Title: Review of Serious Adverse Events (SAE) Reports

SOP Code: SOP12/v2

Effective Date: 15/07/2016

Prepared by:

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1. **Purpose:**

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures to be followed for the review of initial and follow-up reports of serious adverse events (SAE) reported to the YEC-1 for any study within the oversight of the Yenepoya University Ethics Committee (YEC-1).

2. **Scope:**

This SOP applies to the review of SAE reports (Adverse events/ SAE onsite as well as SAEs of the multicentre studies occurring at other sites offsite) submitted to the YEC-1

3. **Responsibilities:**

It is the responsibility of the YEC-1 to review all SAEs reported to the YEC-1 in a timely manner.

4. **Definitions:**

4.1 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[1].

4.2 Serious Adverse Event or Serious Adverse Drug Reaction: An AE or ADR that is associated with death, inpatient hospitalization (in case the study was being conducted on out-patients), prolongation of hospitalization (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[2].

4.3 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 unfavourable

[1] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline accessed on 15 July 2016 at 2235 hours
[2] http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 15 July 2016 at 2245 hours

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[3].

5. Detailed instructions

5.1 SAE sub-committee:

5.1.1 An SAE sub-committee may be constituted within YEC-1 if the institutions have a large number of SAE reports for review.

5.1.2 The Serious Adverse Event (SAE) sub-committee of Yenepoya University Ethics Committee' (YEC-1) will review all serious adverse events (SAE) at the site / other sites involving human participants approved by YEC-1.

5.1.3 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.

5.1.4 **Composition of the SAE sub-committee:**

- The SAE sub-committee will be appointed by the Chairperson of YEC-1.
- The SAE Sub-committee will be multidisciplinary and multi-sectoral in composition.
- The SAE Sub-committee will be composed of at least 5 and a maximum of 10 individuals who are members of YEC-1.
- The composition shall be as follows:
  - Chairperson of the SAE Sub-committee
  - Executive-Secretary
  - At least one member with postgraduate qualification in the discipline of Medicine or Pharmacology or any other relevant clinical specialty

5.1.5 The YEC-1 Member-Secretary shall be ex-officio member of the SAE sub-committee.

5.1.6 The SAE Sub-committee may invite legal expert of YEC-1 to provide opinion on the legal implication of adverse event.

5.1.7 The Chairperson of the SAE Sub-committee will be responsible for

[3] ICH GCP-Guideline (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline

conducting SAE sub-committee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.

5.1.8 The Chairperson of the SAE Sub-committee/ Executive Secretary will sign minutes of the SAE sub-committee meetings.

5.1.9 In case of anticipated absence, the Chairperson of SAE sub-committee will nominate a SAE sub-committee member as acting Chairperson. The acting Chairperson will have all the powers of the Chairperson of SAE sub-committee for that meeting.

5.1.10 For the SAE sub-committee meeting, a quorum will consist of at least 4 members as follows:

- Chairperson/Acting Chairperson of the SAE sub-committee
- Executive Secretary and
- One member (preferably pharmacologist)
- One member (preferably clinician)

5.1.11 The ordinary meetings of the SAE sub-committee will be at least once in a month. In the event of a report of SAE, the sub-committee will convene extra-ordinary meetings (as many as necessary) within two working days of receiving the SAE report at the YEC-1 Secretariat.

5.1.12 **Membership requirements:**

5.1.12.1 YEC-1 members will be appointed to the SAE sub-committee if they show willingness and commitment in terms of time to perform the role and responsibility as SAE sub-committee member.

5.1.12.2 The Registrar, Yenepoya University is responsible for notifying the SAE sub-committee members, after due approval from the Vice-Chancellor. The names of new members to be appointed may be suggested by the YEC-1 members and the Chairperson to the Registrar. The final decision regarding the appointment will be taken by the Vice-Chancellor of Yenepoya University.

5.1.12.3 The tenure of SAE sub-committee will be for a continuous period of three (3) years from the date of appointment.

5.1.12.4 The retiring member will be eligible to be appointed for the new tenure

consecutively four times.

5.1.12.5 An SAE sub-committee member may resign from membership by submitting a letter of resignation to the Executive Secretary of the SAE sub-committee. The member may or may not assign reasons for resignation.

5.1.12.6 A member may be disqualified from SAE sub-committee if the member fails to attend more than 5 regular consecutive SAE meetings without prior intimation in writing.

5.1.12.7 The Chairperson of SAE sub-committee will inform the Chairperson YEC-1, in writing, if a member has not attended more than five consecutive meetings of the SAE sub-committee.

5.1.12.8 The Chairperson will take up the issue of disqualification for discussion at the YEC-1 meeting and allow the concerned SAE sub-committee member to state his reasons for unauthorized absence.

