**Yenepoya Ethics Committee-1**

**Annexure 1: Ann01/SOP12/v4**

**Checklist for Adverse Events/Serious Adverse Event (SAE) submission**

**(For Onsite SAE)**

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| **Sl No.** | **Reporting Details** | | |
| 1. | **Country** (Name of the country should be specified) |  | |
| 2. | **SAE report of death or other than death**  **Please tick (**✓**)** | **Death** | **Other than** **death** |
| **Yes/No** | **Yes/No** |
| 3. | **In case of Serious Adverse Event (SAE), please specify if there is any injury to the participant**  (Please specify Yes/No) in the box | **Yes/No** | |
| 4. | Protocol Title |  | |
| 5. | Protocol Study No./ ID /Code |  | |
| 6. | Copy of trial permission obtained from CDSCO |  | |
| 7. | CTRI Registration No. |  | |
| 8. | Sponsor (Address with contact no and Email) |  | |
| 9. | CRO (Address with contact no and Email) |  | |
| 10. | Initial/Follow-up (FU) |  | |
| 11. | In case of follow-up: Date & Diary no of initial or recently submitted report information |  | |
| 12. | **Participant Details:**  Initials & other relevant identifiers  Gender  Age and/or date of birth  Weight  Height |  | |
| 13 | **Nature of the intervention:**   1. Suspected Drug(s) 2. Generic name of the drug 3. Indication(s) for which suspect drug was prescribed or tested 4. Dosage form and strength 5. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) 6. Route of administration 7. Starting date and time of day 8. Stopping date and time, or duration of treatment   b. Any other intervention (specify)  *Provide the same information for concomitant drugs (including non prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).* |  | |
| 14 | **Details of clinical findings:**   1. Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. 2. In addition to a description of the reported signs and symptoms, whenever possible, assign a specific diagnosis for the reaction. 3. Start date (and time) of onset of reaction. 4. Stop date (and time) or duration of reaction. 5. Dechallenge/rechallenge information (if any) 6. Setting (e.g. hospital, out-patient clinic, home, nursing home). |  | |
| 15 | **Outcome:**   1. Required hospitalization: Yes/No 2. Number of admission days: 3. Please provide results of specific tests and other laboratory reports (if any) that were carried out in relation to the adverse event: 4. Details of the treatment provided (including procedures or surgeries or other interventions done in relation to the adverse event): 5. Details on the recovery or other sequelae: 6. If discharge summary is available please provide a copy: 7. Any permanent disability or functional loss? 8. Is the adverse event associated with a congenital anomaly? 9. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction (include post mortem findings - if any): |  | |
| 16. | **Other Information:**  *Anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history, findings from special investigations etc* |  | |
| 17. | **Details about the Investigator**  CT Site number, if any  Name  Address  Telephone/Mobile Number & Email  Profession (speciality)  Date of reporting the event to Licensing Authority  Date of reporting the event to Yenepoya Ethics Committee - 1 |  | |
| 18 | **Details about Yenepoya Ethics Committee - 1**  Name and address  Name of Chairman & Address  Telephone/Mobile Number  Email  Whether EC is recognized by DCGI | Yes/No | |
| 20 | **Causality assessment** by investigator. | Related/Unrelated | |
| 21 | **Causality Assessment** by sponsor/CRO | Related/Unrelated | |
| 22 | **Details of compensation provided for injury or death.**  *If no compensation paid, reason for the same* |  | |
| 23 | **Other related documents:**   1. Filled SAE Form as per current regulations 2. Post-mortem report (if applicable) 3. Any additional documents |  | |
| 24 | **Details of payment for medical management of SAE?** (please give information who paid, how much, to whom and evidence of the same) |  | |
| 25 | What is the investigator’s assessment for the amount of compensation to be paid? |  | |
| 26 | What is the sponsor’s assessment for the amount of compensation to be paid? |  | |
| 27 | Has the participant made a claim? | Yes/No  Comment | |
| 28 | If yes for 27, then, for how much amount? |  | |
| 29 | **If no, please ensure that the participant/nominee have been made aware of his/her rights regarding compensation.**  *Please submit documentation regarding the same*. |  | |
| 30 | **Signature of Principal Investigator with date** |  | |
| **Review of the SAE subcommittee** | | | |
| 31 | Brief summary: |  | |
| 32 | Possibility of relatedness  Need for compensation  Quantum of compensation |  | |
| 33 | Decision:   1. No further  action  required: 2. Request information: 3. Recommend  further action |  | |

*Note: Information not relevant to a particular SAE should be marked with NA*