



KAIRUKI UNIVERSITY FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY FOR RESEARCH SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH

INTRODUCTION

Kairuki University

Kairuki University (KU) is an accredited Higher Learning Institution with a Charter, recognised in the United Republic of Tanzania, through the Tanzania Commission for Universities (TCU). The provisions for establishment and functions of the university, administration, appointments of officials, powers and rules governing the university administrative bodies and staff are all stipulated in the university Charter and rules. KU operates as an autonomous, not-for-profit institution (social enterprise) whose main institutional objectives are teaching undergraduate and postgraduate students, carrying out relevant research and rendering community services to Tanzania.

PURPOSE AND OVERVIEW

The purpose of this Financial Conflict of Interest (FCOI) Policy at Kairuki University (KU) is to establish a comprehensive framework to identify, manage, and mitigate financial conflicts of interest that may arise in research funded by the National Institute of Health (NIH).

This policy is designed to uphold the highest standards of research integrity and objectivity by ensuring that all research activities supported by NIH grants and cooperative agreements are conducted without bias or undue influence stemming from personal financial interests.

This policy applies to all key academic and research personnel associated with the University and its sub-recipients, involved in NIH-funded research. It is imperative that these individuals adhere to the policy to maintain the credibility and trustworthiness of the University's research endeavors.

The primary goal of this policy is to foster an environment where research design, conduct, and reporting are free from the potential biases that financial conflicts of interest might introduce.

To achieve this, the policy mandates that all Investigators undergo appropriate FCOI training and disclose significant financial interests (SFIs) that are related to their institutional responsibilities. Disclosures must be made at the time of application, annually, and within 30 days of discovering or acquiring new SFIs. The Institute will assess whether disclosed SFIs are related to the NIH-funded research and determine if they constitute a financial conflict of interest.

The policy aligns with federal regulations, specifically 42 CFR Part 50 Subpart F, and other relevant federal guidelines. It establishes clear procedures for the identification and management of SFIs to prevent any adverse impact on research integrity. This includes implementing

management plans for any identified conflicts, ensuring that research activities remain unbiased and are conducted with transparency.

Key components of the policy involve rigorous training requirements, timely disclosure of financial interests, and systematic review and management of identified conflicts. Investigators are required to complete FCOI training provided by the Institute and maintain up-to-date disclosures. The policy outlines specific thresholds for significant financial interests and mandates detailed reporting and management strategies for any identified conflicts.

The University is committed to full compliance with NIH reporting requirements. This includes providing timely reports of FCOIs through the eRA Commons FCOI Module and ensuring that any financial conflicts are addressed before the expenditure of NIH funds. In cases where noncompliance with the policy is detected, the Institute will conduct a retrospective review to determine if any NIH-funded research has been biased, and will take necessary corrective actions, including reporting any identified biases to NIH.

In addition, the policy stipulates that all records related to FCOI disclosures and management actions shall be maintained for a minimum of three years. It also requires that subrecipients of NIH funds shall adhere to similar FCOI policies, ensuring consistent management of conflicts across all research activities.

By adhering to this policy, Kairuki University aims to protect the integrity of its research and maintain public trust in its scientific contributions. The policy's rigorous standards and procedures are intended to ensure that NIH-funded research is conducted in an unbiased, transparent, and ethical manner.

A. PERSONS COVERED BY THIS POLICY

This policy applies to all key academic and research personnel, as identified in grants of Kairuki University ("KU") who are planning to participate in, or are participating in, National Institute of Health ("NIH") funded research by means of a grant or cooperative agreement. The policy also applies to collaborators or consultants, as noted.

B. PREAMBLE

1. The primary goal of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.
2. This policy is implemented in accordance with 42 CFR Part 50 Subpart F – "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" and other relevant policies of federal funding and oversight agencies.

C. STATEMENT OF GENERAL POLICY

1. The design, conduct, and reporting of Research funded under NIH grants or cooperative agreements should be free from bias resulting from Investigator financial conflicts of interest.
2. To provide a reasonable expectation of achieving the goal of this policy, Investigators shall complete appropriate training as required under this policy; Investigators shall disclose significant financial interests (SFI) that are related to the Investigator's institutional responsibilities at the time of application, annually and provide new or updated financial disclosures within 30 days of acquiring or discovering a new SFI; KU shall determine if the

SFI is related to the research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research) and if the SFI is a financial conflict of interest (i.e., the SFI is related to the research and could directly and significantly affect the design, conduct, or reporting of the NIH-funded research); provide for the management of Financial Conflicts of Interest; and KU shall make reports or disclosures to both the NIH and to the public as required under this policy.

3. Nothing in this policy shall be construed to permit, even with disclosure, any activity that is prohibited by law.

D. DEFINITIONS

“Designated Official(s)” means individual(s) at the institution who is(are) responsible for reviewing SFI disclosures and making determinations of FCOI per the regulatory criteria in 42 CFR 50.604(f).

