**ANNEXURE .11: Form VI**

**DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY**

*Kindly upload soft copy on: iec.igmc.sml@gmail.com*

1. Patient Details:
2. Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)\*
3. Gender
4. Age or date of birth
5. Weight
6. Height
7. Suspected Drug(s):
8. Generic name of the drug\*
9. Indication(s) for which suspect drug was prescribed or tested.
10. Dosage form and strength.
11. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).
12. Route of administration.
13. Starting date and time of day.
14. Stopping date and time, or duration of treatment
15. Other Treatment(s):
16. Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).
17. Details of Serious Adverse Event:

Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event\*

1. Start date (and time) of onset of event.
2. Stop date (and time) or duration of event.
3. Dechallenge and rechallenge information.
4. Setting (e.g., hospital, out-patient clinic, home, nursing home).
5. Outcome:

Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.

1. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; 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.

1. Details about the Investigator\*

Name and Address

Telephone number: Email ID:

Profession (specialty):

Date of reporting the event to Central Licensing Authority:

Date of reporting the event to ethics committee overseeing the site:

Signature of the Investigator or Sponsor

**Note:** Information marked \* must be provided.