# **SERU TEMPLATE FOR REPORTING SAES/ SUSAR/ RESEARCH** RELATED INJURY/HARM

1. Title of Proposal:
2. Principal Investigator(s):
3. SSC/SERU/NON-SSC/NON KEMRI No.
4. PI’s mailing address:
5. Date of Report:
6. Type of Report: Initial or Follow-up
7. Study participant information: Identification number, age, height, weight, etc.
8. SAE/SUSARs/Injury/Harm start date:

SAE/SUSARs/Injury/Harm stop date: *or indicate if Ongoing*

1. State the location of the SAE/SUSAR/Injury/Harm, if applicable:
2. 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.
3. Give a presumptive diagnosis where applicable
4. Describe the investigational drug, medical treatment or procedure or device causing the SAE/SUSAR/Injury/Harm.
5. 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.*

1. Describe the action taken:
2. Specify any simultaneous treatment.
3. 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.*
4. State if the SAE/SUSAR/Injury/Harm is described in the current approved informed consent/assent document.
5. State if the SAE/SUSAR/Injury/Harm requires a change or changes in the consent/assent documents and to the study procedures.
6. 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.
7. Indicate whether the study sponsor and/or the DSMB have been notified.