**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 identifiersGenderAge and/or date of birthWeightHeight |  |
| 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 anyNameAddressTelephone/Mobile Number & EmailProfession (speciality)Date of reporting the event to Licensing AuthorityDate of reporting the event to Yenepoya Ethics Committee - 1 |  |
| 18 | **Details about Yenepoya Ethics Committee - 1**Name and addressName of Chairman & AddressTelephone/Mobile NumberEmailWhether 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/NoComment  |
| 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*