**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**:
9. **SAE/SUSARs/Injury/Harm stop date**: or indicate if Ongoing
10. **State the location of the SAE/SUSAR/Injury/Harm, if applicable**:
11. **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.
12. **Give a presumptive diagnosis** where applicable
13. **Describe the investigational drug, medical treatment or procedure or device causing the SAE/SUSAR/Injury/Harm**.
14. **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.
15. **Describe the action taken**:
16. **Specify any simultaneous treatment**.
17. **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.
18. **State if the SAE/SUSAR/Injury/Harm** is described in the current approved informed consent/assent document.
19. **State if the SAE/SUSAR/Injury/Harm** requires a change or changes in the consent/assent documents and to the study procedures.
20. **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.
21. **Indicate whether the study sponsor and/or the DSMB have been notified**.