In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR ADMINISTRATIVE HOLD, SUSPENSION AND TERMINATION OF APPROVED RESEARCH

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure to suspend or terminate approved research.

2. SCOPE

This SOP applies to all human participant research reviewed and approved by SERU.

3. INTRODUCTION

The SERU Committee Chair or designee has the authority to suspend or terminate approval of research that is not being conducted in accordance with SERU requirements, or has been associated with unexpected serious harm to participants

4. TERMS & DEFINITIONS

4.1 Administrative Hold: An administrative hold is a voluntary action by an investigator or sponsor to temporarily or permanently stop some or all approved research activities as a modification to approved research. Administrative holds are not suspensions or terminations even if requested by SERU chair/designee. Protocols on administrative hold remain open and require continuing review. The administrative hold does not apply to interruptions of research related to concerns regarding the safety, rights or welfare of human research participants or others. Administrative holds must not be used to avoid reporting deficiencies or circumstances that otherwise require reporting by SERU

4.2 Suspension: A suspension of SERU approval is a directive of the convened SERU committee, or SERU chairperson/designee either to stop temporarily some or all previously approved research activities, or to stop permanently some previously approved research activities. Suspended protocols remain open and require continuing review. For example, SERU may stop the enrolment of new participants, but allow the continuation of currently enrolled participants, if appropriate. The convened SERU committee would review the investigator's response, if any.

4.3 Termination: A termination of SERU approval is a directive of the convened SERU committee or SERU chairperson/designee to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

5. OBJECTIVES

To ensure that research administrative hold, Suspension and termination of approved research is documented.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Email
6.4 Phone

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Record of received application

8. KEY PERFORMANCE INDICATORS

8.1 No. of Administrative hold, Suspension and Termination applications Received.

9. RESPONSIBILITY AND AUTHORITY

9.1 SERU- has the authority to suspend or terminate approval of research that is not being conducted in accordance with its policies or when in their judgement there is need to do so to protect the rights and safety of participants

9.2 Principal Investigator (P.I)- May place a voluntary administrative hold on previously approved research when, in the judgment of the P.I, an administrative hold is appropriate to protect the rights or welfare of participants

10. DETAILS OF PROCEDURE

10.1 Administrative Hold

10.1.1 Investigator informs SERU of the request for administrative hold through a notification

10.1.2 The investigator explains:

10.1.2.1 The event or reason triggering the administrative hold and whether the hold is initiated by the investigator or the sponsor of the research

10.1.2.2 Describes the research activities to be stopped (e.g., recruitment; enrollment, interventions or interactions, follow-up or all);

10.1.2.3 Indicates number of participants currently enrolled and proposed actions to protect their rights and welfare during the hold

10.1.2.4 Describes plans for implementing the proposed actions, reporting to SERU, and rescinding the administrative hold.

10.1.3 The SERU head or designee, reviews the information for completeness, contacts the investigator if necessary for additional information and makes a preliminary assessment of whether the request for administrative hold is appropriate.

10.1.4 If action is needed before the convened SERU committee meeting, the request is referred to the SERU Chair or designee. If not, it is added to the agenda of the next meeting. The action of the SERU chair or designee is reviewed by the convened SERU committee at the next meeting.

10.1.5 The minimum materials provided to SERU for review and evaluation of the request for administrative hold include:

10.1.5.1 Administrative hold notification;

10.1.5.2 Any follow-up information gathered by SERU head/Chair or designee;

10.1.5.3 Current approved research protocol;

10.1.5.4 Current approved consent document; and

10.1.5.5 Access to the complete research protocol file.

10.1.6 Determinations that may be made by SERU (or SERU chair or designee) include:

10.1.6.1 Approval of the administrative hold and action plan provided by the investigator;

10.1.6.2 Approval of the administrative hold following acceptance by the investigator of additional SERU-mandated corrective actions;

10.1.6.3 Request for further information;

10.1.6.4 Disapproval of the administrative hold;

10.1.6.5 Whether or not the event represents an unanticipated problem involving risks to participants or others or serious or continuing non-compliance;

10.1.6.6 Suspension or termination of part or all of the research.

10.1.7 Actions implemented by SERU (or SERU Chair or designee) to ensure the rights and welfare of subjects may include:

10.1.7.1 Requirement for the P.I to notify participants of the administrative hold through oral or written communications approved by SERU;

10.1.7.2 Other measures to protect the rights and welfare of participants and ensure the safe withdrawal of participants (e.g., more frequent monitoring of research or consent process).

