|  |  |
| --- | --- |
|  | **(Annexure 7B)**  **Serious Adverse Event Reporting Format(Clinical trials)**  Rajiv Gandhi Centre for Biotechnology  **EC Ref. No*.(for office use):*** |

|  |
| --- |
| Title of study:  Principal Investigator (Name, Designation and Affiliation) |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | Participant details : | | | | | | | |
|  | Initials and Case No./Subject ID | Age at the time of event | | | | Gender  Male  Female | Weight:     (Kgs)  Height:      (cms) | |
| 2. | Report type: Initial  Follow-up  Final  If Follow-up report, state date of Initial report Click here to enter a date.  What was the assessment of relatedness to the trial in the initial report?   |  |  |  | | --- | --- | --- | | By PI- Related | By sponsor - Related | By EC - Related | | Unrelated | Unrelated | Unrelated | | | | | | | | |
| 3. | Describe the event and specify suspected SAE diagnosis: | | | | | | | |
| 4. | Date of onset of SAE: Click here to enter a date. | | | | Date of reporting: Click here to enter a date. | | | |
| 5. | Onset lag time after administration of intervention: | | | | Location of SAE (Clinic/Ward/Home/Other) | | | |
| 6. | Details of suspected study drug/device/investigational procedure causing SAE: | | | | | | | |
|  | 1. Suspect study drug (include generic name) device/intervention: | | | | | | | |
| 1. Indication(s) for which suspect study drug was prescribed or tested: | | | | | | | |
| 1. Route(s) of administration, daily dose and regimen, dosage form and strength: | | | | | | | |
| 1. Therapy start date: Click here to enter a date. Stop date: Click here to enter a date. | | | | | | | |
| 7. | Was study intervention discontinued due to event? Yes  No | | | | | | | |
| 8. | Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes  No  If yes, provide details about the reduced dose. | | | | | | | |
| 9. | Did the reaction reappear after reintroducing the study drug / procedure? Yes  No  NA  If yes, provide details about the dose. | | | | | | | |
| 10. | Concomitant study drugs history and lab investigations:   1. Concomitant study drug (s) and date of administration: Click here to enter a date.      1. Relevant test/laboratory data with dates:Click here to enter a date.      1. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc) | | | | | | | |
| 11. | Have any similar SAE occurred previously in this study? If yes, please provide details. Yes  No | | | | | | | |
| 12. | Seriousness of the SAE: | | | | | | | |
|  | Death  Life threatening  Hospitalization-initial or prolonged  Disability | |  | Congenital anomaly  Required intervention to prevent permanent impairment / damage  Others (specify) | | | |  |
| 13. | 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). | | | | | | | |
| 14. | Outcome of SAE: | | | | | | | |
|  | Fatal  Continuing  Recovering | |  | Recovered  Unknown  Other (specify) | | | |  |
| 15. | Was the research subject continued on the trial? Yes  No  NA | | | | | | | |
| 16. | Provide the details about PI final assessment of SAE relatedness to trial. | | | | | | | |
| 17. | Has this information been communicated to sponsor/CRO/regulatory agencies? Yes  No  Provide details if communicated (including date) | | | | | | | |
| 18. | Does this report require any alteration in trial protocol? Yes No | | | | | | | |
| 19. | Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom)  Signature of PI: Click here to enter a date. | | | | | | | |