



| | |
|-------------------------|---|
| Policy Title | Financial Conflict of Interest for Research Policy |
| Issue Date | May 1, 2025 |
| Effective Date | May 1, 2025 |
| Last Updated / Reviewed | March 3, 2025 |
| Deactivation | NA |
| Responsible Office | Office of Research Integrity |
| Contact Information | Office of Research Integrity Phone: 470-578-4941 Email: resinteg@kennesaw.edu |

1. Policy Purpose Statement

As a recipient of funds from public and private sources to support research activities, Kennesaw State University is required to maintain policies and processes consistent with federal regulations and policies of individual research sponsors concerning financial conflicts of interest (FCOI) in research. These requirements exist to maintain the trust of the public, our research volunteers, and the University community.

2. Background

KSU recognizes and values the importance of researcher relationships with external entities. While such relationships provide benefit and support to our research activities, in some instances such activities give rise to financial conflicts of interest. Conflicts of interest have the potential to influence key elements of a research program, such as study design, data collection and analysis, as well as choice of vendors for research supplies. These conflicts are not inherently bad, nor are they always evidence of bias. However, our role as stewards of research funding requires that we identify and manage such conflicts so as not to put our research, or public confidence in our research, at risk.

Kennesaw State University's policy on financial conflict of interest (hereinafter, the FCOI Policy) conforms to the 2011 revised FCOI regulation from the National Institutes of Health (NIH), [Promoting Objectivity in Research \(42 CFR Part 50 Subpart F\)](#), as well as the National Science Foundation (NSF) [Proposal & Award Policies & Procedures Guide \(Chapter IX.A\)](#).

3. Scope (Who is Affected)

The FCOI Policy applies to each Investigator who is planning to participate in or is participating in research.

4. Exclusions or Exceptions

None

5. Definitions and Acronyms

Investigator: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

Institutional Responsibilities: an Investigator's professional responsibilities on behalf of Kennesaw State University, including, but not limited to, teaching, research, extension/outreach, professional practice, and institutional committee memberships.

Externally Funded Research: research funded by a public or private entity separate from the university through a gift, grant, award, contract, cooperative agreement or similar arrangement and administered through the University or the Office of Sponsored Program Administration.

Significant Financial Interest (SFI): a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, an SFI exists if the sum of any remuneration received from the entity in the twelve (12) months preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, 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;
- With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) of any value; or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose any reimbursed travel or travel paid on behalf of the Investigator (*i.e.*, not reimbursed to the Investigator), related to their KSU responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency; a U.S. Institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S.-based research institute that is affiliated with a U.S. Institution of higher education.
- The following are excluded from the definition of SFI:
 - Salary, royalties, or other remuneration paid by KSU to the Investigator if the Investigator is currently employed or otherwise appointed by KSU;
 - Intellectual Property Rights assigned to KSU or the KSU Research & Service Foundation (KSURSF) and agreements to share in royalties related to such rights;
 - Income or equity interest from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, a U.S. institution of higher education as defined at

20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S.-based research institute that is affiliated with a U.S. institution of higher education; or

- Income from service on advisory committees or review panels for a federal, state or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S.-based research institute that is affiliated with a U.S. institution of higher education.

Financial Conflict of Interest (FCOI): an SFI that could or does directly and significantly affect the design, conduct, or reporting of research, or otherwise reasonably creates the appearance of bias or impartiality in favor of the Investigator's interests.

Sponsor or financially interested company of any research conducted by an Investigator is an entity which

- Funds such research in whole or in part, whether through a gift, contract, or other arrangement
- Supplies devices or other goods that are the subject of such research, or services or other deliverables in connection with the research by a research agreement or otherwise
- Owns, licenses, or has other contractual interest in a technology investigated in the research
- Acts for or on behalf of another entity, directly or indirectly

Public Health Service (PHS) Agencies: includes the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), Agency for Toxic Substances & Disease Registry (ATSDR), Office of Global Affairs (OG), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Planning & Evaluation (ASPE), Office of the Assistant Secretary for Preparedness & Response (ASPR), Office of Public Health and Science (OPHS), Administration on Aging (AoA), Federal Occupational Health (FOH).

