

---

---

## Financial Conflict of Interest (FCOI) in Research (20-117)

---

---

**APPROVAL:** *Signature on file in the HR office*

**DATE:** August 14, 2012

---

---

### **PURPOSE/SUMMARY**

This General Order is designed to meet the requirements of Code of Federal Regulations, [Title 42, CFR Part 50, Subpart F](#) Promoting Objectivity in Research and [Title 45, CFR Part 94](#) Responsible Prospective Contractors. These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from US Department of Health and Human Services, Public Health Service (PHS) Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts.

Investigators who conduct research or studies regulated/funded by other federal agencies, including the Food & Drug Administration or National Science Foundation, are subject to agency-specific regulations for FCOIs in research (see Sections XI.C and XI.D) and are advised to review such regulations prior to submission of a research application.

### **SCOPE**

This policy applies to all persons at ATSU who meet the following definition of Investigator, and to all ATSU activities meeting the following definition of research where the activity is sponsored or, if non-sponsored, involves human subjects. Investigators must pre-disclose to ATSU's Institutional Official in the Division of Research, Grants, and Information Systems (RGIS) any real or potential financial interest (and those of his/her spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities.

---

---

### **DEFINITIONS**

- A. **Disclosure**—Investigator's disclosure of financial interests to ATSU.
  - B. **Entity**—A non-ATSU organization, whether public or private (e.g., a company, partnership, professional associations, voluntary health organizations, etc.).
  - C. **Financial Conflict of Interest (FCOI)**—A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
  - D. **Financial Interest**—Anything of monetary value, whether or not the value is readily ascertainable.
  - E. **Human Subjects Research**—Research conducted with a living individual about whom an Investigator obtains; data via intervention or interaction with the individual; or identifiable private information.
  - F. **Institutional Responsibilities**—An Investigator's professional responsibilities on behalf of ATSU, which may include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels, such as Institutional Review Board (IRB) or data and safety monitoring boards.
  - G. **Investigator**—The project director or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include subgrantees, contractors, collaborators, or consultants.
- 
-

- H. **Manage**—Take action to address a financial conflict of interest (FCOI), which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias or appearance of bias.
- I. **Research**—A systematic investigation, study, or experiment designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development.
- J. **Senior/Key Personnel**—Project director or PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS.
- K. **Significant Financial Interest (SFI)**
  - 1. Any financial interest of the Investigator (and those of his/her spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities, including:
    - a. **Publicly traded entity**—Value of any remuneration received from an entity in the 12 months preceding the disclosure and value of any equity interest in the entity as of date of disclosure, when aggregated exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
    - b. **Non-publicly traded entity**—Value of any remuneration received from an entity in the 12 months preceding disclosure, when aggregated exceeds \$5,000; or any equity interest (e.g., stock, stock option, or other ownership).
    - c. **Intellectual property rights and interests** (e.g., patents, copyrights, and royalties from such rights)—upon receipt of income related to such rights and interests.
  - 2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of and not reimbursed to Investigator), related to their ATSU responsibilities. However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in the regulation.
  - 3. Significant financial interest excludes:
    - a. salary, royalties, or other remuneration paid by ATSU to the Investigator if the Investigator is currently employed or otherwise appointed by ATSU, including intellectual property rights assigned to ATSU and agreements to share in royalties related to such rights;
    - b. income from investment vehicles (e.g., mutual funds and retirement accounts) as long as the Investigator does not directly control the investment decisions made in these vehicles;
    - c. income from seminars, lectures, teaching engagements, or travel reimbursed or sponsored by excluded sources provided in the regulation; or income from service on advisory committees or review panels for excluded sources provided in the regulation.
- L. **Special project**—Any service, educational, or training initiative pursued by an Investigator that would involve ATSU resources, services, and/or facilities.
- M. **Sponsored travel**—Travel expenses that are paid on behalf of the Investigator and not reimbursed to Investigator so that the exact monetary value may not be readily available.

## OVERVIEW

### I. TRAINING

Investigators must complete and provide evidence of FCOI training prior to engaging in research related to any PHS grant or in human subjects research (sponsored or non-sponsored). To this end, Investigators must certify that they have: 1) reviewed General Order No. 20-117, 2) completed the [NIH FCOI Online Tutorial](#) (Section XI.E) or other relevant training option authorized by the Institutional Official (defined in Section II), and 3) forwarded training certification to RGIS. Training will be overseen by the Institutional Official, and must be updated every four years. Additional training may be required when there is a change in ATSU policy that affects Investigator requirements, an Investigator is new to the University, or in the case of noncompliance.

