

ATSU POLICY NO. 20-117: FINANCIAL CONFLICT OF INTEREST (FCOI) IN RESEARCH

DATE APPROVED: July 10, 2020

SIGNATURE: *Signature on file in HR*

Purpose/Summary

This general order is designed to meet 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 applying for or receiving research funding from U.S. Department of Health and Human Services, Public Health Service (PHS) Awarding Components, including 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 Food and Drug Administration or National Science Foundation, are subject to agency-specific regulations for FCOIs in research (see Sections XI.B and XI.C) and are advised to review such regulations prior to submission of a research application.

Please also see [ATSU Policy No. 10-212: Conflict of Interest](#).

Scope

This policy applies to all persons at ATSU meeting the following definition of investigator, and to all ATSU activities meeting the following definition of research where activity is sponsored or, if non-sponsored, involves human subjects. This policy also applies to external investigators affiliated with ATSU who do not have a PHS-compliant FCOI policy. Investigators must pre-disclose to ATSU's institutional official in the Division of Research, Grants, & Scholarly Innovations (RGS) any real or potential financial interest (and those of his/her spouse and/or dependent children) reasonably appearing to be related to 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 association, voluntary health organization, etc.).
- C. **Financial conflict of interest (FCOI)** – A significant financial interest that could directly and significantly affect design, conduct, or reporting of PHS-funded research or non-sponsored research involving human subjects.
- 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 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, including Institutional Review Board (IRB) or data and safety monitoring boards.
- G. **Investigator** – Project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for design, conduct, or reporting of research funded by PHS or non-sponsored research involving human subjects; or proposed for such funding, which may include sub-grantees, contractors, collaborators, or consultants.
- H. **Manage** – Take action to address an FCOI, which may include reducing or eliminating FCOI, to ensure, to the extent possible, 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** – PD or PI and any other person identified as senior/key personnel in the grant/research application, progress report, or any other report submitted to PHS.
- K. **Significant financial interest (SFI)**

1. Any financial interest of the investigator (and those of his/her spouse and dependent children) reasonably appearing to be related to the investigator's institutional responsibilities, including:
 - a. **Publicly traded entity** – Value of any remuneration received from an entity in 12 months preceding 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 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 occurrence of any reimbursed or sponsored travel (i.e., 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 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 investigator if 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 investigator does not directly control 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.
 - d. 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 involving ATSU resources, services, and/or facilities.
- M. **Sponsored research or program** – An exchange transaction for any externally or internally funded research or scholarly activity having a defined scope of work and/or set of objectives, which provides a basis for sponsored expectations.
- N. **Sponsored travel** – Travel expenses paid on behalf of investigator and not reimbursed to investigator such 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 they have: 1) reviewed General Order No. 20-117, 2) completed relevant FCOI training option authorized by institutional official and recognized by respective campus IRB, and 3) forwarded training certification to RGS. Training will be overseen by institutional official and must be updated every four years. Additional training will be required when there is a change in ATSU policy affecting investigator requirements, an investigator is new to the University, or in the case of noncompliance.

II. Institutional official

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

III. Conflict of Interest Review Committee

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

IV. Disclosures process

A. Before submission/initiation of research – Prior to 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.F) describing any SFIs (and those of investigator's spouse and dependent children) that appear reasonably related to his/her institutional responsibilities. Process shall include:

1. For sponsored submissions, using ATSU's Grant/Contract Application: Internal Approval Form, each investigator shall indicate if s/he has any projected or potential SFI relative to proposed project. If so, investigator is required to complete ATSU's Financial Interest Disclosure Form and place it in a sealed pre-disclosure packet, containing supporting documentation identifying the business enterprise or entity involved and nature and amount of interest. Completed disclosure form and sealed packet should be marked confidential and must be submitted to institutional official, along with copies of the proposal and completed Grant/Contract: Internal Approval Form. Disclosure packet will be opened only by 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 an 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 disclosure annually during the award period, or for non-sponsored research, annually during conduct of the project. It is the PI's responsibility to ensure 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 institutional official of RGSJ by April 30 each calendar year and may require further review/action by institutional official.

C. Updating/submitting a new disclosure packet for an ongoing project – Changes to 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, including additional consulting, etc.). A disclosure is also required when a new investigator is added to an existing project.

D. External investigators (sub-recipients and contractors) – A written agreement must delineate whether external investigators must comply with ATSU's FCOI policy or their own institution. Such agreements should include a specified time period for meeting disclosure requirements (if applicable) and FCOI reporting requirements to ATSU. External investigators following their institution's own FCOI policy must certify in writing it complies with PHS regulations. During the project period, external investigators must submit an updated disclosure of SFI at least annually per the prescribed written agreement. Moreover, each external 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 – Institutional official shall conduct a review of financial disclosure forms to determine if any disclosed SFI exists that may affect design, conduct, or reporting of proposed research or special project.

1. If no management plan is necessary, institutional official will notify investigator who submitted disclosure, with all related records retained for at least three years from date of submission of final expenditures report or from other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.
2. If it is determined there may be a potential FCOI covered by this policy, institutional official will convene a CIRC. Disclosure form, along with the sealed packet, will then be referred to CIRC for review.

B. CIRC review – CIRC will review disclosure packet. If CIRC determines a conflict exists and if project is initiated or sponsored, then CIRC shall determine what conditions or restrictions, if any, should be imposed to manage actual or potential FCOI. Investigator and CIRC will co-develop an FCOI resolution plan detailing proposed steps to manage, reduce, or eliminate any actual or potential FCOI.

