

Guidelines on Management of Financial Conflict of Interest for PHS-Funded Research (FCOI-PHS)

Details	
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Department	Research Services Office
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Responsible University Officer	Dean, Research and Innovation

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Definitions:

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research

Institution or University- (used interchangeably) means Strathmore University, a private university established by Charter whose address is Madaraka Estate, Ole Sangale Road Post Office Box Number 59857-00200 Nairobi

PHS means the Public Health Service of the U.S. Department of Health and Human Services and any of its components such as the National Institutes of Health (NIH).

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 PHS-funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

1. Summary:

- 1.1. Institutional action to address financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, will ensure, to the extent possible, that the design, conduct, and reporting of PHS-funded research will be free from bias.
- 1.2. Investigators have special obligations to make full declarations of any financial interest or fiduciary roles, according to these guidelines, when involved in any PHS-funded project. These disclosures must be updated annually and may need to be updated at the start and/or the conclusion of a research project as well.
- 1.3. A Financial Conflict of Interest (FCOI) exists when the Institution, through its designated official(s), reasonably determine that an Investigator's Significant Financial Interest constitutes an FCOI with the PHS-funded research and could directly and significantly affect its design, conduct or reporting.

2. Other related Institutional Policies

These guidelines are anchored to the following institutional policies and other applicable statutes, rules and regulations not listed here:

- 2.1. *Regulations.* The regulations obligate the University, through the Research Services Office, to ensure that ethics governing research is understood, practiced and communicated to students and researchers. This includes avoiding conflicts of interest (or disclosing them when they cannot be avoided), and making only honest and accurate claims in reporting research. {see *Strathmore University Regulations of 2019, regulation 1 article 4 (d)*}
- 2.2. *Research Policy.* The University shall endeavour to improve on and align with global best practices regarding ethics in research. {see *Strathmore University Research Policy of 2020, regulation 1 article 4 (d)*}
- 2.3. *Conflict of Interest Policy.* In this policy, conflict of interest exists whenever personal, professional, commercial, or financial interests or activities outside of the University have the possibility (either in actuality or appearance) of compromising a staff member's judgment; biasing the nature or direction of decision making; influencing a staff member's decision or behaviour with regard to University matters. A potential Conflict of Commitment exists when a staff member's external relationships or activities have the possibility of interfering or competing with the University's educational, research, or service missions, or with the individual's ability or willingness to perform the full range of responsibilities associated with his/her position. Violations of Conflict of Interest Policy shall be considered to amount to gross misconduct on the part of the researcher concerned and may be subject to sanctions up to and including termination of employment in accordance with the University's disciplinary procedures. Violations shall include but shall not be limited to situations in which a researcher fails to make full disclosure or knowingly discloses inaccurate information of known situations of a potential or actual conflict of interest

or fails to abide fully by the required plan for avoiding or managing the conflict. {see *Strathmore University Conflict of Interest Policy*}

- 2.4. *Ethical Financial Conduct Policy*. This policy sets out standards of conduct that are expected of all individuals who manage and affect the finances, books and records, public reporting, and financial transactions of Strathmore University. {see *Strathmore University Ethical Financial Conduct Policy*}
- 2.5. *Policy & Procedures on Disclosure*. This policy sets out procedures for individuals to raise serious concerns about malpractice or serious wrongdoing in ways which will protect them from reprisal. The policy is intended to assist individuals who believe they have discovered malpractice or serious wrongdoing provided that they make the disclosure in accordance with the policy. It is not designed to question financial or business decisions taken by the University nor may it be used to reconsider any matters which have already been addressed under sexual harassment, grievance or disciplinary procedures. Individuals who make disclosures outside the procedures set out in that policy will not be protected under the policy. {see *Strathmore University Policy & Procedures on Disclosure*}

3. Rationale and Purpose:

- 3.1. University policies require commitment from staff in identifying and avoiding situations and activities that constitute conflict of interest in the execution of their duties for the University. Provisions for the disclosure and management of conflicts of interest have also been outlined in those policies.
- 3.2. These guidelines are necessary to address the expectation of research funding agencies, particularly, the PHS, that the university will conduct its affairs with integrity and objectivity. PHS-funded grant and cooperative agreement awards, demand compliance with the requirements of these guidelines as a condition of funding to the university.
- 3.3. These guidelines are anticipated to promote objectivity in research by providing a reasonable expectation that the design, conduct, and reporting of PHS-funded research is free from bias resulting from Investigator financial conflicts of interest
- 3.4. Investigators should not be discouraged from exploring or engaging in PHS funded projects, especially if such an exploration or engagement could bring a potential conflict of interest into being. These guidelines provide a procedure for the open disclosure and management of any resulting conflict of interest with balance, fairness, integrity and transparency.

