# IU Procedures for the Regulation of Financial Conflicts of Interest

The following procedures implement the Indiana University Policy on Financial Conflicts of Interest in Research (Policy). The Procedures set forth below shall supersede any previous procedures and/or guidelines for handling conflicts of interest as they relate to university responsibilities.

These procedures apply to all persons at IU who are Investigators on university Research, whether funded or unfunded, or Sponsored Programs.

There is a separate university policy on conflicts of interest that applies to staff who are not responsible for the design, conduct, or reporting of research. See <https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.html>.

## Definitions

Definitions not found in these procedures for capitalized terms may be found in the Policy.

* 1. **Conflict of Interest (COI) Disclosure** means the Indiana University Financial Conflict of Interest Disclosure Form.
  2. **Financial Conflict of Interest (FCOI)** is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of Research or a Sponsored Program.
  3. **Institutional Official** is the Vice President for Research.
  4. **Institutional Official Designee** is the campus appropriate Conflict of Interest Committee and Conflict of Interest Office.
  5. **Key Personnel** are those listed as such in university Research and Sponsored Programs.
  6. **Public Accessibility** is the publishing of the Policy and responding to requests for FCOI information on PHS investigators.
  7. **Records** shall include COI Disclosures, COI Committee meeting minutes, and correspondence.
  8. **Relatedness** means directly and significantly associated with the Investigators’ research, i.e., when an Investigators’ SFI is associated with his or her research based on topic, use of products, potential for an increase in the value of the SFI or the company in which the SFI is held.
  9. **Retrospective Review** means a review conducted by the university when an investigator fails to report a SFI in a timely manner or when noncompliance with the PHS regulation and/or a university issued management plan is discovered.
  10. **Significant Financial Interest (SFI)** means significant financial interest as defined in the Policy.
  11. **Travel** means reimbursed or sponsored travel related to an Investigator’s University Responsibilities, which when combined with any other remuneration from the entity meets the $5,000 reporting threshold. Investigators need not disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an Institution of higher education.

## COI Disclosure

* 1. Annual disclosure by all Investigators of SFIs shall be made each year, as designated by the Institutional Official. Such disclosure shall be made on uniform disclosure forms provided by the Office of the Vice President for Research.
  2. When SFIs are added or changed after an annual COI Disclosure has been submitted, Investigators must submit a new disclosure within thirty (30) days of discovering or acquiring the new SFI.
  3. Submission of all COI Disclosures are made to the COI Office for review. The COI Office will provide the school administration with Investigators’ COI Disclosure for their review and recommendation.
  4. Any reimbursed or sponsored Travel related to a Investigator’s University Responsibilities, which when combined with any other remuneration from the entity meets the $5,000 reporting threshold, must be reported to the COI Office with the exception of Travel sponsored by the following:
     1. Federal, state or local government agency,
     2. An institution of higher education as defined by 20 U.S.C. 1001(a),
     3. An academic teaching hospital,
     4. A medical center, or,
     5. A research institution that is affiliated with an institution of higher education.
  5. SFIs shall be reported for the previous twelve (12) months; however, planned Travel may be reported prospectively as well.
  6. Training will be included as part of the COI Disclosure and must be completed annually prior to submission of the COI Disclosure, and immediately whenever: the Policy changes, an Investigator is new to the university, or noncompliance with PHS regulations and/or a university issued management plan is discovered.

## Conflicts of Interest Committee

The COI Committee’s objective shall be to attempt to manage, reduce, or eliminate conflicts in an efficient and amenable manner.

* 1. *Membership.*

The COI Committee shall be appointed by the Vice President of Research and shall include:

* + 1. at least three faculty members;
    2. one or more associate deans for research;
    3. a chair or co-chairs, who must be tenured faculty member(s),
    4. a member of the community,
    5. the COI Committee shall be composed of no less than five voting members, and;
    6. all members shall sign a confidentiality agreement.
  1. *Terms.*

COI Committee chairs and members shall serve for renewable two-year terms totaling six years.

* 1. *Authority.*

The COI Committee is established pursuant to the Policy and these procedures, and is empowered to:

* + 1. Oversee the uniform disclosure of SFIs for Investigators;
    2. Review annual COI Disclosure forms in which real or apparent FCOIs have been identified, and, where appropriate, develop management plans or other means of managing, reducing, or eliminating real or apparent COIs;
    3. Consult with appropriate administrative officials in the development of such plans;
    4. Coordinate with the campus Institutional Review Board(s) to identify and address real or apparent FCOIs arising in human subjects research; and,
    5. Help conduct and support education of faculty, staff, and students on COI issues.