1. No member of CIRC who holds an SFI in a project may participate in the review process.
2. CIRC meetings are closed to the public.

3. CIRC will give primary consideration to nature of the research, nature/size of the SFI, degree to which conflict is related to the research, extent to which the interest could be affected by the research, and any management strategies that may mitigate or eliminate the conflict. Ultimately, the plan will be reviewed and approved by 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 informed consent form specific to human research subjects, and via written notification to 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 financial interest giving rise to the conflict.
 - g. Severance of relationships that are the source of the FCOI.
 - h. Removing contract terms creating FCOI in research (e.g., where payment depends on 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 safety or effectiveness of a drug, medical device, or treatment, given disclosure or standard FCOI management strategies may be inadequate or impossible to implement. This prohibition applies to PI of a clinical research project as well as any investigator involved in design, conduct, or reporting of the research. ATSU may waive this prohibition only where investigator provides a compelling justification. In considering a waiver request, CIRC will require investigator to address:
 - a. Nature of research project (e.g., 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 financial interest may be affected by the research.
 - e. Degree of risk to research participants.
 - f. Investigator's proposed role in research (e.g., 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 requiring research be performed at ATSU (e.g., 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. Approved resolution plan will be articulated into an MOU detailing conditions or restrictions imposed on investigator in conducting the project or in the relationship with the business enterprise or entity. Institutional official will produce MOU for signature by investigator. Signed MOU copies will be provided to investigator's director/department chair and dean, and in the case of human subjects research, to relevant campus IRB.
- D. **Monitoring requirements** will be outlined in approved management plan and articulated in MOU with investigator(s). Monitoring will be ongoing until research project is complete.
- E. **Retrospective review** – Should ATSU identify an SFI 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 institutional official has determined 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 SFI. Within 120 days of its determination of noncompliance, CIRC will complete a retrospective review of investigator's research activities associated with the project to determine whether research conducted during the period of noncompliance was biased in 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 institutional official determines the disclosed SFI constitutes an FCOI subject to management under this policy, a CIRC will be convened and will review disclosure packet. ATSU will then implement a management plan within 60 days of submission of disclosure. Further, ATSU may determine additional interim measures are necessary with regard to investigator's participation in the research project between date of disclosure and implementation of the University's management plan. Particular consideration will be given to any additional interim measures ATSU's IRB deems necessary for protection of human research subjects.
- G. **Mitigation plan** – If CIRC determines during retrospective review the research was in any way biased, CIRC will recommend a mitigation plan to institutional official to address. Institutional official will notify PHS awarding component of its determination and subsequently follow up with 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 website. Upon request, ATSU will make publicly available information on any disclosed SFI meeting these three criteria: 1) Disclosed SFI is still held by senior/key personnel of an active PHS project; 2) ATSU determines SFI is related to PHS-funded research; and 3) ATSU determines SFI is an FCOI. Written information requests must be made to institutional official, who will respond within five business days of receipt of request. Disclosed information will include minimum elements as provided in the regulation. Any newly determined FCOI will be posted to ATSU's website within 60 days of discovery. The website will be updated annually, and information will remain available for three years from date information was most recently updated.

VI. Appeal

Appeals regarding decisions made via 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 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 investigator is noncompliant and found to have biased design, conduct, or reporting of research in accordance with the process outlined above, institutional official will promptly notify the research sponsor as required by law and describe corrective measures taken or proposed.

Consequences may include requiring investigator to disclose FCOI in each public presentation of research results and/or to request an addendum to previous publications. ATSU may also suspend an ongoing research project, halt expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy. In cases of noncompliance, ATSU will withdraw any affected application for funding if project cannot be otherwise completed without involvement of investigator. If violation results in a collateral proceeding under ATSU's misconduct in science policy (i.e., Order No. 20-113), then CIRC shall defer a decision on sanctions until the misconduct in science process is completed. CIRC's recommendations on sanctions shall be presented to 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 designated PHS funding agency for the institution and its sub-recipients, if applicable, as required:

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

Additionally, ATSU will notify respective PHS agency within 10 business days if bias is found with 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 management plan appears to have biased design, conduct, or reporting of PHS-funded research.

IX. Maintenance of records

Led by institutional official, ATSU RGSJ shall, with confidentiality, maintain records of all investigator disclosures of financial interests and ATSU's review of, and response to, such disclosures (whether 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 date of submission of 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 participation of human research subjects may not participate in solicitation, negotiation of contract terms or conditions, oversight of research (unless named as a research team member), or management of any FCOI held by research team members.

XI. ADDENDA

- A. NIH Public Health Service regulations: <https://grants.nih.gov/grants/policy/coi/index.htm>
- B. Food and Drug Administration regulations: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=54&showFR=1>
- C. National Science Foundation regulations: <https://nsf.gov/policies/conflicts.jsp>
- D. ATSU Grant/Contract Application: Internal Approval Form (attached)
- E. ATSU PHS FCOI flowchart (attached)
- F. ATSU Financial Interest Disclosure Form (attached)
- G. NIH frequently asked questions for responsibility of applicants for promoting objectivity in research <https://grants.nih.gov/faqs#/financial-conflict-of-interests.htm>

Responsibility

- A. Institutional official – ATSU's institutional official is responsible for reviewing and updating this policy as needed.
- B. Investigators – ATSU investigators are required to be in compliance with this policy and federal law and regulations as applied to FCOI in research.