

Financial Conflicts of Interest in Federally Funded Research (CAES FCOI Policy)

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| Policy Name: | Managing Financial Conflicts of Interest in Federally Funded Research (CAES FCOI Policy) |
| Policy Owner: | The Connecticut Agricultural Experiment Station |
| Applies to: | All CAES staff undertaking PHS-funded research in an investigator or key personnel capacity |
| Effective Date: | April 1, 2021 |
| For More Information, Contact | Michael Last, CAES FCOI Officer |
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| Official Website: | https://portal.ct.gov/CAES |

1. BACKGROUND

Investigators at the The Connecticut Agricultural Experiment Station (CAES) promote the research mission of CAES relating to the discovery and dissemination of knowledge that emerges from that research. The station’s motto is “putting science to work for society”. Basic and applied research and participation in activities of professional associations, industry collaborations, and other public and private entities can assist in advancing science and serving the residents of Connecticut. In addition, such participation brings enhanced national and international recognition to CAES and the State.

CAES continues to engage in research and service activities that result in benefits to science and grow our local economy. The State of Connecticut has determined that the research pursued is critical to Connecticut’s long-term economic growth. However, it is vital that Investigators adhere to state and federal regulations dealing with avoiding and managing potential and existing conflicts of interest. In order for CAES to maintain public trust and support in carrying out its mission, including all sponsored activities, CAES must demonstrate that it subjects itself to the highest standards of ethical behavior.

2. PURPOSE

This Policy on Financial Conflicts of Interest in Research (Policy) provides guidelines to promote objectivity in research. The Policy establishes standards to ensure that the design, conduct, and reporting of research funded by extramural sponsors will not be biased by any conflicting financial interest of an Investigator. CAES encourages Investigators to engage in appropriate outside relationships, but significant financial interests related to these relationships need to be disclosed, reviewed, and managed in accordance with this Policy.

3. APPLICABLE FEDERAL REGULATIONS

The following federal regulations inform this policy:

Public Health Service (PHS)

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

National Science Foundation (NSF)

http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp

Food and Drug Administration (FDA) <https://www.fda.gov/RegulatoryInformation/>

In summary, the federal policies and regulations stipulate:

- a. Disclosures of significant financial interests by ALL Investigators;
- b. Institutional certification that all proposed and ongoing sponsored research is either free of financial conflicts of interest, or that such conflicts are managed, reduced or eliminated, and reported as required by applicable regulations;
- c. The implementation of an institutional mechanism for managing financial conflicts of interest in research;
- d. Notification of sponsors, as required, of management plans and if the CAES is unable to manage financial conflicts of interest satisfactorily;
- e. Monitoring of compliance, procedures for retroactive review in cases of non-compliance, enforcement mechanisms, and sanctions where appropriate;
- f. Maintenance of records relating to this policy for at least three years following the termination of a given project; and,
- g. Providing information and training to Investigators, as required by applicable regulations.

4. DEFINITIONS

Business means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.

Financial Conflict of Interest (FCOI) means a situation in which significant financial interests in a business, or other personal considerations provided by a business, may compromise, or have the appearance of compromising, an Investigator's professional judgment in conducting or reporting research, the results of which could affect the aforementioned business, either directly or indirectly. An FCOI exists when CAES, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a research project and could directly and significantly affect the design, conduct or reporting of the research.

Immediate Family means the Investigator's spouse and dependent children.

Institutional Responsibilities are an Investigator's professional responsibilities on behalf of CAES, which include research, teaching, and service as, e.g., outlined in the Code of Ethics Policy ([Code of Ethics \(ct.gov\)](#)).

Intellectual Property means a product of the intellect that has commercial value, including copyrighted works, patents, business methods, and industrial processes.

Investigator means the principal investigator and any other person (regardless of title or position) who is responsible for the design, conduct or reporting of research or educational activities. This may include faculty and research staff (research associates and assistants, postdoctoral fellows, graduate students, visiting scientists engaged in research conducted at CAES) as well as consultants.