10.1.7.3 SERU clarifies to the P.I in writing whether resumption of study activities requires SERU approval or a notification to SERU indicating that the administrative hold has been lifted and study activities resumed would suffice

10.1.8 In accordance with clause 6.17 above, the P.I. submits a notification to SERU lifting the administrative hold and/or seeks SERU approval to resume study activities..

10.2 Suspension

10.2.1 Suspension may be initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the investigator or his/her personnel.

10.2.2 Suspension of approved research by SERU may arise from an evaluation of unanticipated problems involving risks to participants or others, Violation of the rights or welfare of human participants or others substantive allegations of serious or continuing non-compliance with Federal regulations, IRB policies or institutional policies; or findings arising from continuing review or monitoring of research activities.

10.2.3 The review process depends on the event (i.e., unanticipated problem/event, non-compliance) triggering the determination of suspension. Minimum materials provided to SERU (or SERU chair or designee) include:

10.2.3.1 Report of event prompting consideration of suspension;

10.2.3.2 Any follow-up information gathered by SERU staff/Chair;

10.2.3.3 Current approved research protocol;

10.2.3.4 Current approved consent document; and

10.2.3.5 Access to the complete research protocol file.

10.2.4 The SERU committee (or SERU Chair, designee) determines and documents whether or not to suspend the research, the reason for suspending the research and the activities to temporarily stop (e.g., recruitment, enrollment, some or all interventions or interactions, follow-up, data analysis or all research activities).

10.2.5 When approval of all or part of the protocol is suspended, the SERU committee (or SERU head ordering the suspension) considers actions to protect the rights and welfare of currently enrolled participants, including, but not limited to:

10.2.5.1 Notification of participants of the suspension through oral or written communications approved by SERU;

10.2.5.2 Allowing currently enrolled participants to continue if it is in their best interest.

10.2.5.3 Changes to the protocol, consent form or other documents to correct any deficiencies and protect the rights and welfare of participants;

10.2.5.4 Procedures for withdrawal of current participants, when necessary, that take into account their rights and welfare, such as:

10.2.5.4.1 Transfer of participants to another investigator;

10.2.5.4.2 Arrangement for clinical care outside of the research;

10.2.5.4.3 Continuation of some research activities under the supervision of an individual monitor;

10.2.5.4.4 Permitting follow-up for safety reasons

10.2.5.4.5 Follow-up procedures permitted or required by SERU; or

10.2.5.4.6 Requiring the reporting of unanticipated problems involving risks to participants or others

10.2.6 The SERU Head/Committee Chair notifies the PI in writing of the suspension. The communication contains:

10.2.6.1 Description of the research activities that are suspended;

10.2.6.2 Reasons for the suspension;

10.2.6.3 Corrective actions mandated by SERU and measures needed to lift the suspension;

10.2.6.4 A request for the number of currently active participants and any measures needed to protect their rights and welfare if some or all research activities are stopped;

10.2.6.5 Timelines for implementing the proposed actions and follow-up reporting to SERU;

10.2.6.6 Notification that any request by the investigator for SERU to reconsider the suspension should be submitted within 30 days

10.2.7 The actions of the convened SERU committee are documented in the minutes of the meeting.

10.2.8 When the PI has addressed the concerns; the convened SERU committee may lift the suspension. If the concerns are not addressed, SERU may terminate the research or take other action to protect the rights and welfare of participants or others (e.g., make a finding of serious or continuing non-compliance).

10.3 Termination

10.3.1 The SERU committee shall have the authority to terminate the approval of any research for which it has granted clearance when:

10.3.1.1 There is gross misconduct by a PI or any investigators on the study that is evidently confirmed.

10.3.1.2 The research presents excessive risks to research participants i.e. the actual risk-benefit status of the study is not consonant with the predicted risk-benefit ratio prior to implementation of the study.

