



CLINICAL RESEARCH CENTRE

Policy Title		Financial Conflicts of Interest (FCOI) in Federally Funded Research Activities	
Responsible Officer		FCOI Officer	
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1. Introduction

This policy governing financial conflict of interest (FCOI) applies to all Public Health Services (PHS) of the U.S. Department of Health and Human Services (DHHS) -funded Investigators and their families of Africa University Clinical Research Centre (AU CRC) in accordance to the 42 C.F.R. Part 50, Subpart F and the 45 C.F.R. Part 94. AU CRC is responsible for ensuring implementation and adherence to this policy as well as suspending all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institution is implemented. Africa University Clinical Research Centre (AU CRC), being the Institution shall appoint a FCOI Officer who is responsible for the implementation and monitoring of the policy including training the Investigators and ensuring adherence to PHS FCOI reporting requirements. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy.

1.1 Purpose

To set out clear guidelines, standards and the responsibilities of all individuals, investigators or key persons involved in research to preserve the integrity of research, protect the rights and safety of research participants, and prevent bias in the design, conduct and reporting of research funded under PHS grants or cooperative agreements that may result from any financial conflict of interest (FCOI).

1.2 Violation of Policy

Any Investigator or AU CRC employee and/or affiliate who contravenes any part of this policy shall be liable to disciplinary or corrective action and in addition the personnel may be requested to step down from the research project or give up the gift or business concerned.

2. Definitions

Financial Conflict of Interest (FCOI) - A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest - Anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

PHS - The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Research - a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Senior/Key Personnel - The Principal Director or Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

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 funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Institutional responsibilities - An Investigator's professional responsibilities on behalf of the Institution which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Significant Financial Interest (SFI):

1. 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) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - i. 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 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;
 - ii. 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 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
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The following travel details are required:
 - i. Purpose of trip;
 - ii. Name of sponsor/organizer;
 - iii. Destination (city and state or country if outside the U.S.);
 - iv. Duration of trip; and
 - v. Total cost of trip including lodging; registration; fare for mode of travel (air, train, car, etc); per diem and any other miscellaneous expenses.
3. Significant financial interest does not include:
 - i. Salary royalties, or other remuneration paid by the Institution 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;
 - ii. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - iii. 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;
 - iv. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or

- v. Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Subrecipient - An organization or researcher that participates in research with the awardee Institution (e.g. subcontractors or consortium members).

3. Policy

3.1 Disclosure, Review and Monitoring Requirements

3.1.1. Investigator and Key Personnel Responsibility

1. Any Africa university employee or affiliate that serves as an investigator or key personnel and who is planning to participate in PHS-funded research must disclose to the FCOI Officer any significant financial interest (i.e of the investigator's or key personnel's spouse and dependent children) no later than the time of application for PHS-funded research using the FCOI form provided by the FCOI Officer.
2. Annual disclosures - Investigators or key personnel who are currently participating in PHS-funded research must disclose any significant financial interest (of the investigator's or key personnel's spouse and dependent children) for the previous calendar year no later than 31 January every year, using the prescribed FCOI form.
3. Annual FCOI reports submitted to the FCOI Officer shall include any information that was not previously disclosed.
4. Adhoc disclosures - Within 30 days of discovering or acquiring a significant financial interest, an investigator or key personnel shall submit an updated FCOI form to the FCOI Officer within the course of the year.
5. Travel - Investigators also must disclose within 30 days the occurrence of any reimbursed or sponsored travel as defined above in the definition of Significant Financial Interest and in accordance to the required travel details. The FCOI Officer will determine if additional information is required.

3.1.2 Responsibilities of the Africa University Clinical Research Centre

1. AU CRC shall update and enforce this written policy and will make the policy and applicable federal regulations available on the AU CRC website.
2. AU CRC will inform each investigator and key personnel about the following:
 - i. Information about this policy;
 - ii. Responsibility of the investigator and key personnel to disclose any significant financial interest to the FCOI Officer and mandatory FCOI training requirements.
3. If AU CRC subcontracts elements of the PHS-funded research, each sub-recipient investigator or key personnel shall be required to comply with this policy or provide documentation that the sub-recipient institution is compliant to PHS FCOI regulations. The following will be required to be done;
 - i. A written agreement with the sub-recipient must identify whether the sub-recipient investigator and key personnel will comply with the FCOI provisions of the sub-recipient institution or AU CRC.
 - ii. If the sub-recipient will comply with his or her institutional FCOI policy, the written agreement must specify that any FCOI disclosures reported to the sub-recipient's institution must be reported to Africa University's FCOI Officer within 30 days.
 - iii. If the sub-recipient does not have FCOI policy, the written agreement must indicate that the sub-recipient will comply to Africa University's FCOI policy.

