Title: Review of Serious Adverse Event (SAE) Reports

SOP Code: SOP 12/V1 Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) reported to the IEC for any study under the oversight of the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of SAE reports (Adverse events/ SAE onsite as well as SAEs of the multicenter studies occurring at other sites offsite) submitted to the IEC.

3. Responsibility

It is the responsibility of the IEC to review all SAEs reported to the IEC in a timely manner.

4. Definitions

1] Serious Adverse Event:

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect *[ICHGood-Clinical-Practice-Guideline http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline]*

2] Serious Adverse Event or Serious Adverse Drug Reaction

An AE or ADR that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening. *[Indian Good-Clinical-Practice-Guideline guidelines http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf]*

3] Adverse Event

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. *[ICH Good-Clinical-Practice-Guideline*

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline]

5. Detailed instructions

5.1 SAE Subcommittee

- An SAE Subcommittee may be constituted within the IEC for big institutions having a large number of SAE reports for review.
- The Serious Adverse Event (SAE) Subcommittee of the Institutional Ethics Committee' (IEC) will review all serious adverse events (SAE) at the site / other sites involving human participants approved by IEC.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

Composition of the SAE Subcommittee

- The SAE Subcommittee will be appointed by the **Chairperson of IEC**
- The SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
- The SAE Subcommittee will be composed of at least 5 and a maximum of 10 individuals who are members of the IEC.
- The composition shall be as follows:
  - ✓ Chairperson of the SAE Subcommittee

- ✓ One Executive Secretary
- ✓ At least one member with post graduate qualification in the discipline of
    - Medicine
    - Medical Pharmacology
    - Any other relevant clinical specialties in the institution

- IEC Secretary will be Ex-Officio member of the SAE Subcommittee.
- The SAE Subcommittee may invite legal expert of the IEC to provide opinion on the legal implication of adverse event.
- The Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.
- The Head of the SAE Subcommittee/ Executive Secretary will sign minutes of the SAE Subcommittee meeting.
- In case of anticipated absence, the Head of SAE subcommittee will nominate a SAE subcommittee member as acting head. The acting Head will have all the powers of the Head of SAE subcommittee for that meeting.
- For the SAE Subcommittee meeting, a quorum will consist of at least 4 members as follows- one member (preferably pharmacologist), one member (preferably clinician), executive secretary and Head/ Acting head of the SAE subcommittee.
- The SAE subcommittee will meet at least once in a week (or as often as required)

Membership requirements

- IEC Members will be appointed to the SAE Subcommittee if they show willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member.
- The Head of the Institute (HOI) is responsible for appointing the SAE Subcommittee members. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institution

HOI. The final decision regarding appointment of members will be taken by the HOI.

- The tenure of SAE Subcommittee will be for a continuous period of two (2) years from the date of appointment.
- The retiring member will be eligible to be appointed for the new tenure consecutively four times.
- An SAE Subcommittee member may resign from membership by submitting a letter of resignation to the Executive Secretary of the SAE Subcommittee. The member may or may not assign reasons for resignation.
- A SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend more than 5 regular consecutive SAE

  Subcommittee meetings without prior intimation. The Head of SAE Subcommittee will inform Chairperson, in writing, if a member has not attended more than five consecutive regular meetings of the SAE Subcommittee. The Chairperson will take

  up the issue of disqualification for discussion at the full board meeting and allow the concerned SAE Subcommittee member to state his reasons for unauthorized absence.

Functions of the Executive Secretary of the SAE Subcommittee

1. To schedule and organize the SAE Subcommittee meetings.
2. To prepare and maintain meeting agenda and minutes.
3. To conduct SAE subcommittee meetings
4. To prepare the communication letters related to the adverse event reports.
5. To communicate with the IEC members, regulatory authorities and investigators in timely manner.
6. To provide necessary administrative support for SAE Subcommittee related activities.
7. To ensure adherence of the SAE Subcommittee functioning as per SOPs

5.2 ***Onsite SAE***

5.2.a. Receipt of SAE report

- The IEC Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant:
  - i. Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified in *AX 01/SOP 12/V1*.
  - ii. Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE along with the format specified in *AX 02/SOP 12/V1*.
  - iii. Due analysis will also be submitted by the sponsor within 14 days in the format specified in *AX 02/SOP 12/V1*.
  - iv. The follow up reports of all on-site SAE till the event is resolved.
- The IEC Secretariat will verify that the report is complete in all respects and that it has been received at the IEC office within the specified timelines.
- If the report has been received beyond the specified time, it will be considered as a protocol violation and action should be taken as described in SOP 11
- The IEC Secretariat will sign and write the date on which the report is received.
- The Secretariat will forward these reports to the IEC Member Secretary or Executive Secretary of the SAE Subcommittee (if constituted) within two working days.

