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**Guidelines for Submitting Serious Adverse Events**

**Serious Adverse Event (SAE):** A serious adverse event (SAE) in human drug trials is defined as:

Any untoward medical occurrence that at any dose results in

1. Death
2. Is life-threatening
3. Requires inpatient hospitalization or prolongation of existing hospitalization
4. Results in persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

**Procedure for reporting:**

All interventional trials approved by the JSSDCH IEC will come under the purview of this policy (drugs, devices, and behavioral or educational interventions; single or multiple armed trials, randomized or non-randomized).

**For all SAE reports:** Within **24 hours** of learning about an unanticipated or serious adverse event, the principal investigator is responsible for notifying the **DCGI, the Study Sponsor (if external), and the chairperson of the Institutional Ethics Committee (jssdchiec@gmail.com).**

Within **10 days** the principal investigator has to submit a follow-up report to the same list of people as above. **IF IT IS A DEATH REPORT, THEN THIS MUST ALSO BE SENT TO THE EXPERT COMMITTEE OF DCGI, JSSDCH IEC, AND THE HEAD OF THE INSTITUTION (both should have a copy of the original report to the DCGI).**

**REFER TO THE CDSCO GUIDELINES FOR THE FORMAT OF SAE REPORTING.**

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

*1. Patient Details*

1. Initials & other relevant identifier (hospital/OPD record number etc.) \*
2. Gender
3. Age and/or date of birth
4. Weight
5. Height
6. *Suspected Drug(s)*
7. Generic name of the drug\*
8. Indication(s) for which the suspect drug was prescribed or tested
9. Dosage form and strength
10. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
11. Route of administration
12. Starting date and time of day
13. Stopping date and time, or duration of treatment
14. *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).

1. *Details of Suspected Adverse Drug Reaction(s)*
2. Full description of reaction(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. \*
3. Start date (and time) of onset of reaction
4. Stop date (and time) or duration of the reaction
5. Dechallenge and rechallenge information
6. Setting (e.g., hospital, out-patient clinic, home, nursing home)
7. *Outcome*
8. Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted
9. For a fatal outcome, cause of death, and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.
10. Other information: anything relevant to facilitate the 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\**

1. Name
2. Address
3. Telephone number
4. Profession (specialty)
5. Date of reporting the event to Licensing Authority:
6. Date of reporting the event to the Ethics Committee overseeing the site:

\*Information asked must be provided.

Name and Signature of Principal Investigator / Student with Date