**(Annexure 7)**

## Serious Adverse Event Reporting Format

This form must be completed and returned to the MPHREC secretariat within 24 hours for serious adverse events and unexpected events. One form is to be completed per participant, even if several participants are involved in a similar adverse event.

……………………....…………………………………………………………………………………… ***(Name of the Institution)***  MPHREC Ref. No. ***(For office use):***

Title of study:

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….

Principal Investigator (Name, Designation and Affiliation): ……………………………………………………………………………………………………………………………………………………………………………………………………………………

|  |  |  |
| --- | --- | --- |
| **PARTICIPANT INFORMATION** | | |
| Participant ID: |  | |
| Participant Age: |  | |
| Participant Gender: |  | |
| Weight:……………..(Kgs) |  | |
| Height:.….………….(cms) |  | |
| **SERIOUS ADVERSE EVENT (SAE)** | | |
| Suspected SAE diagnosis:  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| SAE Report Type | Initial  | |
| Follow-up  | |
| Final  | |
| If Follow-up report, state date of Initial report: |  | |
| Describe the event [[1]](#footnote-1): |  | |
| Date of reporting SAE: |  | |
| ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. Details of suspected intervention causing SAE [[2]](#footnote-2)   ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. Have any similar SAE occurred previously in this study? If yes, please provide details. | | Yes **** No **** |
| ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. In case of a multi-centric study, have any of the other study sites reported similar SAEs? | | Yes **** No **** |
| (Please list number of cases with details if available):  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process): 2. Expected event **** Unexpected event **** 3. Hospitalization **** Increased Hospital Stay **** Death ****   Congenital anomaly/birth defect **** Persistent or significant disability/incapacity ****  Event requiring intervention (surgical or medical) to prevent SAE ****  Event which poses threat to life ****Others (specify) ****  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  In case of death, state probable cause of death  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….   1. No permanent/significant functional/cosmetic impairment **** 2. Permanent/significant functional/cosmetic impairment **** 3. Not Applicable **** | | |
| 1. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom):   ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom)   ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. Outcome of SAE | Fatal **** | |
| Continuing **** | |
| Recovering **** | |
| Recovered **** | |
| Unknown **** | |
| Other ***(specify)*  *……………………………………………….*** | |
| 1. Provide any other relevant information that can facilitate assessment of the case such as medical history:   ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| 1. Provide details about PI’s final assessment of SAE relatedness to research:   ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  ………………………………………………………………………………………………………….  …………………………………………………………………………………………………………. | | |
| Signature of PI: |  | |
| Date: |  | |

1. Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious [↑](#footnote-ref-1)
2. Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s) [↑](#footnote-ref-2)