In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR RESEARCH RELATED INJURY OR HARM

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1. PURPOSE

The purpose of this SOP is to outline what is expected of the PI in case of research related injury (injury to participant).

2. SCOPE

This SOP covers expected actions that the investigator shall comply with in the event that a participant gets study related injury.

3. INTRODUCTION

For studies that involve more than minimal risk, SERU requires informed consent documents to contain information on the availability and nature of compensation and medical treatments available if injury occurs, what they consist of, and where further information may be obtained, in accordance with local and international regulations

4. TERMS & DEFINITIONS

4.1 Research-related injury: - When an injury occurs as a result of participation in a research study it is called a “research related injury” and these are sometimes inevitable. Such injuries may range from relatively minor harms (such as bruises due to a study procedure or vomiting due to a new drug) to major injuries (such as organ damage or temporary physical disability) to catastrophic injuries (such as permanent disability or death). Injuries can be physical, psychological/emotional, social or economic and may require only acute or emergency care, or long term medical care

4.2 Adverse event (AE): - any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated

with the use of a medicinal (investigational) product, whether or not causally related to the medicinal (investigational) product.

4.3 Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR): - Any untoward medical occurrence that at any dose:

4.3.1 Results in death

4.3.2 Is life-threatening i.e. the participant was at risk of death at the time of the adverse event

4.3.3 Requires inpatient hospitalization or prolongation of existing hospitalization

4.3.4 Results in persistent or significant disability/incapacity, or

4.3.5 Is a congenital anomaly/birth defect.

4.3.6 Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical/surgical intervention to prevent one of the above outcomes

4.4 An unexpected adverse reaction (UAR) - An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for

an unapproved investigational product or package insert/summary of product characteristics for an approved product).

4.5 Suspected Unexpected Serious Adverse Reaction (SUSAR): - is any UAR that at any dose:

4.5.1 Results in death

4.5.2 Is life-threatening i.e. the participant was at risk of death at the time of the adverse event

4.5.3 Requires inpatient hospitalization or prolongation of existing hospitalization

4.5.4 Results in persistent or significant disability/incapacity, or

4.5.5 Is a congenital anomaly/birth defect.

4.5.6 Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical/surgical intervention to prevent one of the above outcomes

4.6 Harm: - is defined as economic, physical, psychological and social damage.

4.6.1 Economic Harm is financial loss resulting from participation in a research project, which may include direct losses such as amounts the claimant had to spend to try to mitigate problems and consequential economic losses resulting from lost income.

4.6.2 Physical Harm is death, bodily injury to, illness or disease in any person. Physical harms that meet the criteria of Serious Adverse Events should be reported to SERU within 10 working days

4.6.3 Psychological Harm is negative self-perception, emotional suffering (e.g., anxiety or shame), aberrations in thought or behaviour, or long-lasting intense psychological distress and fear, which in extreme cases might result into suicide.

4.6.4 Disability is physical or mental impairment that substantially limits one or more of the major life activities of such individuals including communication, walking, and self-care (such as feeding and dressing oneself) and which is likely to continue indefinitely, resulting in the need for supportive services.

4.6.5 Social harm refers to discomfort or suffering either physically, emotionally or sometimes economically, that a participant experiences during their participation in the study and that socially disadvantages the participant in one way or another

e.g. separation with a spouse, domestic violence, public shaming due to inadvertent disclosure of one's HIV status, etc

5. OBJECTIVES

To ensure research related injury/injury 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 investigator to notify KEMRI SERU of any research-related injury that occurs during his conduct of the study.

10. DETAILS OF PROCEDURE

10.1 Investigator is required to mention that in case of research related injury the participant should contact him. This information must be put in the protocol and the informed consent documents.

10.2 The investigator must include his/her contact details by which the participant can reach him/her in the informed consent document

10.3 The Investigator should provide a description of the arrangements for insurance coverage pertaining to research-related injury for participants of clinical trials.

10.4 Appropriate treatment shall be available to any subject injured as a result of participating in a research project. Treatment shall be considered an ethical obligation rather than any admission of liability. Consent forms shall indicate within the risks section the nature of available treatment for any possible serious side effects.

