Annexure 21A

Data Elements for reporting serious adverse events occurring in a clinical trial

(Schedule Y http://dbtbiosafety.nic.in/act/schedule_y.pdf)

1. Patient Details
   - Initials & other relevant identifier (hospital/OPD record number etc.)*
   - Gender
   - Age and/ or date of birth
   - Weight
   - Height
2. 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

3. 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).
4. Details of Suspected Adverse Drug Reaction(s)
   - Full description of reaction(s) including date, time, 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.*
   - Setting (e.g. hospital, out-patient clinic, home, nursing home).
5. 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.

6. Details about the Investigator*
   - Name
   - Address
   - Telephone number
   - Profession (speciality)
   - Date of reporting the event to Licensing Authority:
   - Date of reporting the event to Ethics Committee overseeing the site:
   - Signature of the Investigator