- Other sponsors also follow the same policies as PHS agencies. At the time of this writing these include (but may not be limited to) the Alliance for Lupus Research (ALR), the Alpha-1 Foundation, the American Cancer Society (ACS), the American Heart Association (AHA), the American Lung Association (ALA), the Arthritis Foundation (AF), CurePSP, the Juvenile Diabetes Research Foundation (JDRF), the Lupus Foundation of America (LFA), the Patient-Centered Outcome Research Institute (PCORI), Susan G. Komen for the Cure, the Alzheimer's Drug Discovery Foundation (ADDF), the Crohn's and Colitis Foundation (CCF), Johnson & Johnson.

6. Policy (For review and feedback by shared governance groups)

Mandatory Training

Each Investigator must complete FCOI training prior to engaging in research related to any externally funded project and at least once every four years thereafter, and immediately under the following circumstances:

- KSU FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to KSU

- KSU finds an Investigator noncompliant with its FCOI policy or management plan

Current information on the training program can be found at the [Research Integrity FCOI website](#), as well as posted in the FCOI for Research Process document.

Disclosure Procedures

Disclosures are submitted and managed via the [Cayuse Research Suite](#). There are two types of disclosures:

- *Annual Disclosure*: A list of all SFIs that are related to a researcher's job duties and/or expertise
- *Research-Based Disclosure*: A list of SFIs that are relevant to a particular research project (this disclosure form is typically only submitted when requesting funding from the National Science Foundation)

All research-active faculty are expected to file at least one disclosure every 12 months. If there are no SFIs to disclose, researchers are expected to file the disclosure form attesting to the lack of relevant SFIs.

When to disclose:

- **At Time of External Funding Application**
 - Each Investigator, including subrecipient Investigators, if applicable, must do one of the following:
 - Ensure that they have an *Annual Disclosure* of SFIs filed within the last 12 months via the [Cayuse Research Suite](#); or
 - Submit an updated *Research-Based Disclosure* to the Office of Research Integrity via the [Cayuse Research Suite](#) at time of application (required for NSF proposals regardless of annual disclosure status).
- **Annually**
 - Each Investigator must submit a new *Annual Disclosure* of SFI at least annually, to be done via the [Cayuse Research Suite](#).
 - There will be a reminder campaign in January to facilitate timely annual disclosures.
- **At Time of Acquisition**
 - Within 30 days: Each Investigator must submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. The disclosure can be either the Annual or Research-Based form and is submitted via the [Cayuse Research Suite](#).

Review of Disclosure Forms

Upon initial receipt, the Office of Research Integrity will pre-review all disclosure forms. Those which attest no SFIs to disclose will be marked as resolved with no conflicts. Those which include one or more SFIs will be forwarded to the members of the FCOI Committee for their review. The **FCOI Committee** comprises the Vice President for Research, the Associate Vice President for Research Operations, the Associate Vice President for Innovation and Commercialization, and at least two members of the tenured/tenure-track faculty who do not serve in administrative roles. Faculty members will be chosen by the VPR in consultation with College leadership. In addition, the research FCOI Manager (representing the Office of Research Integrity) and a representative from the Office of Legal Affairs will serve in advisory, non-voting roles on the Committee. Committee members may submit comments individually via the Cayuse system, or they may meet (in person, virtually, or hybrid) to discuss the disclosure on an *ad hoc* basis. The Committee will collectively make the decision on whether a FCOI exists. The FCOI Committee may solicit expertise and advice from other individuals

as needed, including but not limited to units on campus (e.g., the Office of Sponsored Programs Administration) or experts from outside the University.

If a meeting of the FCOI Committee is convened, the Committee shall designate from among its membership in attendance a chair, who shall oversee the meeting and, with input as needed from advisory members in attendance, resolve any substantive or procedural matters. The chair shall also be responsible for authoring the Committee's findings. Quorum shall be 3 voting members, and any ties in committee votes will be decided by the Vice President for Research.

