



In Search Of Better Health

K E M R I

**STANDARD OPERATING
PROCEDURE FOR
CONFLICT OF INTEREST**



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: **CONFLICT OF INTEREST**

REF NO: **KEMRI/SERU/SOP/PI/COI**

Version: **1**

PAGE: **2 of 8**

Document Control Schedule

Name of department:	SERU
Document Type:	Management Procedure
Document Ref:	KEMRI/SERU/SOP/PI/COI
Process owner:	Head Compliance SERU
Signature:	
Approved By:	Head SERU
Signature:	
Effective Date:	October 18, 2017

Controlled copy: Circulation authorized by the Head SERU.



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1. PURPOSE

The purpose of this Standard Operating Procedure is to establish uniform procedures for consideration of potential conflicts of interest in human research. This document covers procedures for dealing with Investigator's responsibilities to disclose conflict of interest involving research protocols, or other matters involving research audit

2. SCOPE

This SOP applies to all research conducted under the authority of the SERU. This SOP applies to PIs, named investigators, collaborators, institutional officials

3. INTRODUCTION

3.1 Researchers submitting protocols for SERU review may find themselves in any of the following conflicts of interest (conflict of interest here used as defined in section 4 below):

- 3.1.1 Stock ownership in any commercial companies involved
- 3.1.2 Consulting arrangements with the Sponsor or Funder where the arrangement may have an impact on study conduct or study-related decisions or study outcomes
- 3.1.3 Career interests strongly linked to product or technique assessed by study
- 3.1.4 Emotional involvement in the study that may affect study decisions, conduct or study outcomes
- 3.1.5 Investment (financial and intellectual) or career in competing products
- 3.1.6 Investigators may have the potential for conflict of interest when approached to conduct research sponsored by organizations with which they have a financial interest..



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4. TERMS & DEFINITIONS

- 4.1 Conflict of interest:** A convergence of an individual's private interests with his or her research interests, such that an independent observer might reasonably question whether their professional actions or decisions are improperly influenced by considerations of personal gain, financial or otherwise.
- 4.2 Disclosure:** Disclosure is the formal written process of declaring and documenting all potential conflicts of interest.
- 4.3 Institutional conflict of interest:** An institutional conflict of interest may occur when the institution, or any of its senior management or an affiliate foundation or organisation, has an external relationship or financial interest in a company or organisation that itself has a financial interest in an investigator's research project.
- 4.4 Institutional officials:** Individuals in a position to make decisions with institution-wide implications.
- 4.5 Personal conflict of interest:** A Personal Conflict of Interest exists when personal obligations compromise or appear to compromise an individual's or group's professional judgment in conducting, reviewing, or reporting research. This may occur when the investigator serves dual roles, such as investigator and primary health care provider to the research participant. It may also involve issues of nepotism. Other interests such as publications, promotion or tenure can also become conflicts of interest that may affect an investigator's judgment.
- 4.6 Royalty:** A royalty is compensation for an invention.

5. OBJECTIVES

To ensure that research is conducted without conflicting Interests.

6. INPUTS/RESOURCES

- 6.1 Personnel
- 6.2 Stationery and office equipment
- 6.3 Emails
- 6.4 Phone

7. EXPECTED OUTPUTS

- 7.1 Record of the conflict of Interest
- 7.2 Agenda



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8. KEY PERFORMANCE INDICATORS

8.1 No. of Conflict of Interest reviewed

9. RESPONSIBILITY AND AUTHORITY

9.1 The Principal Investigator (PI)

9.1.1 Will act on behalf of all Investigators and key personnel on the proposed study by completing the conflict of interest declaration form and include it in the submission package for all new studies.

9.1.2 The PI will also be responsible for bringing to the SERU's attention any potential conflict of interest that occurs at any point throughout the conduct of the study.

9.1.3 The **Institutional officials** will take responsibility of declaring any institutional conflict of interest.

10. DETAILS OF PROCEDURE

10.1 Complete the conflict of interest declaration form and submit this along with initial review submission documents to the SERU.

10.2 Complete and submit to the SERU the conflict of interest declaration form for any new conflicts of interest that arise during the conduct of the study.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Conflict of interest	Research misconduct	Failure to disclose conflict of interest	To identify all possible conflict of interest

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Conflict of interest	Training	Attending trainings in regards to research misconducts.



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12. REFERENCE DOCUMENTS

12.1 None

13. ANNEXES

13.1 Flow chart Procedures.

ANNEX 1: PROCESS FLOW CHART



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<u>Players</u>	<u>Activity</u>	<u>Flow Chart</u>
Principal Investigator Centre Compliance Officer	Submitting the Signed Conflict of Interest to SERU Receives, pre-reviews and records all Conflict of Interest submitted to SERU	<pre>graph TD; Start([Start]) --> Submits[Submits application]; Submits --> Receives[Receives application]; Receives --> Application{Application}; Application --> Corrects[P.I Corrects Application]; Corrects --> Submits; Application --> Agenda[Agenda]; Agenda --> End([End]);</pre>