

CONFLICT OF INTEREST POLICY FOR RESEARCH AND SPONSORED PROGRAMS - St. Cloud State University



“The public trust in what we do is just essential and we cannot afford to take any chances with the integrity of the research process.” Dr. Francis Collins, Director, National Institutes of Health

I. PURPOSE

Research objectivity is crucial and is the basis for obtaining and maintaining public trust in the research process. United States Department of Health and Human Services regulations are designed to promote objectivity in research by establishing standards which provide a reasonable expectation that the design, conduct and reporting of federally funded research will be free from bias resulting from investigator financial conflicts of interest (42 CFR Part 50, Subpart F).

II. DEFINITIONS

- **Conflict of interest** exists when personal, professional, financial or other private interests of a person or institution compromise, have the potential to compromise, or may be perceived to compromise, the exercise of professional judgment or obligations.
- **Financial conflict of interest** is any financial interest or a significant financial interest which could directly and significantly affect the design, conduct or reporting of externally funded research.
- **Institution** means St. Cloud State University.
- **Investigator** includes the project director, principal investigator or any other person, regardless of title or position (whether they are faculty, staff, collaborators, consultants, post-doctoral fellows, graduate students, etc.), who is responsible for the design, conduct or reporting of research funded or proposed for funding.
- **Investigator institutional responsibilities** include activities such as research, research consultation, teaching, professional practice, institutional committee membership, serving on panels, etc. performed on behalf of the institution.
- **Public Health Service agencies** means any component of the U.S. Public Health Service, including 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 and Medicaid Services (CMS), Administration for Children and Families (ACF), and the Administration on Aging (AOA).
- **Significant financial interest** has a monetary value, whether or not the value is readily ascertainable, to the investigator or his/her spouse, domestic partner or dependent children related to the investigator’s institutional responsibilities.

III. DISCLOSURE REQUIREMENTS

Investigators are required to disclose to the institution the following interests before or when applying for external research funding:

- Salary and any payment for services (consulting fees, honoraria, paid authorship, etc.) from a public or non-public traded entity exceeding \$5,000 in the twelve months preceding the disclosure
- Equity interest (stock, stock options or other ownership interest) in a publicly traded entity exceeding \$5,000 as of the date of the disclosure
- Any equity interest (stock, stock options or other ownership interest) in a non-publicly traded entity
- Salary, payment for services or equity interest aggregated which exceeds \$5,000
- Income related to intellectual property rights and interests (patents, copyrights, etc.) paid by any source other than the institution
- Any reimbursed or sponsored travel paid by an external entity, including non-profit organizations, related to his/her institutional responsibilities. Disclosure does not apply to travel reimbursed or sponsored by a federal, state or local government, a United States institution of higher education or its affiliated research institute, a medical center or an academic teaching hospital.

Investigator significant financial interests do not include:

- Salaries, royalties or other remuneration paid to the investigator by St. Cloud State University.
- Investment income from mutual funds or retirement accounts if the investigator does not control the investment decisions.
- Any reimbursed or sponsored travel paid by a federal, state or local government, a United States institution of higher education or its affiliated research institute, a medical center or an academic teaching hospital.
- Phase I Small Business Innovation Research (SBIR) Program or Small Business Technology Transfer (STTR) Program applications or awards.

Investigators must report to the university the existence of any financial conflict of interest before or at the time of application for external research funding. Investigators must update annually and within 30 days of acquiring or discovering (through purchase, marriage, inheritance, etc.) a new financial interest during the period covered by the grant or contract. Initial reporting will be facilitated by identifying a possible financial conflict of interest on the institution's transmittal form. The Office of Research and Sponsored Programs would then contact the investigator to complete the Conflict of Interest Disclosure Form. Any investigator applying for or receiving Public Health Service (PHS) funding must complete the disclosure form. If applicable, investigators will comply with the institution's Conflict of Interest Management Plan and maintain appropriate compliance documentation.

IV. TRAINING REQUIREMENTS

Financial conflict of interest training shall be provided through the Collaborative Institutional Training Initiative (CITI) required and elective courses. Investigators identifying a conflict of interest on an externally funded grant or contract or all new or existing investigators of PHS-funded research are required to complete conflict of interest training prior to engaging in the research and every four years thereafter. Training is also required when the institution finds an investigator not in compliance with the institution's financial conflict of interest policy or management plan.