5.1.13 **Functions of the Executive Secretary of the SAE Sub-committee**

5.1.13.1 To schedule, organize and conduct SAE sub-committee meetings.

5.1.13.2 To prepare and maintain meeting agenda and minutes.

5.1.13.3 To prepare the communication letters related to the adverse event reports.

5.1.13.4 To communicate with the YEC-1 members, regulatory authorities and investigators in timely manner.

5.1.13.5 To provide necessary administrative support for SAE sub-committee related activities.

5.1.13.6 To ensure adherence of the SAE Sub-committee functioning as per SOPs.

5.2 On-site SAE

5.2.1 **Receipt of SAE report**

5.2.1.1 The YEC-1 Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant:

- Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified in Ann01/SOP12/v2.
- Due analysis should be submitted by the PI within 14 days from the

occurrence of the SAE along with the format specified in Ann02/SOP12/v2.

- Due analysis will also be submitted by the sponsor within 14 days in the format specified in Ann02/SOP12/v2.
- The follow up reports of all on-site SAE till the event is resolved.

5.2.1.2 The YEC-1 Secretariat will verify that the report is complete in all respects and that it has been received at the YEC-1 office within the specified timelines.

5.2.1.3 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 SOP11/v2.

5.2.1.4 The YEC-1 Secretariat will sign and write the date on which the report is received.

5.2.1.5 The Secretariat will forward these reports to the YEC-1 Member-Secretary or Executive Secretary of the SAE Sub-committee (if constituted) within two working days.

5.2.2 Review and Decision on SAE Reports and Communication to PI and Regulatory Authority by YEC-1

5.2.2.1 Member Secretary or Executive Secretary of the SAE will review the SAE report and present to the YEC-1/SAE sub-committee (as applicable) for review and opinion.

5.2.2.2 At the meeting of YEC-1 or SAE sub-committee, 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[4]. Formula for calculating amount of compensation study related death[5,6] and for study related injury other than death[7].

5.2.2.3 If deemed necessary, a decision to hold emergency YEC-1 meeting may be taken to discuss about financial compensation. An emergency YEC-1 meeting will be scheduled within 7 days for the same.

[4] http://cdsco.nic.in/writereaddata/GSR%2053(E)%20dated%2030.01.2013.pdf
[5] http://www.iscr.org/pdf/Gazaate_notification.PDF dated 12th December 2014,
[6] http://www.cdsco.nic.in/writereaddata/formula2013SAE.pdf
[7] http://www.cdsco.nic.in/writereaddata/uploaded_for_website.htm

5.2.2.4 The Executive Secretary of the SAE sub-committee may refer the SAE report to full board for review if deemed necessary.

5.2.2.5 Minutes of SAE Sub-committee/YEC-1 meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE .

Participant ID	Letter No & Date of report	Type of Report (Initial or Follow up)	Date of onset	Whether study drug withheld	SAE outcome	Causality in the opinion of the PI	Recommendation by YEC-1/ SAE sub committee

5.2.2.6 The minutes will be circulated to the YEC-1 members via email and approval/ objection will be sought from the members in a period of 5 working days.

5.2.2.7 The YEC-1 secretariat will draft a formal letter to the concerned PI and inform him/ her about the YEC-1 decision. This letter will be signed and dated by the Member-Secretary or Chairperson and will be sent to the PI within a period of 7 days from the date of the SAE sub-committee meeting.

5.2.2.8 The PI will be requested to reply to the query letter on the SAE report within 7 working days.

5.2.2.9 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.'

5.2.2.10 The YEC-1 Secretariat will file a copy of these letters in the study file.

5.3 Report of SAE occurring at other sites:

5.3.1 The investigator will need to submit the SAEs occurring at other sites 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 (Initial or Follow up)	SAE event	Date of onset	Date of report	Out come	Causality	
							Investigator	Sponsor

5.3.2 For every SAE term, a separate row of the above table is to be used (the SAE terms should not be combined).

5.3.3 Causality to be stated as related (R) or not related (NR).

5.3.4 The SAEs occurring at other sites will be reviewed by the Secretary of the YEC-1/ SAE Sub-committee (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 On-site Adverse Event:

5.4.1 The YEC-1 Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by YEC-1:

- On site AE reports to be submitted by the PI annually in the continuing review report
- In view of the risk assessment of a given research proposal the YEC-1 can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

5.4.2 YEC-1 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 YEC-1 office within the specified timelines. If the report has been received beyond the specified time, it will be considered as deviation.

5.4.3 For all the onsite AE reports received at the YEC-1 office, the Secretariat will forward these reports to the Member-Secretary for review.

5.4.4 Member-Secretary may put the AE reports for full review discussion if deemed necessary.

5.4.5 Queries, if any on the report will be communicated to the PI by the Member-Secretary following full review at the YEC-1 meeting.