***5.2 b*. Review and Decision on SAE Reports and Communication to PI and Regulatory Authority by IEC**

- Member Secretary or Executive Secretary of the SAE will review the SAE report and present to the full board / SAE subcommittee (as applicable) for review and opinion.
- At the meeting of IEC or SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion [http://cdsco.nic.in/writereaddata/GSR%2053(E)%20dated%2030.01.2013.pdf http://www.iscr.org/pdf/Gazaate_notification.PDF_dated_12th_December_2014, Formula for calculating amount of compensation study related death, http://www.cdsco.nic.in/writereaddata/formula2013SAE.pdf) and for study related injury other than death http://www.cdsco.nic.in/writereaddata/uploaded_for_website__1_final2014.pdf]
- If deemed necessary, a decision to hold emergency IEC meeting may be taken to discuss about financial compensation. An emergency IEC meeting will be scheduled within 7 days for the same.
- The Executive Secretary of the SAE subcommittee may refer the SAE report to full board for review if deemed necessary
- The minutes of the SAE Subcommittee/ IEC meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE .

Particip ant ID	Letter no./and date of reportin	Type of Report (I/FU)	Date of onset	whether study drug withheld	SAE Outc ome	Causality in the opinion of PI	Recommen dation(s) by the SAE Sub

	g							Committee

I-initial, FU- Follow-Up

The minutes will be circulated to the IEC members *via* email and approval/ objection will be sought from the members in a period of 5 working days.

- The IEC secretariat will draft a formal letter to the concerned PI and inform him/ her about the IEC decision. This letter will be signed and dated by the Member-Secretary or Chairperson (IEC) and will be sent to the PI within a period of 7 days from the date of the SAE subcommittee meeting.
- The PI will be requested to reply to the query letter on the SAE report within 7 working days.
- The opinion regarding relatedness, medical management and compensation for research related injury will be communicated to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE in case of regulatory clinical trials.
- The Administrative Officer will file a copy of these letters in the study file.

5.3. Reports of SAE Occurring at other Sites

The investigator will need to submit the SAEs occurring at other sites (CIOMS and SUSARS) in the form of soft copies only (CD) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:.

Sr. No.	Country.	Type of Report (I/FU)	SAE event	Date of onset	Date of report	Out come	Causality	
							Investigator	Sponsor

I-initial, FU- Follow-Up

- For every SAE term, a separate row of the above table is to be used (the SAE terms should not be combined).
- Causality to be stated as related (R) or not related (NR)
- The SAEs occurring at other sites will be reviewed by the Secretary of the IEC / SAE Subcommittee (as applicable) and informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites.

5.4. Onsite AE

The IEC Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by the IEC:

1. On site AE reports to be submitted by the PI annually in the continuing review report.

2. In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

- The IEC Secretariat will verify that the report is complete in all respects and signed and dated by the PI and that it has been received at the IEC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as deviation.
- For all the onsite AE reports received at the IEC office, the Administrative Officer will forward these reports to the Member Secretary of IEC for review.
- Member Secretary of IEC may put the AE reports for discussion at full board if deemed necessary
- Queries, if any on the report will be communicated to the PI by the Member Secretary of IEC following full board meeting
- The Administrative Officer will file a copy of these letters in the study file.

5.5. Review During the Full board IEC meeting

- The IEC Member Secretary will read out the minutes of all the weekly SAE Sub-committee meetings including the recommendations/ decisions of the SAE sub-committee (if constituted).
- In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.
- The decision can be arrived at by consensus. If not agreed by consensus, the issue would be put for voting. (a majority vote for a decision is 2/3rd majority of the members present and voting)

5.6 Decision of IEC on SAE review

The SAE Subcommittee/IEC may take one or more of the following decisions on review of the SAE reports.