Research (PHS regulation 45 CFR 46.102(d)) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this Policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

Significant Financial Interest (SF

1. *Significant Financial Interest* means:

For PHS and all sponsors that follow the 2011 PHS FCOI Regulations

With regard to any **publicly traded entity**, an SFI exists if the value of any **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) received from the entity in the twelve 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**; or With regard to any **non-publicly traded entity**, an SFI exists if the value of any **remuneration** received from the entity in the twelve months **preceding** the disclosure, when aggregated, exceeds **\$5,000**, or when the Investigator (or the Investigator's Immediate Family) 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.

For NSF and all other sponsors:

An **equity interest** that when aggregated for the Investigator and the Investigator's Immediate Family exceeded **\$5,000** over the **last 12 months**, and/or is expected to exceed **\$5,000** in value over the **next 12 months** as determined through reference to public prices or other reasonable measures of fair market value; or when the Investigator (or the Investigator's Immediate Family) holds a 5% or greater equity interest (e.g., partnership, ownership, stock, stock option, or other ownership interest) in a single publicly traded entity or holds any equity interest in a non-publicly traded entity; or **Salary, royalties or other payments** not from the CAES for services (e.g., consulting fees or honoraria) that when aggregated for the Investigator and the Immediate Family over the **last 12 months** exceeded **\$5,000** or are expected to exceed **\$5,000** over the **next 12 months**;

2. In addition, the following needs to be disclosed for **Clinical Investigations** covered by FDA regulations:

- a. Compensation made to the Investigator in which the value of compensation could be affected by the outcome of the study/research project.
 - b. A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement.
 - c. Significant payments of other sorts, which are payments that have a cumulative monetary value of \$25,000 or more made by the sponsor of a covered study to the investigator or the investigators' institution to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for one year following completion of the study.
3. The term *Significant Financial Interest* **does not** include the following types of financial interests:
- a. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the CAES, including intellectual property rights assigned to CAES and agreements to share in royalties related to such rights;
 - b. 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;
 - c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
 - d. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
 - e. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Sponsor means an individual company, or any entity which takes responsibility for the initiation, management, and/or financing of a research project, but which does not actually conduct the investigation.

5. PROCEDURES

I. Notification

A copy of this policy will be sent to all current Investigators and will be provided to all new Investigators upon hire. The policy is also available on CAES website under "CAES Policies."

II. Training

All PHS-funded Investigators must complete training prior to engaging in PHS-funded research and at least every four years thereafter as well as under the following circumstances (in the timeframes noted in parentheses) on the NIH website tutorials below. Copies of Certificates of completion should be provided to the FCOI Officer. Reading the CAES FCOI Policy in its entirety, signing the Declaration (Appendix A) and providing a copy of the Declaration to the FCOI Officer:

- a. CAES's Financial Conflict of Interest policy changes such that Investigator requirements are affected (within 60 days).
- b. An Investigator is new to CAES (prior to engaging in PHS-funded research).

c. CAES finds that an Investigator is not in compliance with the Policy or a management plan, as applicable.

The NIH FCOI tutorial is available here:

<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

https://grants.nih.gov/grants/policy/coi/tutorial2011/Financial_Conflict_Of_Interest-FCOI.pdf (pdf format)

III. Disclosure of Significant Financial Interests

Each Investigator must disclose his/her known SFIs (including those of the Investigator's Immediate Family) that reasonably appear to be related to the Investigator's Institutional Responsibilities, or that would reasonably appear to be affected by the research for which funding is sought or are in entities whose financial interests would reasonably be affected by the research. In determining whether a financial interest has to be disclosed, the Investigator shall consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure.

1. *Disclosure for each Proposal Submission:* At the time of submission of a new proposal, an Investigator must have completed their financial disclosure. CAES will not submit a proposal until such disclosure has been submitted.
2. *Changes in SFI:* An updated disclosure shall be completed and filed within thirty (30) days at any time when an Investigator acquires or discovers a new reportable SFI not disclosed in the last disclosure. For existing Investigators on a project, new or newly identified SFIs will be reviewed promptly to determine if an FCOI exists, create a management plan if necessary and report the newly identified FCOI to the sponsor within 60 days if required.
3. *New Investigators:* If research is ongoing and an Investigator newly participating in the project discloses an SFI related to that research, those SFIs will be reviewed promptly to determine if an FCOI exists, create a management plan if necessary and report the newly identified FCOI to the sponsor within 60 days if required.