4. Applicability:

- 4.1. Any research at the university, when it is authorized under PHS or other US statutory authority, such as a research grant, career development grant, centre grant, conference grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. The university may be the prime or sub-recipient of the award

- 4.2. Each Investigator who is a member of the university and is participating in an application or award under the PHS or other US statutory authority.
- 4.3. The sub-recipients and investigators of awards under the PHS or other US statutory authority in which the university is the prime. Institutions of higher education or a federal, state, or local government agencies within the U.S. are to be excluded from the requirements of disclosing financial interests.

5. Significant financial interest

- 5.1. Investigators are required to disclose their Significant Financial Interests (SFIs) (and those of the Investigator's spouse and dependent children). A significant financial interest exists if the value of any remuneration received by the Investigator (and the Investigator's spouse and dependent children), in the twelve months preceding the disclosure, when aggregated, exceeds US\$5,000 or the equivalent in Kenyan shillings. The financial interests that must be disclosed by the Investigator include the aggregated amounts or values of financial interests held by the Investigator and his/her spouse and dependent children.
- 5.2. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Strathmore University to the Investigator, if the Investigator is currently employed or otherwise appointed by the Institution; intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- 5.3. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) constitute significant financial interests:
 - the value of any equity interest in any publicly traded entity the entity as of the date of disclosure, when aggregated, exceeds \$5,000;
 - the value of any remuneration received from a non-publicly traded entity in the twelve 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) in excess of \$5,000;
 - income related to intellectual property rights and interests (e.g., patents, copyrights),
 - any sponsored travel (disclosure of the purpose of the trip, the identity of the sponsor/organizer, the destination, monetary value and the duration is required in order to determine whether the travel constitutes an FCOI with the PHS-funded research). Travel paid for by the institution or government entities are excluded from disclosure.
- 5.4. Any income that is subject to the definition of "Significant Financial Interest," the following disclosure considerations apply:

- Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to the Institution no later than at the time of application for PHS-funded research.
- Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs at least annually.
- Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.

6. Compliance Thresholds

6.1. **Public Availability of Financial Conflict of Interest Guidelines:** For PHS-funded grants, the Institution is required to post its FCOI guidelines on its publicly available website.

6.2. **Training of Investigators:** The Institution shall inform each Investigator of the compliance requirements of the financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- The Investigator is new to the Institution; or
- The Institution finds that an Investigator is not in compliance with the financial conflict of interest policy or management plan.

The institution may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements. However, the institution will also provide additional training regarding Investigator's responsibilities for disclosure of Significant Financial Interests and institution-specific information on financial conflicts of interests.

6.3. **Compliance by Sub-recipients:** The institution will take reasonable steps to ensure that investigators from sub-recipient entities such as subcontractors or consortium members are compliant with these guidelines through a contractual obligation. Awardee Institutions are responsible for monitoring sub-recipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

6.4. **Designation of an institutional official(s):** The Dean, Research and Innovation and the Chief Internal Audit and Compliance Officer are the designated university officials to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in the PHS-funded research at the institution.

6.5. **Disclosure of significant financial interest and financial conflict of interest:** The investigators will disclose their SFIs to the Dean, Research and Innovation and the

Chief Internal Audit and Compliance Officer: chiefinternalauditor@strathmore.edu.
For the purposes of a determination of FCOI, the disclosure should include at a minimum the following information:

- Investigator's name
- Entity name in which the Investigator (and spouse and dependent children) has an SFI
- Disclosure of financial interests in the 12 months preceding the disclosure and value of equity interest as of the date of disclosure
- Provide for disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests (Note: US\$5,000 or its equivalent in Kenyan Shillings threshold has been imposed for IP rights and interests).
- Provide for the disclosure of sponsored travel that includes at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. (Travel paid for by the institution or government entities are excluded from disclosure)
- Provide a distinction whether the SFI is from a publicly traded or non-publicly traded entity.
- Provide a description of the value and nature of the significant financial interest (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- Provide an indication whether the SFI is related to any Public Health Service application and/or funded project and an explanation for the relatedness.

6.6. Determination of significant financial interest and financial conflict of interest:

An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. ("significantly" means "...the financial interest would have a 'material effect on the research'...")

6.7. Financial conflict of interest management plan: A management plan is required in instances in which a determination has been made of that a financial conflict of interest exists and if not addressed, it could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The key elements of the Institution's management plan including the following:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;

- Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance
- 6.8. **Management of financial conflict of interest:** The following actions may be taken by the institution to address a financial conflict of interest:
- Public disclosure of FCOI (e.g., when presenting or publishing the research);
 - Disclosure of FCOI directly to human subjects research participants;
 - Monitoring of research by independent reviewer(s);
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)
 - Severance of relationships that create financial conflicts.