“Disclosure” means an Investigator’s disclosure of significant financial interests to the University.

“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. Note: A Financial Conflict of Interest exists when the University, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to a NIH-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

“FCOI Report” means the University’s report of a Financial Conflict of Interest to a PHS Awarding Component.

“Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.

“HHS” means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

“KU” means Kairuki University.

“Institute Responsibilities” means an Investigator’s professional responsibilities on behalf of the University, and as defined by the university in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, training, professional practice, and service on panels such as Institutional Review Boards or Data Safety and Monitoring Boards.

“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 funded by the PHS, or proposed for such funding, which may include, for example, collaborators, subcontractors, or consultants. The University will consider the role, rather than the title, of those involved in the research and the degree of independence with which those individuals’ word when considering who meets the definition of “Investigator.”

“Manage” means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“Member” means any person executing the University’s Operating Agreement, or thereafter admitted to the Institute as a Member as provided in the University’s Operating Agreement.

“PD/PI” means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

“NIH” means National Institutes of Health (NIH).

“Research” means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a NIH through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institute training grant, program project, or research resources award.

“Senior/key personnel” means the PD/PI and any other person identified as senior/key personnel by the Institute in the grant application, progress report, or any other report submitted to the PHS by the Institute under the regulation. The term is defined only as it relates to the Public Disclosure requirements that require making certain information publicly available when FCOIs are identified for “senior/key personnel” as explained in Section I. below.

“Significant Financial Interest” means:

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 Institute 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 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 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 a management or governance position; or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income in excess of \$5,000 related to such rights and interests.
 - Significant Financial Interests do not include:
 - Salary, royalties, or other remuneration paid by the Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Institute, including intellectual property rights assigned to the Institute and agreements to share in royalties related to such rights.
 - Any ownership interest in the Institute held by the Investigator since the Institute is a for-profit organization.

- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education.
- Income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education.
- 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.

Note: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

- Reimbursed or Sponsored Travel:
 - Investigators also must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds \$5,000 (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 Institute 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 located in the United States, a United States 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 a United States Institution of higher education. Reimbursed or sponsored travel received from a foreign government, or a foreign institution of higher education is required to be disclosed if such income exceeds \$5,000.
 - Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institute will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
 - The initial disclosure must include reimbursed or sponsored travel received over the previous twelve-months. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Note: the Foreign Disclosure Requirements Related to the Exclusions: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or

sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

E. POLICY IMPLEMENTATION

1. Training Required: Investigators shall complete FCOI training provided by the University prior to engaging in NIH-funded research and then every four years thereafter. Training will be informed about the Institute's policy, Investigator's SFI disclosure responsibilities and requirements per the policy, and the Federal regulation. Investigators will be required to complete the NIH FCOI training modules and provide a certificate of completion to the Kairuki University representative. The Kairuki University representative will retain a copy of the certification of completion of FCOI training for audit purposes. Immediate training will be required if the university revises this policy in a manner that affects the Investigator, when an Investigator is new to the university, or as a result of a finding of noncompliance with this policy or a management plan, or other related misconduct.

Training on the FCOI regulation will be provided to "Investigators" by utilizing the NIH training found at [FCOI Training | grants.nih.gov](https://www.grants.nih.gov/grants/financialconflict/) or [FINANCIAL CONFLICT OF INTEREST – NEWEST \(nih.gov\)](https://www.nih.gov/financial-conflict-of-interest).

2. Disclosure Requirement:

- (i) An Investigator shall disclose any Significant Financial Interest as defined and provided for herein. Research should not be undertaken on pending applications where a Significant Financial Interest is present until a determination has been made and is managed pursuant to this policy.
- (ii) Investigators shall keep their "Institute" designated official(s) informed of the Investigator's Significant Financial Interest. If a designated official becomes aware of a significant financial interest that an employee has not disclosed, the supervisor shall discuss the situation with the employee, require that a written disclosure be made as provided in this policy, and inform the President to anticipate the receipt of a new Disclosure.

3. Disclosure Frequency:

- (i) Disclosure must be made no later than at the time of application for NIH-funded research.
- (ii) Disclosure must be made annually to the designated official(s). If no Significant Financial Interest is present, a Disclosure must still be submitted that states "none". The annual Disclosure due date is December 31 and will be disseminated Institute wide.
- (iii) In addition to the annual Disclosure, a new or updated Disclosure must be completed in a timely manner whenever a new Significant Financial Interest arises or when a significant change occurs concerning an existing Disclosure.
- (iv) In any event, an SFI Disclosure must be made within thirty (30) days of discovery or acquiring a new Significant Financial Interest.
- (v) Newly hired Investigators should make a Disclosure as part of their new hire employment process.