IV. Determination, Resolution, and Management of a Conflict of Interest

1. The FCOI OFFICER will review SFI Disclosure Forms and, if an SFI is disclosed, the Investigator will be required to complete a *Supplemental Information Request to Significant Financial Interest Disclosure*. The FCOI OFFICER or his/her delegate performs an initial administrative review and refers all disclosed SFIs to the Financial Conflict of Interest in Research Committee.
2. The Financial Conflict of Interest in Research Committee (FCOIRC) is appointed by the FCOI OFFICER and serves as the resource with respect to the determination of relatedness of SFIs and the identification and management of COIs.
3. The FCOIRC, with the help of the Investigator and/or his/her department head and based on guidelines consistent with all applicable regulations, will determine if the SFI is related to a sponsored research project and, if so related, whether the SFI constitutes a financial conflict of interest (FCOI).
4. If the FCOIRC identifies an FCOI, it will resolve the conflict by elimination, mitigation, or the creation of a management plan. The Investigator has to agree in writing to the conditions listed in such management plan. The following are examples of conditions that may be imposed:
Public disclosure of SFIs, including disclosure on manuscripts submitted for publication, on abstracts and posters submitted for presentation, and on informed consent documents;
 - a. Monitoring of the research by independent reviewers;
 - b. Modification of the research;

- c. Disqualification from participation in all or a portion of the activities that could be affected by the FCOI;
 - d. Divestiture or reduction of the SFI;
 - e. Severance of relationships that create actual or potential conflicts.
5. An FCOI must be eliminated or a management plan agreed to before a related award will be set up. Neither the institution nor an Investigator may expend funds unless it has been determined that no FCOI exists or that the FCOI is manageable in accordance with the terms of a management plan.

V. Notification/Reporting

If an FCOI is identified, the FCOI Officer is responsible for:

1. Notification of the Investigator of the management plan designed by the Committee for his/her FCOI;
2. Notification of the Department Head to assure that no spending of funds from related grants occurs without prior approval of the FCOI Officer.
3. Notification of research sponsors, as required, of any FCOIs, including any measures taken to reduce, manage, or eliminate such conflicts. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations.

Reasonable efforts will be made to maintain the privacy of information gathered in the FCOI Officer's deliberations, within the limits imposed by applicable laws and regulations.

VI. Maintenance of Records

All records related to the implementation of this policy (e.g., *Individual Financial Disclosure Forms*, *Supplemental Information Forms*, notifications to funding agencies, actions taken to resolve or mitigate FCOIs, etc.) will be maintained securely by the FCOI OFFICER for a period of at least three (3) years beyond the termination or completion of the sponsored award to which they relate, or until the resolution of any action involving those records, whichever is longer. FCOI records shall be subject to periodic review for compliance with this policy by the FCOI OFFICER or by any agency per applicable regulations.

VII. Subrecipients

If a subrecipient carries out a portion of the work, CAES shall take reasonable steps to ensure that any subrecipient and subrecipient Investigator complies with the applicable FCOI regulation.

CAES will establish, via a written agreement, the governing FCOI policy.

1. Sub-recipient will certify that its FCOI policy complies with the respective regulations and, further, sub-recipient will report identified FCOIs for its investigators in a time frame that allows CAES to report identified FCOIs to the awarding agency.
2. Alternatively, if a sub-recipient lacks a compliant FCOI policy, the subrecipient will be governed by the CAES's FCOI policy; CAES will solicit and review sub-recipient Investigator disclosures and identify, manage and report FCOIs to the sponsor.

In the event that a sub-recipient notifies CAES of an FCOI for sub-recipient Investigators for which CAES is the prime awardee, CAES will promptly notify the sponsor.