### II. INSTITUTIONAL OFFICIAL

The highest ranking individual in RGIS responsible for the oversight of research activities at ATSU shall be designated as the Institutional Official. This individual shall solicit and review pre-disclosures of SFIs of the Investigator (and those of the Investigator's spouse and/or dependent children) related to an Investigator's Institutional responsibilities as outlined in the attached FCOI flowchart (Section XI.F).

### III. CONFLICT OF INTEREST REVIEW COMMITTEE

The Institutional Official shall appoint a Conflict of Interest Review Committee (CIRC). Membership shall be comprised of at least the Institutional Official (or his/her designee), general counsel, the director of research support for the respective campus, an IRB member from the respective campus, one faculty member from each ATSU campus, and an at-large community member. The CIRC will be appointed and convened, as needed.

### IV. DISCLOSURE PROCESS

- A. **Before submission/initiation of research**—Prior to the Investigator's submission of a grant application, execution of a cooperative agreement or sponsored research contract, or initiation of any human subjects research (sponsored or not), each Investigator is required to submit a Financial Interest Disclosure Form (Section XI.G) describing any SFIs (and those of Investigator's spouse and dependent children) that reasonably appear to be related to his/her Institutional responsibilities. The process shall include the following:
1. Using ATSU's Grant/Contract Application Approval Form (Section XI.H), each Investigator shall indicate if s/he has any projected or potential SFI relative to the proposed project. If so, the Investigator is required to complete ATSU's Financial Interest Disclosure Form and place in a sealed pre-disclosure packet, containing supporting documentation that identifies the business enterprise or entity involved and the nature and amount of interest. The completed disclosure form and sealed packet should be marked confidential and must be submitted to the Institutional Official, along with copies of the proposal and completed Grant/Contract Approval form. The disclosure packet will be opened only by the Institutional Official.
  2. An Investigator, in his/her own best interest, may choose to pre-disclose any other financial or related interest that could present an actual FCOI or be perceived to present a FCOI. Pre-disclosure is a key factor in protecting an Investigator's reputation and career from potentially embarrassing or harmful allegations of misconduct.
- B. **Annual Updates**—Each Investigator who submits a disclosure form is required to update that disclosure annually during the period of the award, or for non-sponsored research, annually during the conduct of the project period. It is the responsibility of the PI to ensure that each Investigator working on/who will work on the project submits a timely annual update to a previously submitted disclosure form. Annual updates must be submitted to the Institutional Official of RGIS by April 30 of each calendar year, and may require further review/action by the Institutional Official.
- C. **Updating/Submitting a New Disclosure Packet for an Ongoing Project**—Changes to the information provided annually must be submitted within 30 days of discovering or acquiring any new SFI (e.g., creation of a new start-up company, sponsorship of research by a new outside entity, changes in amount of personal financial remuneration from outside entities—such as additional consulting, etc.).

- D. **Subrecipients**—A written agreement must delineate whether subrecipient Investigators must comply with ATSU's FCOI policy or that of their own institution. Such agreements should include a specified time period for meeting disclosure requirements (if applicable) and FCOI reporting requirements to ATSU. Subrecipients following their institution's own FCOI policy must certify in writing that it complies with PHS regulations. During the project period, subrecipient Investigators must submit an updated disclosure of SFI at least annually per the prescribed written agreement. Moreover, each subrecipient Investigator must submit an updated disclosure of SFI within 30 days of discovering or acquiring a new SFI.