4. Review and Management of SFIs and Determinations of FCOI:

5. The designated official(s) shall solicit and review SFI Disclosures and determine if they are a FCOI. A Financial Conflict of Interest exists when the Institute, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and constitutes FCOI. The SFI is related to the NIH-funded research when:
 - the Significant Financial Interest could be affected by the research or
 - the Significant Financial Interest in an entity whose financial interest could be affected by the research.

If the SFI is determined to be related to the NIH-funded research, an FCOI exists when the designated official(s) determine the SFI could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

- Members shall review SFI Disclosures and determine if they are a FCOI when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.
 - Members shall review SFI Disclosures and determine if they are a FCOI and implement a management plan within 60 days whenever the Institute identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institute.
- (v) If a determination is made that a FCOI exists, then the Members shall seek input from the Investigator and recommend to the President a suitable action plan ("Management Plan) to manage the FCOI consistent with the objectives of this policy. The Management Plan shall provide for its periodic review and update at least annually. If there is no reasonable way to manage a FCOI, then the Investigator may be prohibited from participating in the related Research until such a time as the FCOI is eliminated.
- (vi) Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.;
 - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - Appointment of an independent monitor 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 research;
 - Reduction or elimination of the financial interest (e.g. sale of an equity interest);
or
 - Severance of relationships that create financial conflicts

- The President shall review the proposed Management Plan and can approve, modify and approve, or return to the Members for additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

F. VIOLATIONS AND SANCTIONS

1. **Sanctions:** Violations of Institute policies, including the failure to avoid a prohibited activity or disclose a Significant Financial Interest in a timely manner, will be dealt with in accordance with applicable policies and procedures that may include disciplinary actions up to and including termination of employment.
2. **Clinical Research Requirements:** In any case in which the HHS determines that a NIH-funded project of 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 FCOI that was not managed or reported by the Institute as required by this policy, the Members shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

G. INSTITUTE REPORTING

1. The Institute, through its eRA Commons FCOI Module assigned FCOI Signing Official (SO) will provide annual and revised reports of FCOI to National Institutes of Health (NIH) via the eRA Commons FCOI Module:
 - (i) Prior to the expenditure of funds under a new award;
 - (ii) Within sixty days of identification for an Investigator who is newly participating in the project.
 - (iii) Within sixty days for new or newly identified FCOIs for existing investigators.
 - (iv) At least annually (at the same time as when the Institute 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 retrospective review to update a previously submitted report, if new information is discovered that was not previously reported to the NIH.

H. ACTIONS RELATED TO NONCOMPLIANCE WITH THE POLICY

1. Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
 - Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institute to constitute a Financial Conflict of Interest;
 - Failure by the Institute to review or manage such a Financial Conflict of Interest; or
 - Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Institute shall, within 120 days of the Institute's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

The Institute shall document the retrospective review which must include at least the following key elements:

- Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has a financial conflict of interest
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
 - Findings of the review; and
 - Conclusions of the review.
2. The Institute, through its Members, shall notify NIH of bias found in the design, conduct, or reporting of NIH funded Research including whether Investigator failure to comply with this FCOI policy or management plan appears to have caused such bias. In the event bias is found, Institute will submit a Mitigation report in accordance with the regulation. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of 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 (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). If the FCOI was previously reported to the NIH, the mitigation report will be submitted as a "Revised FCOI Report." Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

I. MAINTENANCE OF RECORDS

The Institute will keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (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. The records of financial disclosures and any resulting action will be maintained by the Institute for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

J. SUBRECIPIENTS

Institute, through its Members, shall require sub-recipient compliance with the FCOI requirements as mandated by PHS regulation:

1. If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
2. If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the Institute to report identified FCOIs to NIH as required by the regulation (i.e., prior to the expenditure of subrecipient funds and within 50-55 days of identifying an FCOI during the period of an award) to allow the Institute to report the FCOI to the NIH as required by the regulation (i.e., prior to the expenditure of funds and within 60 days of identifying an FCOI during the period of an award).
3. Alternatively, if the subrecipient does not have a compliant policy, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures of SFIs. The subrecipient Investigator must disclose SFIs to the Institute that are directly related to the subrecipient's work for the Institute to enable the Institute to identify, manage, and report identified FCOIs to NIH. The Institute will monitor subrecipient Investigator compliance with any implemented management plan.

K. PUBLIC ACCESSIBILITY REQUIREMENT

1. Institute shall post this FCOI policy on the Institute public website, as required by the NIH Grants Policy Statement Section 4.1.10 Financial Conflict of Interest at [1.10 Financial Conflict of Interest \(nih.gov\)](#)
2. FCOI Informational requests by the public concerning identified FCOIs held by senior/key personnel should be made to the requestor within five (5) business days with minimum reporting elements as provided for under applicable regulation 42 CFR 50.605(a)(5)(ii).