VIII. Public Accessibility

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the FCOI OFFICER shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning an SFI which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related

to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the FCOI Regulations.

IX. Monitoring Compliance /Mitigation

1. The FCOI OFFICER will monitor for compliance with the policy.
2. If the FCOI OFFICER learns of an SFI that was not timely disclosed or was not timely reviewed, the FCOI OFFICER, or his/her delegate, shall, in consultation with the FCOIRC and no later than the sixtieth (60th) day after learning of the SFI:
 - a. determine whether the SFI is an FCOI; and
 - b. if an FCOI exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.
3. If an FCOI was not timely identified or managed or if an Investigator fails to comply with a management plan, the FCOI OFFICER shall no later than the 120th day after determining noncompliance:
 - a. complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
 - b. implement any measures necessary with regard to Investigator's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.
4. For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the Financial Conflict of Interest Report, notifying the PHS awarding component, and submitting a mitigation report as required by federal regulation.
5. CAES will notify the PHS of instances in which the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of funded research. The CAES will make information available to HHS or the PHS awarding component as required by federal regulation.

X. Appeals

1. In situations where an Investigator disputes the decision of the FCOIRC, the Investigator may request to present the case to the FCOIRC in person. An Investigator who disagrees with the FCOIRC's determination may appeal in writing to the FCOI OFFICER. An appeal may be made in regard to whether the professional judgment of the Investigator is likely to affect his or her conduct of research, but Investigators may not contest the terms and conditions of this.
2. The FCOI OFFICER may agree with the FCOIRC's findings and/or recommendations, or may amend such findings and/or recommendations. The FCOI OFFICER shall promptly notify the Investigator and the FCOIRC in writing of the conclusions of his/her review, including the actions that must be taken by the Investigator to comply with this policy.
3. Upon receipt of the FCOI OFFICER's written report, the Investigator must promptly comply with the actions specified in that report.

XI. IMPLEMENTATION AND ENFORCEMENT

The FCOI Officer is the senior administrator of the implementation of this Policy. The FCOI Officer has delegated the disclosure/review/management process to the Director or his/her designee (FCOI OFFICER). The FCOI OFFICER, in consultation with the Director and the Investigator(s) Department Head, will review all breaches of the policy, including:

- a. failure to comply with the process (by refusal to respond, by responding with incomplete or knowingly inaccurate information, or otherwise);

- b. failure to remedy conflicts; and
- c. failure to comply with a prescribed management plan

Sanctions and penalties for those who knowingly and willfully disregard this policy, or refuse to comply with its terms, will be determined by the FCOI OFFICER, in consultation with the Director with advice from the Investigator(s) Department Head. Sanctions include, but are not restricted to:

- Letter of reprimand
- Notification to professional and/or scientific societies, funding agencies and/or professional journals
- Reassignment of duties
- Termination of grant support
- Adjustment of research space allocation
- Adjustment of salary
- Suspension
- Dismissal

Appendix A: CAES FCOI Policy Declaration

Please review The Connecticut Agricultural Experiment Station (CAES) policy on Managing Financial Conflicts of Interest in Federally Funded Research (CAES FCOI Policy) and sign and date the declaration below to indicate that you understand your responsibilities as an investigator/key personnel in PHS-funded research.

I have read the CAES FCOI Policy and understand the definition of Significant Financial Interest (SFI) and how it applies to me and my family.

I will promptly and fully disclose any Significant Financial Interest (including those of a spouse or dependent child) that reasonably relate to my PHS-funded research at CAES and, if applicable, will comply with any financial conflict of interest management or mitigation plans.

I will submit in writing to the CAES FOCI Officer annually, and within 30 days of discovering or acquiring a new significant financial interest.

I will undertake CAES FCOI training:

- Prior to engaging in PHS-funded research;
- At least every 4 years thereafter; and
- Whenever directed to do so by the CAES FCOI Officer

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| Signed: | |
| Print name: | |
| Job title: | |
| Role in PHS-funded research: | |
| Date: | |