In the performance of its duties under the paragraph above, the COI Committee may impose conditions or restrictions to manage, reduce, or eliminate a real or apparent COI. Such conditions or restrictions may include, but are not limited to:

* + 1. Public disclosure of SFI;
    2. Modification of the research plan;
    3. Disqualification from participation in all or part of a project in which an actual or potential COI exists;
    4. Divestiture of SFI;
    5. Severance of relationships that create actual or reasonably perceived COIs; and,
    6. Prohibition of students working for faculty start-up companies.

The COI Committee and its designee is authorized to collect sufficient information to allow it to identify the existence and extent of a real or apparent FCOI and the feasibility of options for managing, reducing, or eliminating such a conflict.

* 1. *Procedures*
     1. Voting. Each COI Committee member, other than the ex officio members, shall have one vote. Voting shall proceed within the COI Committee, after an opportunity for full discussion has been afforded.
     2. Notice. The COI Committee, via the COI Office, will provide written or electronic notice to the Investigator whose real or apparent conflict has been reviewed, of the COI Committee determination regarding (1) the existence of a real or apparent COI; and (2) appropriate steps for managing, reducing, or eliminating the COI.
        1. The Investigator may respond in writing (including electronic writing) to the COI Committee’s determinations within a reasonable deadline as established by the COI Committee. Alternatively, the Investigator may request to meet with the COI Committee at its next regular meeting or at a special meeting to answer questions or address issues of the COI Committee.
     3. Timeframe for Review. The COI Committee shall use its best efforts to reach a final determination as to any real or apparent COI referred to them within a reasonable timeframe which is compliant with any applicable regulations.
     4. Management of SFI(s). The COI Committee shall review the SFI(s) and the individual’s University research to determine if a management plan or best practices memo is needed.
        1. Best Practices Memo: put in place when the SFI is remotely related to the individual’s University research (i.e. equity ownership or stock options in a large public company, spouse employment at an entity related to Investigator’s research, compensation from a non-profit entity, in addition to those circumstances in which the COI Committee determines a Best Practices Memo is appropriate).
        2. Management Plan: put in place when the SFI is directly and significantly related to the individual’s University research (i.e. start-up company, consulting for a company that sponsors the individual’s University research, significant financial interests in areas related to the Investigator’s research, in addition to those circumstances in which the COI Committee determines a Management Plan is appropriate).
     5. Noncompliance. Failure of an individual to cooperate with the COI Committee that may result in delay or interfere with the COI Committee’s resolution of a financial COI under its jurisdiction shall be reported to the Vice President for Research for further action consistent with paragraph 7. of the Policy or such other applicable policies of the University, as may exist from time to time.
     6. Appeals. All efforts shall be made to resolve conflicts of interest issues at the COI Committee level. If the COI Committee and an Investigator fail to agree as to whether there is an actual or potential conflict, or fail to agree on a plan of disclosure and management, the final determination shall be made by the Vice President for Research or his/her designee, upon consultation with the COI Committee and the appropriate school dean.
  2. *Departmental Review*
     1. Investigator’s disclosure is routed by COI Office to the department head for input.
        1. Department heads will be asked if the SFI requires management in their opinion, and for an explanation of whether the SFI relates to Research/Sponsored Programs or university responsibilities of the Investigator.
        2. Department heads will be asked for recommended management approaches, if that person believes the outside interest should be managed.
        3. Department heads will have two weeks to provide input and recommendations. If no input is received within the identified timeframe, the disclosure will continue to the COI Committee without a departmental review.
  3. *Administrative Review* 
     1. Effective September 2015, SFI Disclosures may be routed for administrative review to one or more staff in the Office of Research Compliance or IU counsel’s office knowledgeable about financial COI, human subject research, and sponsored program matters (administrative reviewers). Individual members of the Administrative Review Committee may review SFI Disclosures that meet the following criteria:
        1. The related SFI or combination of related SFIs does not exceed $25,000, and
        2. The SFI does not involve a new startup company.