If a member of the FCOI Committee is the disclosee, or otherwise has a conflict of interest due to personal or professional connection to the disclosee, then they will recuse themselves from the relevant reviews and discussions. The conflicted member shall be temporarily replaced for discussion and decision on that particular issue by an *ad hoc* alternate selected with the approval of the Vice President for Research.

An Investigator's SFI is *related to research* when the KSU FCOI Committee reasonably determines that the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. KSU may involve the Investigator in the FCOI Committee's determination of whether an SFI is related to the research.

A *financial conflict of interest (FCOI)* exists when the KSU FCOI Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research, or otherwise reasonably creates the appearance of bias or impartiality in favor of the Investigator's interests.

Management of FCOIs

Where an FCOI has been identified, the Office of Research Integrity (with assistance from the FCOI Committee as needed) will work with the Investigator to develop a resolution plan to manage, reduce, or eliminate any actual or potential FCOI presented by an SFI. Possible approaches include, but are not limited to, the following:

- Public disclosure of SFIs
- Appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI
- Modification of the research plan
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the related project or research
- Reduction or elimination of the SFI (e.g., sale of an equity interest)
- Severance of relationships that create actual or potential financial conflicts

Whenever KSU identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University, within 60 days the Office of Research Integrity and/or the FCOI Committee will: review the SFI; determine whether it is related to the Investigator's institutional responsibilities; determine whether a FCOI exists; and, if so:

- Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI going forward.
- Within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If necessary, KSU will notify any sponsoring agency or institution, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, KSU is

required to notify the sponsor promptly. KSU may determine that additional interim measures are necessary.

The Office of Research Integrity will monitor compliance with the agreed-upon management plan, including periodic (e.g., quarterly) communications with any independent oversight monitors or others with knowledge of the SFI and the mitigation plan.

Resolution of FCOI Disputes

Any dispute, controversy, sanction, or appeal in relation to disclosure, management, or elimination of financial conflicts of interest shall be submitted in writing to the Office of Research Integrity no later than 30 days following the action/inaction/decision alleged to be improper, and thereafter resolved by the FCOI Committee, which shall convene in the same matter as set forth above. The Committee's decision shall be considered final subject to review and modification by the Provost, President, and the University System of Georgia Board of Regents.

Reporting of FCOIs

Public Health Service (PHS)-funded Research

In the event an investigator has a FCOI related to PHS funding, KSU is required to file certain reports to the PHS funding agency. These reports are completed by staff in the Office of Research, and do not need to be completed by the investigator. Reports are triggered in the following circumstances.

- **Identification of an FCOI:** Prior to KSU's expenditure of any funds under a PHS-funded research project, KSU is required to provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by the University to be conflicting and ensure that KSU has implemented a management plan in accordance with the FCOI policy. This report must be filed within 60 days and include the following:
 - Project number
 - Name of Principal Investigator or Project Director
 - Name of the investigator with a conflict
 - Nature of the financial interest (e.g., equity, consulting income, honorarium)
 - Value of the financial interest in dollar ranges (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000)
 - A description of how the financial interest relates to the PHS-funded research and the basis for KSU's determination that the financial interest conflicts with such research
 - A description of the key elements of the Institution's management plan
- **Annual Report:** For any FCOI previously reported by KSU with regard to an ongoing PHS-funded research project, the University shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. KSU must provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
- **Late Certification or Review:** For any SFI that KSU identifies as conflicting subsequent to its initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), within 60 days KSU must provide to the

PHS Awarding Component an FCOI report regarding the FCOI and ensure that KSU has implemented an FCOI management plan.

- Retrospective Review: If the FCOI report involves an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed, KSU must complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, KSU is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Pursuant to PHS FCOI regulations, prior to spending any funds under a PHS funded research project, KSU will ensure public accessibility, via written response to any requestor within five business days, of information concerning any SFI disclosed to the University that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel
2. KSU determines that the SFI is related to the PHS-funded research
3. KSU determines that the SFI is a FCOI.