V. INVESTIGATOR RESPONSIBILITIES

Investigators with conflicts of interest are responsible to:

- Become familiar with federal regulations and the institution's policies related to conflict of interest
- Disclose to the institution any financial conflicts of interests before or when applying for external research funding. Update disclosure annually and within 30 days of acquiring or discovering (through purchase, marriage, inheritance, etc.) a new financial interest during the period covered by the grant or contract.
- Comply with the institution's development and implementation of any conflict of interest management plan and maintain appropriate compliance documentation
- Complete conflict of interest training prior to engaging in externally funded research and every four years thereafter. Training is also required when the institution finds an investigator not in compliance with the institution's financial conflict of interest policy or management plan.
- The investigator must agree in writing to abide by a management plan determined under this policy. Failure to agree to sign the management plan or to comply with the management plan shall result in the investigator's disqualification from further activity in research and may result in disciplinary action by the university.

VI. UNIVERSITY RESPONSIBILITIES

The university shall:

- Maintain a conflict of interest policy in compliance with 42 CFR Part 50, Subpart F and post the policy on the university's website
- Notify investigators of federal regulations and the institution's policies related to conflict of interest
- Notify investigators of their responsibility to disclose conflicts of interest
- Provide applicable conflict of interest training to investigators
- As part of a written agreement with a subawardee on a federally funded research project, document whether the federally compliant financial conflicts of interest policy of the awardee institution or that of the subrecipient will apply to the subrecipient's investigators
- Timely provide financial conflict of interest reports to the Public Health Services awarding component regarding all significant financial conflicts of interest of all awardee and subrecipient investigators consistent with 42 CFR Part 50, Subpart F
- Designate university official(s) to review disclosures by investigators of conflicts of interest or significant financial conflicts of interest
- Follow the university's conflict of interest policy when the designated university official(s) reasonably determine a significant financial interest could directly or significantly affect the design, conduct or reporting of federally funded research and implement a management plan to manage, reduce or eliminate the conflict of interest
- Maintain records related to investigator disclosures of financial conflicts of interest and the institution's review of, and response to, such disclosures for the required length of time

VII. DISCLOSURE OF INVESTIGATOR'S INSTITUTIONAL RESPONSIBILITIES

When an investigator discloses a significant financial conflict of interest, the dean or supervisor must review and determine whether the significant financial interest may be related to the investigator's university

responsibilities. Such review will include consideration of the following related to the investigator's involvement and the proposed research project:

- Financial interest with a company, foundation, etc. which provides products or services in the investigator's academic discipline or area of study
 - o Whether such entity may likely make use directly or indirectly of the scholarly work or research
- Financial interest with a member of an industry, trade or advocacy group funding scholarly work or research in the investigator's academic discipline or area of study
- An external entity has some other relationship not described above which could be related to or could be affected by the investigator's university responsibilities

VIII. RESEARCH AND SPONSORED PROGRAMS RESPONSIBILITIES

Research and Sponsored Programs shall review the potential conflict of interest, obtain additional information from the investigator as necessary and shall make a determination of whether the financial conflict of interest is significant or not. If it is determined to be a significant financial conflict of interest, the director shall recommend an action to manage, reduce or eliminate the conflict of interest. The role is to assist the university and investigators in identifying, managing or eliminating conflicts of interest. Review must include the potential impact of the financial interest on the following:

- Research integrity of the project
- Risks to the rights and safety of human research subjects
- Risks to the rights and obligations of students and trainees participating in the research project
- For public interest use, the availability of the research results to the scientific community
- The extent of compromise, potential to compromise or perception of compromise to the exercise of the investigator's professional judgment or obligations

IX. INSTITUTIONAL OFFICIAL RESPONSIBILITIES

As the institutional official, the Associate Provost for Research is responsible for administering the Financial Conflict of Interest Policy and Management Plan and for making the final determination regarding the required action to manage, reduce or eliminate the financial conflict of interest. The final decision shall be communicated to the investigator in writing along with the recommended actions, if applicable.

X. MANAGEMENT PLAN

Any significant financial conflict of interests determined under an NSF- or PHS-funded research shall be subject to a management plan. Management plans for significant financial conflict of interests on NSF- or PHS-funded research must be in place prior to the expenditure of federal grant dollars related to the research. The management plan must include:

- Grant/contract number
- Project director/principal investigator
- Name of investigator with a financial conflict of interest
- Role and principal duties of the conflicted investigator in the research project
- Whether conflict was managed, reduced or eliminated
- Name of the entity with which the investigator has a financial conflict of interest

- Nature of the conflict (such as equity interest, consulting fees, travel reimbursement, honoraria, etc.)
- Value of the financial conflict of interest or a statement that a value cannot be readily determined
- Description of how the financial interest relates to the federally funded research and the basis for the institution's determination that the financial interest conflicts with such research
- Description of how the management plan is designed to safeguard objectivity in the research project
- Notification to the investigator that PHS regulations require the institution to provide in writing to any requestor within five business days of a request the following information:
 - o Investigator's name
 - o Investigator's title and role with respect to the research project
 - o Name of the entity in which the significant financial interest is held
 - o Nature of the significant financial interest and the approximate dollar value of the significant financial interest 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
- The investigator must agree in writing to abide by the management plan. Failure to agree to sign the management plan or to comply with the management plan shall result in the investigator's disqualification from further activity in research and may result in disciplinary action by the university.
- For the duration of the research award, the investigator shall annually document the investigator's ongoing compliance with the management plan. The institutional official shall ensure such documentation has been filed.