If the Administrative review identifies other issues that should be considered by the full COI Committee, or other concerns or questions arise that the reviewer or reviewers do not believe they are qualified to address, the SFI Disclosure will be reviewed by the full COI Committee with any additional information. The determinations of the Administrative Review will be reported to the full Conflict of Interest Committee.

* 1. *Subcommittees*

Subcommittees of the COI Committee may also be used to review SFI disclosures.

* + 1. Subcommittees may meet in person, via telephone or review and decide via email.
    2. Decisions made by the subcommittees will be submitted to the full COIC for informational purposes.
  1. *Meetings*
     1. Meetings. The Committee shall meet, as needed, throughout the academic year unless a meeting is cancelled by the Co-Chairpersons for good cause. Notice of time and place shall be given at least one week in advance to COI Committee members. The Co-Chairpersons may call a special meeting upon three days written, electronic or telephonic notice.
     2. Minutes. Minutes of each meeting shall be kept by the COI Office. COI Committee members will be provided with the minutes of the last meeting in advance of the next meeting for review, correction and approval.
     3. Quorum. A quorum, which shall consist of a simple majority, is necessary to conduct the business of the COI Committee. In the absence of a quorum, the voting members present at a meeting may review disclosures and recommend COI Committee action, which must be subsequently ratified by a majority of the COI Committee members prior to taking effect. COI Committee member ratification may take place via electronic mail once given the opportunity to review the meeting materials. The action of a quorum of the voting COI Committee members via an electronic mail or telephonic vote on an agenda item shall constitute official COI Committee action on the proposed agenda item.
     4. Expedited Review. When necessary, an expedited review of the COI Committee may be obtained by discussion of the issue among the COI Committee Co-Chairpersons, university counsel and the COI Office. Any action taken upon an expedited review shall be presented to the COI Committee at the next scheduled meeting for ratification. A disclosure may qualify for expedited review by the COI Committee in the following situations:
        1. A legitimate business need or other good cause to review the COI Disclosure prior to the COI Committee’s next scheduled meeting date; and,
        2. The delay in review was not caused by any action of the Investigator requesting expedited review.

* 1. *Participation of Non-Members*
     1. Attendance. No person outside the COI Committee has a right to attend COI Committee meetings, nor shall persons outside the COI Committee be permitted to attend a meeting without the consent of the Co-Chairpersons.
     2. Attendance by Invitation. The COI Committee may invite non-members to attend a COI Committee meeting in order to provide the COI Committee with information that is relevant or necessary for its review and analysis.
     3. Request for Invitation. An Investigator may request to meet with the COI Committee after he or she has received notice of the COI Committee’s preliminary findings. Requests may be made via email or telephone to the COI Office.

## Reporting

* 1. NIH Reporting
     1. Within 60 days of discovery of an FCOI related to PHS-funded research, the COI Office will notify the PHS awarding component of the existence of the FCOI and how it is managed.
     2. Included within the PHS report shall be:
        1. PHS Project number
        2. PI/Contact PI name
        3. Title/Role with respect to research project
        4. Name of Entity in which FCOI is held
        5. Nature of Interest
        6. Amount/Dollar Range
        7. Description of how the FCOI relates to the PHS-funded research and the basis for the Institution’s determination that the SFI should be considered an FCOI
        8. Description of the key elements of the management plan, which may include:
           1. Public disclosure of FCOI in publications and/or presentations
           2. Prohibition of students working for the entity in which the FCOI is present
           3. Safeguarding of intellectual property rights
           4. Limitation on use of university resources
        9. Description of how the management plan is designed to guard objectivity
        10. Confirmation of the investigator’s agreement to the management plan and date
        11. General information as to how the management plan will be monitored
     3. Thereafter, COI Office will provide the PHS with annual reports for any FCOI still being managed.
     4. If an Investigator’s FCOIs change during the course of the year, an updated FCOI report may need to be provided to the PHS awarding component.
  2. Internal Reporting
     1. ORA
        1. A quarterly report of all management plans will be submitted to the Audit Compliance and Effort reporting group. The report shall note which management plans relate to start-up companies.
     2. School/Department
        1. Quarterly reports are provided to schools and departments that detail which faculty have completed their annual COI Disclosure and which have not. Reports may be broken down by department or division by request.