The information that must be made available regarding a determined FCOI includes

- Investigator's name
- Investigator's title and role with respect to the research
- Name of the entity in which the SFI is held
- Nature of the SFI
- The approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

National Science Foundation (NSF)-funded Research

NSF requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest. Guidance for such policies has been issued by university associations and scientific societies.

An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all SFIs of the investigator (including those of the investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

An institutional policy must ensure that investigators have provided all required financial disclosures at the time the proposal is submitted to NSF. It must also require that those financial disclosures are updated during the period of the award, either on an annual basis, or as new reportable SFIs are obtained.

An institutional policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

KSU is required to notify the NSF Office of the General Counsel if the institution finds that it is unable to satisfactorily manage a conflict of interest.

Subrecipient Monitoring

When KSU carries out any externally funded research through a subrecipient, the University will take reasonable steps to ensure that any subrecipient Investigator complies with applicable FCOI regulations by:

1. Incorporating terms as part of a written agreement with the subrecipient that establish whether KSU's FCOI policy or the subrecipient's policy will apply to the subrecipient's Investigators.
2. If the subrecipient's Investigators are to comply with the subrecipient's FCOI policy, the subrecipient must certify that its policy complies with any sponsor-imposed FCOI regulations and the agreement will specify the time period(s) for the subrecipient to report all identified FCOIs to KSU. If the subrecipient cannot provide such certification, its Investigators must comply with KSU's FCOI policy.
3. If the subrecipient's Investigators are to comply with KSU's FCOI policy, the agreement will specify the time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to KSU.

7. Associated Policies/Regulations (Enter NA if not applicable)

- a. National Institutes of Health (NIH), [Promoting Objectivity in Research \(42 CFR Part 50 Subpart F\)](#)
- b. National Science Foundation (NSF) [Proposal & Award Policies & Procedures Guide \(Chapter IX.A\)](#)
- c. University System of Georgia Conflict of Interest Policy
- d. [KSU Conflict of Interest Resources](#)

8. Procedures Associated with this Policy (Enter NA if not applicable)

- a. Required Training (see <https://www.kennesaw.edu/research/resources/research-integrity/conflict-interest.php>)
- b. FCOI Verification & Reminder Process (most up to date procedure available at <https://www.kennesaw.edu/research/resources/research-integrity/conflict-interest.php>)
- c. International Activities & Required Disclosures (most up to date procedure available at <https://www.kennesaw.edu/research/resources/research-integrity/conflict-interest.php>)

9. Forms Associated with this Policy (Enter NA if not applicable)

- a. Cayuse Outside Interests Annual Disclosure online form (<https://kennesaw.app.cayuse.com/>)
- b. Cayuse Outside Interests Research-based Disclosure online form (<https://kennesaw.app.cayuse.com/>)

10. Violations (Enter NA if not applicable)

The Office of Research Integrity will monitor for compliance with this Policy and any Management Plans.

Violators of this policy as determined by the Vice President for Research and/or the FCOI Committee may be subject to institutional sanctions up to and including termination of appointment. No penalty

involving dismissal from the University or other serious sanction may become effective except in accordance with the provisions of the [University Handbook](#), Employee Handbook, Faculty Handbook and/or College and Departmental bylaws, depending on an Investigator's position at KSU.

11. Review Schedule

The Office of Research Integrity will review the Financial Conflict of Interest for Research Policy on a biannual basis.

12. Review History

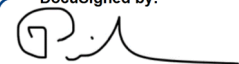
Initial Approval April 14, 2025

At Kennesaw State University, institutional policies that have undergone the established shared governance review and feedback process are presented to the President and Provost for final approval. The signatures below indicate this institutional policy has been reviewed and approved by the President and Provost.

DocuSigned by:

11EA3F49C7FD4B9... April 15, 2025

Dr. Kathy S. Schwaig
President
Kennesaw State University

DocuSigned by:

26412C41D0DE4E2... April 15, 2025

Dr. Ivan Pulinkala
Provost and Executive Vice President for
Academic Affairs
Kennesaw State University