***5.6a*. Type of Actions Taken by IEC/ SAE Subcommittee on Review of SAE Report:**

Following detailed review of the SAE reports and related documents, the IEC/ SAE Subcommittee (if constituted) can suggest one of the following actions:

- Note the information about the SAE in records for future reference.
- Request further follow up information and/ or additional details.
- Ask for periodic follow-up of the research participant till SAE is resolved
- Depending on complexities of issue, **IEC/ SAE Subcommittee** may decide to seek opinion of outside expert consultant who is requested to respond within 14 working days.
- Provide recommendations regarding/ raise queries related to compensation for study related injury and death

***5.6b*. Type of Actions Taken by IEC following full board review**

- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents.
- Suspend the study till additional information is available.
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).
- Suspend the study till amendments requested for by the IEC are carried out.
- Suspend enrollment of new participants.

- Suspend certain activities under the protocol.
- Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.
- Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional
- procedures, additional investigations, etc. as prescribed in the amendment.
- Terminate the study.
- Any other appropriate action.

- The decision shall be recorded in the minutes of the full board IEC meeting.
- If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the PI through telephone, fax or email within 24 hours. Such a communication will be documented by the IEC Member-Secretary in the study file. A formal letter to the PI informing about the IEC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

6. References to other applicable SOPs

- **SOP 07A/V1** - *Initial Full-Board Review of Research Study Protocols*
- **SOP 08/V1** - *Agenda Preparation, Meeting Procedures and Recording of Minutes*
- **SOP 10/V1** - *Continuing Review of Study Protocols*

6. Annexures

Annexure 1 *AX 01/SOP 12/V1* – As per Schedule Y Appendix XI: Data Elements for Reporting serious adverse events occurring in a clinical trial (Schedule Y http://dbtbiosafety.nic.in/act/schedule_y.pdf)

Annexure 2A *AX 02A/SOP 12/V1* - Checklist for Onsite Serious Adverse Event submission

Annexure 2B *AX02B/SOP12/V1 – Onsite* Serious Adverse Event Analysis Report

Annexure 1: AX 01/SOP 12/V1

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 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).

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

Annexure 2A: AX 02A/SOP12/V1

Checklist for Serious Adverse Event (SAE) submission

(For Onsite SAE)

Sr. No.	**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	**Page 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		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
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.	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		

b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13.	**Suspected Drug(s)**		
a)	Generic name of the drug		
b)	Indication(s) for which suspect drug was prescribed or tested		
c)	Dosage form and strength		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)		
e)	Route of administration		
f)	Starting date and time of day		
g)	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).		
15.	**Details of the events**		
a)	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.		
b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		

16.	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	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**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term/ Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by		

	Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23.a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Note: Information not relevant to a particular SAE should be marked with NA

Annexure 2B: AX 02B/SOP 12/V1

Serious Adverse Event (SAE) Analysis Report

(For Onsite SAE)

Sr. No.	**Details**		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death,** Please tick (✓)	**Death** ☐ **Yes / No**	**Other than Death** ☐ **Page 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		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from		

	CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
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.	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13.	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength.		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
e)	Route of administration.		
f)	Starting date and time of day.		
g)	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).		
15.	**Details of the events**		

a)	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.		
b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	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**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee		

	overseeing the site:		
h)	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)

What is the investigator's assessment for the amount of compensation to be paid?

What is the sponsor's assessment for the amount of compensation to be paid?

Has the participant made a claim? Yes No

If yes, for how much amount _____

If no, please ensure that the participant / nominee have been made aware of his/her' rights regarding compensation. Please submit documentation regarding the same

_____

_____

Signature of the Principal Investigator : Date:_____

6. Flowchart

No.	Activity	Responsibility
1	Receipt of SAE report	IEC Secretariat
2.	Submission of SAE report to the SAE Subcommittee	IEC Secretariat
3	Agenda and Minutes of the Subcommittee (if constituted)	Executive Secretary of the SAE Sub-committee (if constituted)
4.	Review and discussion of SAE report at the Subcommittee meeting (if constituted)	SAE Subcommittee members (if constituted)
5.	Review and discussion of SAE report at the full Board meeting	Member Secretary
6.	Communication of the IEC decision about SAE review to the Licensing authority	Executive Secretary of the SAE Sub-committee (if constituted)/ Member Secretary
7.	Communication of the IEC decision about SAE review to the principal investigator	Executive Secretary of the SAE Sub-committee (if constituted)/ Member Secretary,IEC Secretariat