10.5 Example of the language that should be included in clinical trials' consent forms as per international guidelines such as Good Clinical Practice Guidelines, Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) Guidelines:

> ***WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?***
> *It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.*
> *If you are injured as a result of being in this study, (site name) will provide necessary medical treatment. The costs of the treatment may be covered by the (site name) or the study sponsor [sponsor name]. If the study sponsor covers these costs, they will need to know some information about you like your name, date of birth, and your national identification number. The study sponsor will not use this information for any other purpose. The (site name) and the study sponsor provide/does not provide other form of compensation for injury. For more information about this, you may call the KEMRI SERU at 0717 719 477 or send an email to seru@kemri.org .*

The P.I first reports any research-related injury, SAE or SUSAR to SERU via email within 48 hours of occurrence or becoming aware of the event

The P.I subsequently submits hard copies of any research-related injury, SAE or SUSAR to SERU within 5 working days of occurrence or becoming aware of the event (*See Appendix 1 - SERU template for reporting SAEs/SUSARs/Research-related Injury/Harm*).

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of research related injury application	1.Miss classification of an event by the Principal investigator 2.Submission of documents that do not meet the criteria for acceptance by the Centre Compliance Officer 3.Late submission of research related injury reports to SERU thus putting the participant at risk 4.Denial, withholding or unknowingly withholding care to participant	1.Principal Investigator failure to correctly classify an event 2.Principal investigator failure to submit all the required documents 3.Failure by the principal investigator to submit the reports within the stipulated timelines 4.Failure by the principal investigator to take care of the participant	Attend Trainings

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunity
Submission of research related injury application	Trainings on research related injury application	Scheduling training programs for both KEMRI and no KEMRI based principal investigators

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 ICH GCP E6 Guidelines
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

12.2.2 *US Department of Human health Services (DHHS) Regulations:* Elements of Informed Consent: 45 CFR 46.116(a) (6) (7)
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

12.2.3 *FDA Regulations:* Elements of Informed Consent: 21 CFR 50.25(a) (6) (7)
https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm291085.pdf

12.3 Other information sources

12.3.1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601709/

12.3.2
http://ora.research.ucla.edu/OHRPP/Documents/Policy/10/Treatment_Compensation.pdf

13. ANNEXES

13.1 See Annex 1 - SERU template for reporting SAEs/SUSARs/Research-related Injury/Harm

KENYA MEDICAL RESEARCH INSTITUTE

ANNEX I: SERU TEMPLATE FOR REPORTING SAES/ SUSAR/ RESEARCH RELATED INJURY/HARM

A. Title of Proposal:
B. Principal Investigator(s):
C. SSC/SERU/NON-SSC/NON KEMRI No.
D. PI's mailing address:
E. Date of Report:
F. Type of Report: Initial or Follow-up
G. Study participant information: Identification number, age, height, weight, etc.
H. SAE/SUSARs/Injury/Harm start date:
   SAE/SUSARs/Injury/Harm stop date: *or indicate if Ongoing*
I. State the location of the SAE/SUSAR/Injury/Harm, if applicable:
J. Describe the SAE/SUSAR/Injury/Harm: Describe the signs, symptoms, severity, time course, relevant medical history and laboratory data. Include results of confirmatory procedures, if any. Indicate any medication required to treat the SAE/SUSAR/Injury/Harm and the outcome.
K. Give a presumptive diagnosis where applicable
L. Describe the investigational drug, medical treatment or procedure or device causing the SAE/SUSAR/Injury/Harm.
M. Describe the circumstances of the occurrence of the SAE/SUSAR/Injury/Harm, where applicable:
   E.g. Death (whether an autopsy was done), congenital abnormality, indicate whether it is life-threatening, if prolonged hospitalization is required, if persistent or significant disability occurred, if the study participant requires medical or surgical intervention to prevent other outcomes.
N. Describe the action taken:
O. Specify any simultaneous treatment.
P. State the relationship to the drug/participation in a project *e.g. not-related, possibly, probably, definitely, unlikely related to drug/participation and explain why.*
Q. State if the SAE/SUSAR/Injury/Harm is described in the current approved informed consent/assent document.
R. State if the SAE/SUSAR/Injury/Harm requires a change or changes in the consent/assent documents and to the study procedures.
S. State whether or not the enrolled study participants will be advised of the SAE/SUSAR/Injury/Harm. If yes, explain how this new information will be conveyed. If not, explain why.
T. Indicate whether the study sponsor and/or the DSMB have been notified.

ANNEX 2: PROCESS FLOW CHART

Players	Activity	Flow Chart
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