10.3.1.3 A PI or study team members fail to comply with research regulations.

10.3.2 The SERU Committee Chair shall request an immediate termination of further accrual of new study participants or of continued participation of previously enrolled study participants whenever any of the conditions outlined in Clause 6.1 apply.

10.3.3 The committee Chairperson shall convene a special meeting at the earliest convenience to review the termination report. The actions the SERU may request for include (but are not limited to):

10.3.3.1 A summary of the study protocol and the accrued data.

10.3.3.2 Submission of the study results at the time of termination.

10.3.3.3 Establishment of a mechanism for an extended follow-up to monitor safety issues.

10.3.3.4 Require the PI to debrief study participants of the termination and also notify those study participants who have completed study activities.

10.3.3.5 Compensation of study participants, where applicable

10.3.3.6 A requirement that the principal investigator and the study team members undertake health research ethics and GCP re-training

10.3.3.7 Perform an audit of other active studies of the principal investigator.

10.3.4 The SERU committee shall give reasons for its action and advise the PI and study sponsor, in writing, of such termination and the measures needed.

10.3.5 The termination shall occur within six (6) working days of the date the SERU committee makes the determination and no later than five (5) working days after the PI has received the notice of termination.

10.3.6 SERU shall notify the PI of the unacceptable increased risk to the participants within six (6) working days.

10.3.7 The PI shall not resume a terminated study.

10.3.8 The Committee Chairperson shall inform the study sponsor, the Director KEMRI and the Chair and Secretary of the National Bioethics Committee and, where relevant, the OHRP of the termination or withdrawal of any ethical approval.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Administrative Hold, Suspension and Termination of Approved Research	Loss of funds	Failure to submit research progress to sponsors	Ensure all the records are properly kept and consenting process is properly done.

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities

Administrative Hold, Suspension and Termination of Approved Research	Training on proper consenting	Organize training on consenting process and research management monthly

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 Final SERU SOPs Version 1.0_27 Sep 2016

12.2 External References

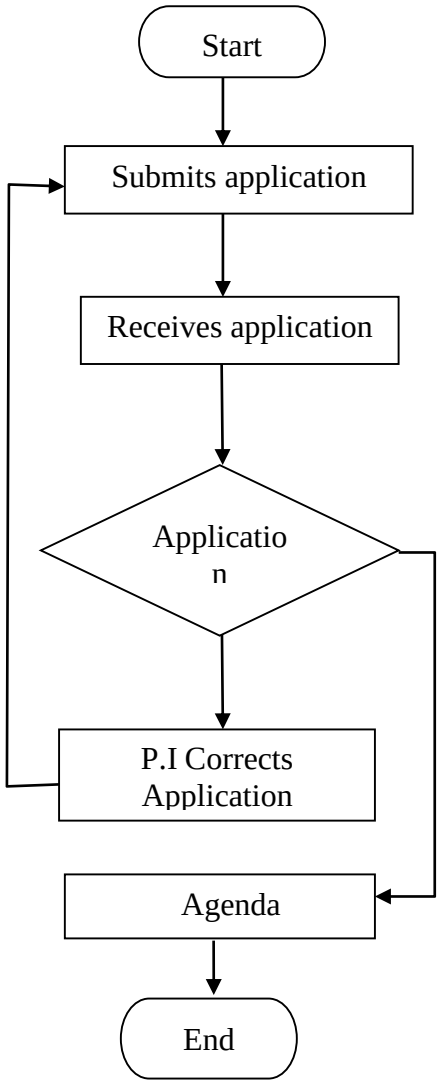
12.2.1 ICH GCP https://www.ich.org/fileadmin/Public.../ICH.../Guidelines/.../E6/E6_R1_Guideline.pdf

12.2.2 Helsinki declaration http://www.who.int/bulletin/archives/79%284%29373.pdf

13. ANNEXES

13.1 Flow chart Procedures.

ANNEX 1: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal Investigator	Submitting an application for administrative hold to SERU	
Centre Compliance Officer	Receives, pre-reviews and records all administrative hold s applications submitted to SERU	