In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR EXPEDITED REVIEW

Document Control Schedule

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

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1. PURPOSE

The purpose of this SOP is to outline the criteria for expedited review to enable investigators realize if their proposal may be reviewed through expedited process.

1.1 Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110 (*Appendix I: Expedited review research categories*). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

1.2 The categories in this list apply regardless of the age of participants, except as noted.

1.3 The expedited review procedure may not be used where identification of the Participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

1.4 The expedited review procedure may not be used for classified research involving human subjects.

1.5 IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

1.6 Categories one (scope) pertain to both initial and continuing IRB review.

2. SCOPE

This SOP describes the categories and process that are necessary for conduct of expedited/Quick turnaround review. Categories of research that qualify for expedited review as described in categories on the Annex I.

3. INTRODUCTION

There are circumstances where there maybe need to review a new protocol, ongoing approved protocol OR continuing review report through an expedited means. The review may only proceed if the document OR proposal has met the conditions allowed under OHRP guidelines.

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

4.3 ***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.

5. OBJECTIVES

To ensure expedited review 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
7.3 Receipts for amounts paid for Expedited Initial Applications (Non KEMRI)

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 An **expedited review procedure** consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

10.2 The PI or applicant shall be required to submit five (expedited review) or 10 (quick turn-around) copies of the application (one of which has the original signature) and an Expedited/Quick turn-around review request form *(Appendix II).*

10.3 The SERU secretariat shall evaluate each application for its eligibility for expedited review upon receipt of request by the PI or applicant.

10.4 Only applications which meet any of the following criteria shall be considered for expedited review as per the categories set out in Appendix I:

10.4.1 New minimal risk protocols; or

10.4.2 Modifications of minimal risk studies; or

10.4.3 A Minor modification(s) of greater than minimal risk studies that is already approved.

10.5 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:

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

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

10.5.3 All study-related interventions are completed; or

10.5.4 No study participants have been enrolled and no additional risks have been identified.

10.6 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

10.7 The provisional approval granted by the Chairperson shall be subject to ratification at the next scheduled SERU meeting. *(NB: The P.I may continue with research using the*

provisional approval while awaiting the ratification of the approval at the next available SERU meeting)

10.8 The Reviewers who conduct the expedited review do not have the authority to disapprove an application. Disapproval is an action that may be taken only at a convened SERU meeting.

11 RISKS AND OPPORTUNITIES

11.5 Risks

Process	Risk	Risk Source	Mitigation
Submitting application for expedited review	1. Wrongful determination of an application as one qualifying for expedited review 2. Submission of incomplete documents	1. Principal investigators failure to determine if an application qualifies for expedited review 2. Principal investigator's failure to comply to list of requirements	Training of principal investigators

11.6 Opportunities

Process	Opportunities	Action plan to maximize the opportunity
Submitting application for expedited review	Training	Participate in trainings on expedited review

12 REFERENCE DOCUMENTS

12.1 **Internal References**

12.1.1 SERU SOPs version 1.0 dated 27 September 2016

12.2 **External References**

12.2.1 **ICH Guideline for Good Clinical Practice**
https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf

12.2.2 45 CFR 46 https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

13 ANNEXES

13.1 Annex I – Expedited Review Research Categories

13.2 Annex II – Expedited Review Request Form

ANNEX I: EXPEDITED REVIEW RESEARCH CATEGORIES

ANNEX II: 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 III: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	Submitting expedited review request	
Centre Compliance Officer	Receives, pre-reviews and records all the expedited review request applications submitted to SERU