**CHECKLIST FOR SUBMISSION OF SERIOUS ADVERSE EVENT REPORT (SAE) OCCURRING IN CLINICAL TRIALS**

|  |  |
| --- | --- |
|  | **Information**: |
| Subject No:Details: |  |
| SAE report of death or other than death, Please tick (✓)Death □Other Than Death □ |  |
| In case of Serious Adverse Event(SAE) ,please specify if there is any injury to the subject in the box: |  |
| Copy of Clinical Trial permission obtained from CDSCO |  |
| CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09) |  |
| In case of follow-up: Date & Diary no of initial or recently submitted report information |  |
| Initials & other relevant identifier (hospital/OPD record number etc.) |  |
| Suspected Drug(s) |  |
| Generic name of the drug. |  |
| Indication(s) for which suspect drug was prescribed or tested. |  |
| Dosage form and strength. |  |
| Daily dose and regimen (specify units - e.g., mg, ml, mg/kg). |  |
| Route of administration. |  |
| Starting date and time of day. |  |
| Stopping date and time, or duration of treatment |  |
| Other Treatment(s) |  |
| Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s). |  |
| **Details of the events:** |  |
| Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious.In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction. |  |
| Start date (and time) of onset of reaction. |  |
| Stop date (and time) or duration of reaction. |  |
| Dechallenge and rechallenge information. |  |
| Setting (e.g., hospital, out-patient clinic, home, nursing home). |  |
| Outcome |  |
| Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted. |  |
| For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings. |  |
| 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. |  |
| Details about the Investigator: |  |
| CT Site Number, if any |  |
| Name |  |
| Address |  |
| Telephone/Mobile Number & Email |  |
| Profession (specialty) |  |
| Date of reporting the event to Licensing Authority: |  |
| Date of reporting the event to Ethics Committee overseeing the site: |  |
| Signature of the Investigator |  |
| Details about the Ethics Committee: |  |
| Name & Address |  |
| Name of Chairman & XXXXXXXXXXXXX HILLS |  |
| Telephone/Mobile Number |  |
| Email |  |
| Adverse Event Term / Details of SAE |  |
| Causality Assessment (Related/Unrelated) by Investigator |  |
| Causality Assessment (Related/Unrelated) by Sponsor/CRO |  |
| Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same : |  |
| Duly filled SAE Form as per Appendix XI of Schedule Y |  |
| Laboratory investigations report /Discharge summary (if available and applicable) |  |
| Post-mortem report (if applicable)/ Any additional documents) |  |