



Policy Title	Financial Conflict of Interest Policy for Research
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Responsible Office	Office of Research Compliance
Contact Information	Office of Research Compliance Email: researchcomp@kennesaw.edu Phone: 470-578-4941

Introduction

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 in research. These requirements exist to maintain the trust of the public, our research volunteers, and the University community.

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 NIH, [Promoting Objectivity in Research \(42 CFR Part 50 Subpart F\)](#), as well as the National Science Foundation [Grant Policy Manual \(Section 510\)](#).

The FCOI Policy applies to each Investigator who is planning to participate in or is participating in research, whether or not such research is federally funded.

Definitions

1. **Investigator** means 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.
2. **Institutional Responsibilities** means 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.
3. **Externally Funded Research** is 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 Programs.
4. **Significant Financial Interest (SFI)** means 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, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and 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, a significant financial interest 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); 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 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.
5. **Financial Conflict of Interest (FCOI)** means an SFI that could directly and significantly affect the design, conduct, or reporting of research.
6. **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
7. **Public Health Service (PHS) Agencies** include 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 policy 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.

Mandatory Training

Each investigator must complete FCOI training prior to engaging in research related to any externally funded project and at least every four years, 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

Our current training program is offered through the Collaborative Institutional Training Institute (CITI). Investigators must complete the CITI Conflict of Interest module. Researchers need to register for an account with [CITI](#), or log in with an existing account. Instructions for registering, adding an affiliation with KSU, and adding the COI module are available from the Research Compliance website. There are three required modules and one optional module:

- Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (15070)

- Institutional Responsibilities as They Affect Investigators (15072)
- Conflicts of Commitment and Conscience (15073)
- Institutional Conflicts of Interest (16765) (Optional)

CITI COI training is valid for four years, and then must be refreshed. The current refresher modules include:

- Conflicts of Interest and the PHS Regulations (16950)
- Significant Financial Interests (16951)
- Institutional Obligations As They Affect Investigators (16952)
- COI Management Plans and Noncompliance (16953)

Disclosure Procedures

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 SFI filed within the last 12 months via the [Cayuse Research Suite](#); or
 - Submit an updated Research-Based Disclosure to the Office of Research Compliance via the [Cayuse Research Suite](#) at time of application (required for NSF proposals regardless of annual disclosure status).

Annually

- Each Investigator must submit an updated disclosure of SFI at least annually, to be done via the [Cayuse Research Suite](#).

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.

Review of Disclosure Forms

The Director of Research Compliance will review all disclosure forms and consult with the Vice President for Research (VPR) and Associate Vice President for Research (AVPR), acting as the Financial Conflict of Interest Committee (FCOI Committee). This committee will make the decision on whether a financial conflict of interest exists. The FCOI Committee may solicit expertise and advice from other individuals as needed.

An Investigator's significant financial interest is related to research when the KSU FCOI Committee reasonably determines that the significant financial interest 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 a significant financial interest is related to the research.

A financial conflict of interest (FCOI) exists when the KSU FCOI Committee reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

Management of COIs

Where an FCOI has been identified, the Office of Research Compliance and/or the FCOI Committee will work with the employee to develop a resolution plan to manage, reduce, or eliminate any actual or potential financial conflict of interest presented by a significant financial interest. Possible approaches include, but are not limited to the following:

- Public disclosure of significant financial interests
- Appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- 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 significant financial interest (e.g., sale of an equity interest)
- Severance of relationships that create actual or potential financial conflicts

Whenever KSU identifies a significant financial interest 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 Compliance and/or FCOI Committee will: review the significant financial interest; determine whether it is related to the Investigator's institutional responsibilities; determine whether a financial conflict of interest 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 financial conflict of interest 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 financial conflict of interest going forward. If bias is found, KSU is required to notify the sponsor promptly. KSU may determine that additional interim measures are necessary.

Resolution of FCOI Disputes

Any dispute, controversy, sanction, or appeal in relation to disclosure, management or elimination of financial conflicts of interest shall be resolved by the Vice President for Research or the FCOI Committee. The VPR/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.

Violations

Violators of this policy as determined by the VPR 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 [Faculty Handbook](#) and/or College and Departmental bylaws.

Reporting of FCOIs

Public Health Service (PHS)-funded Research

In the event an investigator has a financial conflict of interest related to PHS funding, KSU is required to file certain reports to the PHS funding agency. These reports are completed by the staff of 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 significant financial interest 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 financial conflict of interest 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 financial conflict of interest 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 significant financial interest 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 financial conflict of interest and ensure that KSU has implemented an FCOI management plan.
- **Retrospective Review:** If the FCOI report involves a significant financial interest 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 financial conflict of interest 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 significant financial interest disclosed to the University that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by the senior/key personnel
2. KSU determines that the significant financial interest is related to the PHS-funded research
3. KSU determines that the significant financial interest is a financial conflict of interest.

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 significant financial interest (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 significant financial interests 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 significant financial interests 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 a

significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

KSU is required to notify the NSF's Office of the General Counsel if the institution finds that it is unable to satisfactorily manage a conflict of interest. FCOIs that cannot be managed, reduced, or eliminated must be submitted electronically via the NSF FastLane system.

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 significant financial interests to KSU.