- iv. AU CRC will report sub-recipient significant financial interest to the PHS prior to the expenditure of any funds or within 60 days of receiving sub-recipient disclosure of significant financial interest.
- 4. AU CRC will appoint an FCOI Officer who will solicit and review disclosures of Significant Financial Interest from each investigator or key personnel (and those of the Investigator's or key personnel's spouse and dependent children) who is planning to participate in, or is participating in, PHS-funded research.
- 5. The FCOI Officer will develop and implement management plans, as needed to manage FCOIs.
- 6. The FCOI Officer will maintain all FCOI records for a period of at least 3 years from the date the final grant expenditure report is submitted to the PHS.

3.1.3 Reviewing Disclosures

- 1. The FCOI Officer will review the disclosure form within 60 days of receipt of a significant financial disclosure and determine whether it constitutes Financial Conflict of Interest.
- 2. The FCOI Officer may seek additional information from the Investigator or key personnel.
- 3. If the FCOI Officer determines that a significant financial interest exists that is related to PHS-funded research, the Officer shall identify actions, if any, that must be taken by the investigator or key personnel to manage the financial conflict of interest. The actions may include reduction or elimination of the conflict, as appropriate.
- 4. The FCOI Officer must develop and implement a written management plan to address the FCOI.
- 5. The affected Investigator or Key personnel must formally agree to the proposed management strategies and sign the written management plan before any related PHS-funded research goes forward.
- 6. The FCOI Officer will periodically review the ongoing activity, monitor the conduct of the activity, to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3.1.3 Enforcement Mechanisms, Remedies and Noncompliance

- 1. In the event of non-compliance with the policy by the investigator or key personnel, the FCOI Officer shall promptly notify the PHS that funds the research of any corrective action taken, or that will be taken.
- 2. The Institution will submit, or permit on site review of, all records pertinent to the review of a financial disclosure or FCOI to the PHS.

3.2 Reporting to PHS

- 1. The FCOI Officer will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations as follows;
 - i. Prior to the expenditure of funds
 - ii. Within 60 days of identification for an Investigator who is newly participating in the project
 - iii. Within 60 days for new, or newly identified, FCOIs for existing Investigators
 - iv. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - v. Following a retrospective review to update a previously submitted report, if appropriate.
- 2. The FCOI report shall include the following information;
 - i. The name of the investigator with the FCOI

- ii. The name of the entity with which the investigator has an FCOI
- iii. The nature of the Significant Financial Interest (SFI)
- iv. The value of the financial interest
- v. Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- vi. Description of the key elements of the institution's management plan, including other required information

3.3 Training

1. Each Investigator and key personnel (existing and new) must complete training staff prior to engaging in PHS-funded research and thereafter complete training every 4 years.
2. An Investigator who is not compliant with the policy or management plan will be required to complete additional training.
3. In the event of updates or revisions to the policy that affects the requirements of the Investigator, the investigator or key personnel will be required to undergo further training.
4. Investigators will be encouraged to conduct the NIH online FCOI on https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

3.4 Public Accessibility

1. Prior to the expenditure of funds, the Institution will publish on the AU website or a publicly-accessible website and will be updated at least annually.
2. The Institution will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:
 - i. The Significant Financial Interest was disclosed and is still held by the senior and key personnel
 - ii. A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
 - iii. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
3. The Institution may choose to post FCOI disclosures on its website and if posted will update information every six months.
4. Information concerning significant financial interests shall remain available for public information requests for at least three years from the date that the information was most recently updated.

3.5 Confidentiality

1. All disclosures or information obtained in reviewing a potential FCOI will be kept confidential, except where disclosure is required by federal regulations.
2. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

4.0 References

- 42 CFR 50 – Policies of General Applicability
- 45 CFR 94 – Responsible Prospective Contractors
- DHS/OHA Policy: Conflict of Interest
- AU General Conflict of Interest Policy