclosures). To further evaluate the information, RIA may request additional information from the individual electronically via the COI Reporting System or a meeting to further understand the nature of the disclosed information. RIA may create a summary report that includes information about the SFI(s) and the individual's current research funding. RIA may also perform this step and the following steps throughout the year upon a request to review an SFI for a new federal award to determine relatedness, which will leverage workflows, processes with ORPA and forms established in the COI Reporting System. RIA engages ODOF and OGC throughout the FCOI determination and management process.
6. For any potential FCOIs associated with a disclosure of an SFI or that come to light through any other process, a summary report/case packet is shared with the COIR Panel Chair (Chair), who may also refer it to a subcommittee (1-2 designated



- members) of the Panel, especially in complex and sensitive cases. The Chair or Subcommittee determines whether the SFI(s) is related to one or more of the funded/proposed projects and, if so, whether the SFI(s) constitutes an FCOI.
7. The process may require additional outside expertise to help with the assessments. If this is the case, then RIA works with the Chair and other COIR Panel members to identify a subject matter expert and request their assistance in the deliberative process.
  8. For cases involving an FCOI, the full COIR Panel may engage in proposing and approving a management plan, or may delegate authority to the Chair to do so. In either case, RIA will draft a management plan, and will inform OGC and ODOF of the determination of an FCOI. RIA will request either a designated review by a subcommittee where they review and offer revisions to the draft management plan that either eliminates, minimizes, or otherwise appropriately manages the conflict, or the Chair and/or RIA may refer the draft to the full Panel for review in complex or sensitive cases. The draft, with appropriate revisions, will be finalized by RIA staff and approved by the Chair after delegation of authority from the full COIR Panel.
  9. After Chair approval, the draft management plan is sent to the Investigator and their Department Chair for review and iterative revisions, if requested. RIA will address any changes and obtain the Investigator's signature. Once signed, the management plan is sent to the Chair for final approval and signature. If changes are material or significant, the Chair may wish to obtain approval from the full COIR Panel or ask for a renewed delegation of authority to approve.
  10. If the full COIR Panel is not engaged in determining the existence of a FCOI/COI or perceived FCOI/COI or creating the management plan, the full COIR Panel is notified of such determinations and management plans at the next convened COIR Panel meeting.
  11. Annually, RIA monitors the approved MP by working with the Investigator or department to obtain the necessary information, which includes disclosures in presentations, publications, and to lab members. The monitoring information is shared with the COIR Panel.
  12. RIA may update management plans due to new or inactive grant funding, in which case the updated and signed MP will be shared at the next Panel meeting.
- B. Conflict Management Reporting
- RIA provides the appropriate documentation of FCOIs and institutional policies to federal agencies in accordance with any related federal/sponsor requirements.



### C. Other

1. RIA, ORPA, and other offices within ODFR take primary responsibility for addressing FCOI/COI issues associated with federal and nonfederal (i.e., foundation or industry) sponsored research activities and compliance with sponsor requirements. ODOF takes primary responsibility for other conflicts topics, e.g., COC, COR, or nepotism, where research sponsors may not have specific rules but the university has requirements. ODOF and ODFR offices work collaboratively to holistically evaluate and manage the full range of potential conflicts.

### VERSION HISTORY

Updated April 8, 2024: Significant changes from prior processes that were included in policies and COIR Panel Charter