## V. REVIEW AND MANAGEMENT PROCESS

- A. **Determination of SFI**—The Institutional Official shall conduct a review of the financial disclosure forms for PHS-funded projects, as well as all research involving human subjects (sponsored and non-sponsored), to determine if any disclosed SFI exists that could affect the design, conduct, or reporting of the proposed research or special project.
1. If no management plan is necessary, the Institutional Official will notify the Investigator who submitted the disclosure, with all related records retained for at least three years after the submission of financial expenditure reports or in the case of non-sponsored research, three years following the end of the project.
  2. If it is determined that there may be a potential FCOI covered by this policy, the Institutional Official will convene a CIRC. The disclosure form, along with the sealed packet, will then be referred to the CIRC for review.
- B. **CIRC Review**—The CIRC will review the disclosure packet. If the CIRC determines that a conflict exists and if the project is initiated or sponsored, then the CIRC shall determine what conditions or restrictions, if any, should be imposed to manage the actual or potential FCOI. The Investigator and CIRC will co-develop a FCOI resolution plan detailing proposed steps to manage, reduce, or eliminate any actual or potential FCOI.
1. No member of the CIRC who holds an SFI in a project may participate in review process.
  2. CIRC meetings are closed to the public.
  3. The CIRC will give primary consideration to the nature of the research, nature/size of the SFI, degree to which the conflict is related to the research, extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict. Ultimately, the plan will be reviewed and approved by the Investigator's immediate supervisor/department chair, and/or dean/director.
  4. **Management strategies** may include, but are not limited to:
    - a. Public disclosure of FCOIs in all presentations and publications, within the informed consent form specific to human research subjects, and via written notification to the research sponsor.
    - b. Appointment of an independent monitor capable of protecting the design, conduct, and reporting of research against bias, or appearance of such from FCOI.
    - c. Modification of research plan and establishment of timetables for project delivery.
    - d. Change of personnel or personnel responsibilities, including potential disqualification of personnel from participation in all or a portion of the research.
    - e. Designation of a colleague or department chair with no FCOI relationship to the research to serve as an academic co-advisor or lead Investigator.
    - f. Reduction or divestiture of the financial interest giving rise to the conflict.
    - g. Severance of relationships that are the source of the FCOI.
    - h. Removing contract terms that create the FCOI in research (e.g., where payment depends on the outcome of the research).
  5. **Specific Provisions for Human Subjects Research**—ATSU will not allow any Investigator with an FCOI to conduct a clinical research project to evaluate the safety or effectiveness of a drug, medical device, or treatment, given that disclosure or standard FCOI management strategies may be inadequate or impossible to implement. This prohibition applies not only to the PI of a clinical research project, but also to any Investigator involved in the design, conduct, or reporting of the research. ATSU may waive this

prohibition only where the Investigator provides a compelling justification. In considering a waiver request, the CIRC will require the Investigator to address:

- a. Nature of research project (i.e., early stage or closer to commercial application);
- b. Size and nature of Investigator's financial interest;
- c. Relationship of financial interest to research;
- d. Extent to which the financial interest may be affected by the research;
- e. Degree of risk to research participants;
- f. Investigator's proposed role in research (i.e., design, selection of participants, administration of informed consent, performance of protocol-mandated clinical procedures, evaluation of effectiveness of drug, device, or treatment, and evaluation of adverse effects);
- g. Existence of unique circumstances that would require research to be performed at ATSU (i.e., unique qualification of Investigator or unique resources of ATSU).

- C. **Memorandum of Understanding (MOU)**—Actual or potential FCOIs will be satisfactorily managed, reduced, or eliminated in accordance with this policy prior to accepting any award or starting non-sponsored research involving human subjects, or will be disclosed to the sponsoring agency for action. The approved resolution plan will be articulated into an MOU detailing conditions or restrictions imposed on the Investigator in conducting the project or in the relationship with the business enterprise or entity. The Institutional Official will produce the MOU for signature by the Investigator. Signed MOU copies will be provided to the Investigator's director/department chair and dean, and in the case of human subjects research, to the relevant IRB.
- D. **Monitoring requirements** will be outlined in the approved management plan and articulated in the MOU with the Investigator(s). Monitoring will be ongoing until the research project is complete.
- E. **Retrospective Review**—Should ATSU identify an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University during the ongoing research project, and where the Institutional Official has determined that the undisclosed SFI constitutes an FCOI related to the research project, a CIRC will be convened and will implement a management plan within 60 days of identification of the SFI. The CIRC also will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's research activities associated with the project to determine whether the research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.
- F. **Ongoing Research**—When an Investigator new to the project discloses an SFI or an existing Investigator discloses a new or changed SFI, wherein the Institutional Official determines that the disclosed SFI constitutes an FCOI subject to management under this policy, a CIRC will be convened and will review the disclosure packet. ATSU will then implement a management plan within 60 days of submission of the disclosure.

Further, ATSU may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date of disclosure and the implementation of the University's management plan. Particular consideration will be given to any additional interim measures that ATSU's IRB deems necessary for the protection of human research subjects.

- G. **Mitigation Plan**—If the CIRC determines during the retrospective review that the research was in any way biased, the CIRC will recommend a mitigation plan to the Institutional Official to address. The Institutional Official will notify the PHS awarding component of its determination and subsequently follow up with the mitigation report for the project.
- H. **Public Accessibility of ATSU's FCOI Policy and Access of Disclosed SFI**—ATSU will post its FCOI policy on the Institution's public web site. Upon request, ATSU will publicly make available information on any disclosed SFI that meets the following three criteria: 1) disclosed SFI is still held by the Senior/Key Personnel of an active PHS project; 2) ATSU determines SFI is related to PHS-funded research; and 3) ATSU determines that the SFI is

an FCOI. Written information requests must be made to the Institutional Official, who will respond within five business days of receipt of request. Disclosed information will include the minimum elements as provided in the regulation. Any newly determined FCOI will be posted to the ATSU web site within 60 days of discovery. The web site will be updated annually and information will remain available for three years from the date the information was most recently updated.