6.9. **Actions to be taken in the event that an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or management plan:** When an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or the management plan, the Institution shall within 120 days:

- complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine any bias in the design, conduct or reporting of research;
- document the retrospective review consistent with the institutional guidelines; and
- document the Institution's determination as to whether any PHS-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research. If bias is found, the Institution shall notify the PHS promptly and submit a mitigation report that shall address the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

In determinations in which the PHS-funded project is a clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required, the Institution shall require the Investigator involved 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.

Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review.

- 6.10. **Maintenance of Disclosure Records:** The Chief Internal Audit and Compliance Officer shall maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS
- 6.11. **Submission of an Annual financial conflict of interest Report:** The Research Services Office shall submit the annual report through the eRA Commons FCOI Module each year within a competitive segment of an active grant

FINANCIAL CONFLICT OF INTEREST (“FCOI”) DISCLOSURE FORM

Investigators are responsible to read the NIH Regulations on Financial Conflict of Interest, including details of all disclosure requirements, and the Institutional Policy prior to completing this form:

Investigator Name: _____

Institutional affiliation: _____

School/Research centre: _____

Project Title: _____

NIH grant number: _____

Project PI: _____

PLEASE CHECK ONE OF THE FOLLOWING:

_____ I have NO significant financial interests to disclose which relate to my institutional responsibilities. *(If NO significant financial interests, please read the Certifications below and sign as “Investigator.”)*

OR

_____ I am disclosing significant financial interests (and those of my spouse and dependent children) which relate to my institutional responsibilities. *(Please provide the following details regarding the entity, your financial interest, income and travel, then read the Certifications and sign below as “Investigator.”)*

Name of Entity (corporation, partnership, private practice, non-publicly traded entities, etc.): _____

Address of Entity: _____

Principal Type of Business: _____

How does the financial interest relate to PHS-funded research? _____

Did remuneration received from the entity in the twelve months preceding the disclosure* (see exclusions below*) AND the value of any equity interest in the entity as of the date of disclosure, **when aggregated**, exceed \$5,000? Yes ___ No ___

***Exclusions** -- excluded from income disclosure: salary, royalties, or other remuneration paid by Strathmore University to the Investigator, if the Investigator is currently employed or otherwise appointed by the Institution; intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights

Do you have income from an interest in any intellectual property rights impacted by the project?
Yes ___ No ___

In the last 12 months, did you travel on a sponsored trip **? Yes ___ No ___

If “Yes,” please provide the following trip details:

1. Purpose of trip: _____
2. Sponsor/Organizer: _____
3. Destination: _____
4. Duration: _____

****Exclusions --** excluded from travel disclosure: NOT required to disclose travel that is reimbursed or sponsored by US federal, state, or local government agency, US Institution of higher education as defined at 20 USC 1001(a), or an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education in the United States and All travel paid by Strathmore University.

Investigator Certification:

In signing this document, I confirm:

- I have completed this declaration to the best of my knowledge and have considered all of the potential financial conflicts of interest relating to me, my spouse and dependent children;
- I agree to complete FCOI training *prior to* engaging in research related to any PHS-funded grant or contract and at least every four years thereafter; and, immediately upon other events, as defined per university guidelines. Upon completion of each training session, I will send an email confirming completion to: research@strathmore.edu and to the Chief Internal Audit and Compliance Officer: chiefinternalauditor@strathmore.edu
- If the proposed project is funded by PHS, I agree, for the duration of the project, to update this disclosure either on an annual basis, or within 30 days if new reportable significant financial interests are obtained (such as through purchase, marriage or inheritance, for example).
- I agree to provide additional details needed by Strathmore University to meet PHS requirements, and to cooperate in the development of a Management Plan to address any actual or potential conflict of interest identified via this Disclosure.
- If I participate in a project involving sub-recipient organizations, I agree to assist Strathmore University in obtaining required disclosures in a timely manner from all sub-recipient Investigators, and to assist Strathmore University, if requested, to manage any FCOIs of a sub-recipient Investigator to assure compliance with these regulations.
- I agree to comply with any retrospective reviews, conditions or restrictions imposed by Strathmore University to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signed: _____ Date: _____

Investigator

To be Endorsed/Signed Only by Institutional Official:

Institutional Endorsements: I have reviewed the significant financial interest disclosure and believe that no significant financial interest exists or if one does exist that it is possible to develop and execute, prior to award, a Resolution Plan to manage, reduce or eliminate any actual or potential conflict of interest; and, therefore, I recommend that the proposal be submitted to the agency at this time.

Signed: _____ Date: _____