The management plan may also include any of the following requirements:

- Public disclosure of the financial conflict of interest in all relevant publications or presentations
- Disclosure to the appropriate co-investigators, key personnel, research group members, students and/or trainees
- Disclosure of an investigator's financial interest on human subjects consent forms
- Limiting the role of any investigator having a financial interest when the research involves the use of human or animal subjects. Limitation of roles as the principal investigator, analyzing data, determining potential subjects' eligibility, soliciting consent or determining whether an adverse event report is required. Absent compelling justification as determined by the university, investigators may not participate as principal investigators in greater than minimal risk research projects involving human subjects while they have a significant financial interest in the research project or in a financially interested company.
- Appointment of an independent individual or group to monitor the research activity
- Arrangements to proceed contingent upon the sale or disposal of specific financial interests to reduce or eliminate the financial conflict of interest by a specified date
- Discontinuing relationships which increase or create actual or potential conflicts (such as resigning from a board of directors, terminating a consulting contract, etc.)
- Disqualification from participation in the portion of the research which would be affected by the significant financial interests

- Change of personnel or the roles of personnel in the research
- Any other action needed, as determined by the institutional official

If the institutional official determines imposing conditions or restrictions would be either ineffective or inequitable and the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer or the public health and welfare, then the institutional official may allow the research to go forward without imposing certain conditions or restrictions.

XI. SUBRECIPIENTS OF FEDERAL FUNDS

When the university carries out federally-funded research through a subrecipient, the university must meet applicable agency requirements to ensure subrecipient investigators also comply with federal conflict of interest requirements. Unless the information is publicly available, subawardees on NSF- or NIH-funded research will be required to disclose in writing which entity's conflict of interest policy shall be followed for the duration of each entity's participation in the federally funded project. Subrecipients that do not have a conflict of interest policy in compliance with federal requirements must adhere to the conflict of interest policy established and enforced by St. Cloud State University.

XII. REPORTING AND DOCUMENT RETENTION

As required by PHS regulations, the university must report potential significant financial conflicts of interest involving federally-sponsored research to PHS or NSF prior to the expenditure of their funds or, for potential significant financial conflicts of interest identified after the project has begun, within 60 days of the identification of the conflict of interest. Regularly thereafter report as required by the federal agency of the sponsored research the status of the significant financial conflict of interest, any changes to the management plan and inform the federal funding agency if the institution is unable to satisfactorily manage a conflict of interest.

Disclosures and documentation of plans to manage, reduce or eliminate financial conflicts of interest shall be maintained in the Office of Research and Sponsored Programs. Such documentation shall be retained for at least seven years beyond the termination or completion of the grant to which they relate or until the resolution of any action involving those records, whichever is longer.

For all PHS-funded research projects, the university shall conduct a retrospective review of any cases of reported noncompliance with the regulation but is not required to report the review to the PHS awarding component. The university shall promptly notify and submit a report to the PHS awarding component in cases where bias is found and shall address in the report any impact of the bias on the research project and the actions the university has taken or will take to eliminate or mitigate the effect of the bias.

XIII. COMPLIANCE AND RETROSPECTIVE REVIEWS

The university shall complete a retrospective review of any research in which:

- An investigator fails to disclose a significant financial interest that the institutional official determines to be a financial conflict of interest related to a specific research project;
- The institution fails to properly review or manage a financial conflict of interest; or

- An investigator fails to comply with the terms of the conflict of interest management plan.

The retrospective review must be completed within 120 days of learning of the problem. The retrospective review shall include determination of whether there was any bias in the design, conduct or reporting of the research. The Office of Research and Sponsored Programs shall keep a record of the retrospective review and make any necessary reports to funding agencies in accordance with federal regulations.

XIV. ALLEGATIONS OF MISCONDUCT

In cases where the institutional official or a federal sponsor determines that a financial conflict of interest was not managed or reported by the institution as required by federal law, the investigator(s) involved shall be required to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations disclosing the financial conflict of interest. An investigator in violation of this policy shall also be subject to the Policies and Procedures for the Handling of Allegations of Academic or Research Fraud and Serious Misconduct at St. Cloud State University, System Procedure 1C.01, Employee Code of Conduct and other applicable requirements.