In Search Of Better Health

K E M R I

STANDARD OPERATINGPROCEDURE FOR
REQUEST FOR REVIEW OF APPLICATIONS IN EMERGENCY AND OUTBREAK SETTINGS

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1. PURPOSE

This procedure is to ensure that protocols responding to acute public health events are approved expeditiously.

2. SCOPE

This SOP covers the procedures required for an investigator to be granted a quick turn-around approval.

3. INTRODUCTION

An early response in a timely and effective way to acute public health events will prevent ongoing disease transmission and reduce the negative public health as well as social and economic consequences of disease outbreaks.

4. TERMS & DEFINITIONS

4.1 An expedited review request should be no more than minimal risk*, or a modification of an approved no more than minimal risk study, or a minor modification of a greater than minimal risk approved protocol.

4.2 *Minimal risk: the probability and magnitude of discomfort or harm anticipated in a given research that is no greater than those typically encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples include, document reviews, left over samples, anonymous samples.

4.3 A quick turnaround review request is an application or proposal that requires a faster than usual review due to a major public health concerns e.g. an epidemic.

5. OBJECTIVES

To ensure request for review of applications in emergency and outbreak settings 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

9.1 It is the responsibility of the SERU secretariat to confirm that the submitted proposal/document meet criteria for expedited review.

9.2 It is the responsibility of the investigator to submit study documents that meet criteria for expedited review and filled expedited review form to SERU secretariat for confirmation and processing.

10. DETAILS OF PROCEDURE

10.1 The PI or applicant shall be required to submit ten (10) copies of the application (one of which has the original signature) and 10 copies of the Expedited Review form

10.2 The SERU secretariat shall evaluate each application for its eligibility for expedited review upon request by the principal investigator (PI) or applicant.

10.3 Only applications which meet any of the following criteria shall qualify for expedited review:

10.3.1 New minimal risk protocols; or

10.3.2 Modifications of minimal risk studies; or

10.3.3 Minor modifications of greater than minimal risk studies

10.4 The SERU shall expedite the continuing review of minimal risk studies previously approved by the convened committee provided that any one of the following conditions applies:

10.4.1 Data analysis, report writing or manuscript preparation are the only ongoing research activities; or

10.4.2 There is no screening and/or enrolment of new study participants; or

10.4.3 All study-related interventions are completed; or

10.4.4 The research is active only in the follow-up phase; or

10.5 No study participants have been enrolled and no additional risks have been identified. The secretariat shall review and also nominate at least two (2) SERU members to undertake the expedited review of the application. Should the application be approved by the expedited review team, the Chairperson shall grant provisional approval.

10.6 The provisional approval granted by the Chairperson shall be subject to ratification at the next scheduled SERU meeting.

10.7 Any application that does not meet the criteria set out in Clause 6.3 shall not be evaluated under the expedited review process.

    10.7.1 Quick Turn Around review Request

    10.7.2 A quick turnaround review request is an application or proposal that requires a faster than usual review due to a major public health concern e.g. an epidemic (Such as Ebola, Cholera, Rift Valley Hemorrhagic Fever, Polio, Avian Flu etc.).

    10.7.3 The PI should notify the Head SERU /Secretariat by phone and e-mail of the intention to submit a protocol for quick turnaround review.

    10.7.4 A minimum of 6 reviewers shall be assigned to review the proposal.

10.8 The investigators shall submit a hard and soft copy of a complete application to SERU

10.9 The expedited or quick turn-around review team shall take no longer than six (6) working days to submit their review comments to the SERU Secretariat.

10.10   The PI shall be informed of the decision, in writing, within three (3) working days of receipt of all reviewers' comments or the date of final approval following ratification of the provisional approval by the full committee.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of Request for review of applications in emergency outbreak settings	1. Submission of an application not meeting the criteria for expedited or quick turn-around review 2. Submission of incomplete documents	1. Principal investigator failing to comply with submission requirements	1. Training of principal investigator(s)

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunity
Submission of Request for review of applications in emergency outbreak settings	Training of principal investigator(s)	Organizing training programs for KEMRI and non KEMRI investigators

12. REFERENCE DOCUMENTS

12.1 Internal References
12.1.1 N/A

12.2 External References
12.2.1 N/A

13. ANNEXES

13.1 Annex 1 – Expedited Review Request Form

ANNEX I: EXPEDITED REVIEW REQUEST FORM

KENYA MEDICAL RESEARCH INSTITUTE

SCIENTIFIC AND ETHICS REVIEW UNIT (SERU)

REQUEST FORM FOR EXPEDITED OR QUICK TURN AROUND REVIEW

Protocol Title: ……………………………………………………………………

Protocol Version No. & Date: …………………………………………………..

Centre …………………………….. SERU/SSC No: …...…………….

Name of Principal Investigator: ……………………………………………

Research Programme Area(s): ……………………………………………………….

Key Performance Area: …………………………………………………

Strategy: …………………………………………………………………..

Millennium Development Goal: …………………………………….

(Please refer to SERU page at www.kemri.org for programmes/ /Key Performance Area/Strategy and MDGs)

Study Implementation County (s): ……………………………………………….

Protocol Information:

Date of first submission ……………………….. Amendment No.: ……………..

Protocol Version number and date: _____

CHECK WHICH APPLIES

- ✓ **EXPEDITED** (An expedited request should be no more than minimal risk*, or a modification of an approved no more than minimal risk study , or a minor modification of a greater than minimal risk approved protocol)

- ✓ **QUICK TURN AROUND** this is a proposal that requires a faster than usual review due to a major public health concern e.g. an epidemic

Minimal risk: the probability and magnitude of discomfort or harm anticipated in a given research that is no greater than those typically encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Examples include, document reviews, left over samples, anonymous samples,

JUSTIFCATION:

ANNEX 2: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal Investigator	Submitting request for review of applications in emergency and outbreak settings applications	Start → Submits application
Centre Compliance Officer	Receives, pre-reviews and records all research request for review of applications in emergency and outbreak settings applications submitted to SERU	Receives application → Application Complete? → P.I Corrects Application → Agenda → End