#### **VI. APPEAL**

Appeals regarding decisions made via the FCOI review and management process described herein will be made to the ATSU president whose decision is final.

#### **VII. NONCOMPLIANCE**

Failure to file a complete, truthful disclosure or comply with the conditions or restrictions imposed in the resolution, management, or elimination of FCOIs violates ATSU policy and possibly state and/or Federal law(s). Within 120 days of determination of noncompliance, ATSU will conduct a retrospective review (per Section V.E), and if bias is found, complete a mitigation report, recommending sanctions that may include appropriate disciplinary action. In cases in which the Investigator is noncompliant and found to have biased the design, conduct, or reporting of the research in accordance with the process outlined above, the Institutional Official will promptly notify the PHS awarding component as required by law and describe the corrective measures taken or proposed.

Consequences may include requiring the Investigator to disclose the FCOI in each public presentation of the results of the research and/or to request an addendum to previously published publications. ATSU may also suspend an ongoing research project, halt expenditure of funds, or suspend technology transfer activity to prevent the continued violation of this policy. In cases of noncompliance, ATSU will withdraw any affected application for funding if the project cannot be otherwise completed without the involvement of the Investigator. If the violation results in a collateral proceeding under ATSU's misconduct in science policy (i.e., Order No. 20-113), then the CIRC shall defer a decision on sanctions until the misconduct in science process is completed. The CIRC's recommendations on sanctions shall be presented to the Institutional Official who shall enforce any disciplinary action.

#### **VIII. REPORTING**

ATSU will send initial, annual (ongoing), and any revised FCOI reports (including all required reporting elements) to the designated PHS funding agency for the Institution and its subrecipients, if applicable, as required:

- Prior to expenditure of funds;
- Within 60 days of identification for an Investigator who is newly participating in a project;
- Within 60 days for new, or newly identified, FCOIs for existing Investigators;
- At least annually to provide status of FCOI or any changes to management plan until completion of project;
- Following a retrospective review to update previously submitted report, if appropriate.

Additionally, ATSU will notify the respective PHS agency within 10 business days if bias is found with the design, conduct, or reporting of PHS-funded research including a mitigation report with all elements as required by the regulation.

ATSU will report within 10 business days if an Investigator fails to comply with ATSU's FCOI policy or if the management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.

#### **IX. MAINTENANCE OF RECORDS**

Led by the Institutional Official, the ATSU Division of RGIS shall, with confidentiality, maintain records of all Investigator disclosures of financial interests and ATSU's review of, and response to, such disclosures (whether or not a disclosure resulted in determination of FCOI) and all actions under ATSU's policy or retrospective review, if applicable, for at least three years from the date of submission of the final expenditures report or from other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable. Documents to be retained will include disclosure forms, records, management plans, and CIRC minutes.

#### **X. SIGNIFICANT FINANCIAL INTERESTS HELD BY ATSU OFFICIALS**

ATSU officials with an SFI in an externally-sponsored research project or any project involving the participation of human research subjects may not participate in solicitation, negotiation of contract terms or conditions, oversight of research (unless named as a member of the research team), or management of any FCOI held by members of the research team.

#### **XI. ADDENDA**

- A. [42 CFR Part 50, Subpart F](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f67ea01984581d3934103b5074c05500&rgn=div5&view=text&node=42:1.0.1.4.22&idno=42#42:1.0.1.4.22.6) <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f67ea01984581d3934103b5074c05500&rgn=div5&view=text&node=42:1.0.1.4.22&idno=42#42:1.0.1.4.22.6>
  - B. [45 CFR Part 94](http://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec94-4.pdf) <http://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec94-4.pdf>
  - C. [Food and Drug Administration Regulations](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRSearch.cfm?CFRPart=54&showFR=1) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRSearch.cfm?CFRPart=54&showFR=1>
  - D. [National Science Foundation Regulations](http://nsf.gov/policies/conflicts.jsp) <http://nsf.gov/policies/conflicts.jsp>
  - E. [NIH FCOI Training Tutorial](http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm) <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
  - F. ATSU PHS FCOI Flowchart (Attached)
  - G. ATSU Financial Interest Disclosure Form (Attached)
  - H. ATSU Grant/Contract Application Approval Form (Attached)
  - I. [NIH FCOI Website and Frequently Asked Questions](http://grants.nih.gov/grants/policy/coi/index.htm) <http://grants.nih.gov/grants/policy/coi/index.htm>
- 
- 

#### **RESPONSIBILITY**

ATSU's Institutional Official in the Division of Research, Grants, and Information Systems is responsible for reviewing and updating this policy as needed.