



In Search Of Better Health

K E M R I

**STANDARD OPERATING
PROCEDURE FOR APPEALS OF SERU
DECISIONS**



KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: **APPEALS OF SERU DECISIONS SOP**

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

Version: **1**

PAGE: **2 of 7**

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1. PURPOSE

This SOP describes the procedure to be followed by any investigator while filing an appeal for a decision made by the SERU committee.

2. SCOPE

This SOP outlines the steps to be followed by an investigator who disagrees with the decision made by SERU committee decision.

3. INTRODUCTION

An investigator may disagree with a decision made by SERU. In such circumstance there is a procedure that the aggrieved is required to follow. This will allow the investigator a chance to seek audience and a second chance for the matter to be reconsidered. After which the earlier decision may be given favourable or unfavourable opinion.

4. TERMS & DEFINITIONS

NACOSTI – National Commission for Science, Technology and Innovation

5. OBJECTIVES

To ensure appeals of SERU decision applications are received effectively and efficiently.

6. INPUTS/RESOURCES

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

7. EXPECTED OUTPUTS

- 7.1 Agenda
- 7.2 Record of applications received

8. KEY PERFORMANCE INDICATORS

- 8.1 No. of applications received

9. RESPONSIBILITY AND AUTHORITY

It is the responsibility of the PI to launch an appeal with the relevant authority at KEMRI whenever they have a complaint on a Committee decision made on their proposal.



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10. DETAILS OF PROCEDURE

- 10.1** Any appeals arising from a SERU Committee decision should be filed by the PI.
- 10.2** Any PI with a complaint regarding the SERU Committee's decision on their proposed research study may refer the complaint for review to the Head of SERU in writing, detailing the basis of the complaint.
- 10.3** Upon receipt of the appeal, the appeal is handled in accordance with *KEMRI SERU COMM SOP 3.0_Handling appeals of SERU decisions*
- 10.4** If, after the review of the appeal, the P.I is still dissatisfied with the decision of the SERU Committee, he/she may lodge an appeal/complaint to the National Bioethics Committee of the National Commission for Science Technology and Innovation.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Appealing SERU decisions	Appeal not reviewed by SERU	Failure to use the due process to lodge a complaint	Ensure that complaints are addressed to the Head SERU by writing

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Appealing SERU decisions	Improving review and forming precedent for committee decisions	Organizing meetings for Investigators with complains



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12. REFERENCE DOCUMENTS

11.1 Internal References

KEMRI SERU COMM SOP 3.0_Handling appeals of SERU decisions

11.2 External References

NONE

13. ANNEXES

Process Flow Chart

ANNEX 1: PROCESS FLOW CHART

<u>Players</u>	<u>Activity</u>	<u>Flow Chart</u>
Principal Investigator	Submitting research related injury/harm applications	
Centre Compliance Officer	Receives, pre-reviews and records all research related injury/harm applications submitted to SERU	
	NO	<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>