## Retrospective Review

A retrospective review will take place when a PHS-funded Investigator fails to disclose his or her FCOIs within 30 days of a change to the interest or a new interest arising, if an Investigator fails to comply with a management plan or if the University fails to review or manage an FCOI within 60 days of disclosure.

The retrospective review team shall include, at a minimum, a member of the COI Office staff, a COI Committee member and at least one individual with expertise in the area of research in which the Investigator is studying.

The retrospective review may involve the following:

1. Issue an interim management plan
2. Report to the NIH the following information:
   1. Project Number
   2. Project title
   3. PI/Contact PI
   4. Name of entity
   5. Reason for retrospective review
   6. Detailed methodology used for retrospective review
   7. Findings of review
   8. Conclusion of review
   9. Mitigation report which details the effect of bias on the research project, the harm done and whether the project is salvageable.

## Annual Monitoring

* 1. On an annual basis, at least a 10% sampling of active management plans will be taken for the purpose of monitoring.
  2. The COI Office will contact the individual with a research investigator monitoring letter/email.
     1. Response to the letter/email should be received in the COI office within the timeframe specified which shall be no less than four weeks after receipt of the letter.
     2. If no response is received from the initial communication, a follow-up email will be sent.
     3. If no response is received within a reasonable timeframe, the individual’s Dean will be contacted directly.
     4. If there is no response, an interview will be scheduled with the managed Investigator and his/her department chair.
  3. Public databases will be checked to determine if there are publications or talks resulting from the research.
  4. If there were publications or talks made, the COI Office will verify if the appropriate disclosures were made in a sampling of the publication by requesting;
     1. a copy of the disclosure presentation slide, and/or
     2. a copy of the publication with disclosure.
  5. Results of the audit will be reported to the COI Committee for their review.
  6. If the COI Committee believes appropriate disclosures were not made, the COI Office will provide education to the Investigator and will be selected for annual monitoring again the following year. In addition, the COI Office will require the individual to take any additional compliance action as necessary such as notifying journals of the failure to disclose FCOIs.

## Public Access

* 1. Any institution receiving PHS-funded research projects shall ensure public accessibility of information concerning any FCOI disclosed to the institution provided that:
     1. the FCOI is held by the senior or key personnel on the research project;
     2. the institution has determined that the FCOI is related to the PHS-funded research; and,
     3. the institution has determined it to be a FCOI.
  2. Public accessibility requests must be in writing, whether emailed or mailed via US Post, and include
     1. the name of the senior or key personnel;
     2. the title of the PHS-funded research project;
     3. the PHS grant number if possible.
  3. Requests will be answered in the manner they were received within five business days of receipt by the applicable COI Office and shall include the information required to be disclosed per 42 C.F.R. Part 50, Subpart F.
  4. The information provided will be current as of the date of the correspondence. In order to access annual updates or new FCOIs, a new public accessibility request will be required.

## Maintenance Records

Maintenance by the COI Office or its designee of Records, which shall be retained for three years after the latest of: (i) the termination or completion of any contract or award to which they relate (as determined by the funding agency); (ii) termination or completion of the research or educational activity to which the disclosed conflict relates; or, (iii) the resolution of any action involving those Records.

1. **Enforcement**

Instances of noncompliance (including failure to file as required or knowingly filing an incomplete, erroneous, or misleading disclosure form; violation of the standards set forth in these procedures; or failure to comply with prescribed requirements for resolution of conflicts) will be adjudicated in accordance with applicable disciplinary policies of Indiana University. Possible sanctions include, but are not limited to the following:

* 1. All research funding accounts may be suspended;
  2. Formal admonition such as inclusion in the Investigator's file of a letter from the appropriate dean indicating that the Investigator's good standing as a member of the academic community (Investigator, research scientist/scholar, professional staff, student, etc.) has been called into question. Such information can be used, for example, in establishing annual salaries and for decisions on such conditions of employment as promotion and tenure, graduate student support, etc.;
  3. Ineligibility of the Investigator for submitting grant applications, requests for Institutional Review Board (IRB) approval, or supervision of graduate students;
  4. Report to the Research Integrity Officer of possible research misconduct;
  5. Nonrenewal of appointment; or
  6. Initiation of due process for dismissal from the University.

## Effective Dates

These procedures are effective as of February 22, 2013 and remain in effect until further notice. Revisions effective September 1, 2015 incorporate Administrative Review and other technical changes and revisions for clarity.