5.4.6 The YEC-1 Secretariat will file a copy of these letters in the study file.

5.5 During the full review at YEC-1 meeting:

5.5.1 YEC-1 Member-Secretary will read out the minutes of all the SAE sub-committee meetings including the recommendations/decisions of the SAE sub-committee (if constituted).

5.5.2 In case of the SAE occurring at the site to be discussed in full review at the 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.

5.5.3 The decision can be arrived at by consensus. If not agreed by consensus, the issue would be put for voting. (majority vote for a decision is 2/3rd of the members present and voting).

5.5.4 The decision will be recorded in the minutes of the meeting and circulated.

5.6 Decision of YEC-1 on SAE review:

The SAE sub-committee/YEC-1 may take one or more of the following decisions on review of the SAE reports:

5.6.1 **Type of Actions Taken by YEC-1/ SAE Sub-committee on Review of SAE Report:**

Following detailed review of the SAE reports and related documents, the YEC-1/ SAE Sub-committee (if constituted) can suggest one of the following actions:

5.6.1.1 Note the information about the SAE in records for future reference

5.6.1.2 Request further follow-up information and/or additional details

5.6.1.3 Ask for periodic follow-up of the research participant till SAE is resolved

5.6.1.4 Depending on complexities of issue, YEC-1/ **SAE sub-committee** may decide to seek opinion of outside expert consultant who will be requested to respond within

14 working days.

5.6.1.5 Provide recommendations regarding/raise queries related to compensation for study related injury and death bb

5.6.2 Type of Actions Taken by YEC-1 following full review:

5.6.2.1 Suggest changes amendments in protocol, participant information sheet/informed consent document/investigators' brochure/any other study-related documents.

5.6.2.2 Suspend the study till additional information is available.

5.6.2.3 Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).

5.6.2.4 Suspend the study till amendments requested for by YEC-1 are carried out.

5.6.2.5 Suspend enrollment of new participants.

5.6.2.6 Suspend certain activities under the protocol.

5.6.2.7 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.

5.6.2.8 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.

5.6.2.9 Any other appropriate action

5.6.2.10 The decision shall be recorded in the minutes of the YEC-1 meeting.

5.6.2.11The decision of the YEC-1 requiring immediate action from the PI will be conveyed to the PI through telephone, fax or email within 24 hours. Such a communication will be documented by the YEC-1 Member-Secretary in the study file.

5.6.2.12A formal letter to the PI informing about the YEC-1 recommendations in such situations will be sent within 5 working days of the YEC-1 meeting having taken place.

6. References to other applicable SOPs

- **SOP 07A/v2** - Initial Full Review of Research Study Protocols
- **SOP 08/v2** - Agenda Preparation, Meeting Procedures and Recording of Minutes
- **SOP 10/v2** - Continuing Review of Study Protocols

7. Annexures

Annexure 1: Ann01/SOP12/v2: As per Schedule Y Appendix XI: Data Elements for reporting serious adverse events occurring in a clinical trial

http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf

Annexure 2A: Ann02A/SOP12/v2: Checklist for Onsite Serious Adverse Event submission

Annexure 2B: Ann02B/SOP12/v2: Onsite Serious Adverse Event Analysis Report

Annexure 1: Ann01/SOP12/v2

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

Sl No	Details	Response
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 treatments: *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	Investigator details: 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	
7	Signature (with date) of the investigator (PI)	

Annexure 2A: Ann02A/SOP12/v2
Checklist for Serious Adverse Event (SAE) submission
(For Offsite 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** **Yes/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	**Yes/No**	
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		
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** Initials & other relevant identifier (hospital/OPD record number etc.) Gender Age and/or date of birth Weight Height		

13	**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	
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** 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).	

16	**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.*	
17	**Details about the Investigator** CT Site number, if any Name Address Telephone/Mobile Number & Email 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	
18	**Details about the Ethics Committee** Name and address Name of Chairman & Address Telephone/Mobile Number Email Whether EC is recognized by DCGI	Yes/No

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) d. Any additional documents)	

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

Ann02B/SOP12/v2
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** **Yes/No**	**Other than death** **Yes/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	**Yes/No**	
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		
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** Initials & other relevant identifier (hospital/OPD record number etc.) Gender Age and/or date of birth Weight Height		

13	**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	
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** 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).	

16	**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.*	
17	**Details about the Investigator** CT Site number, if any Name Address Telephone/Mobile Number & Email 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	
18	**Details about the Ethics Committee** Name and address Name of Chairman & Address Telephone/Mobile Number Email Whether EC is recognized by DCGI	Yes/No
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) d. Any additional documents)	
24	**Details of payment for medical management of SAE?** (please give information who paid, how much was paid, to whom and evidence of the same.	
25	**What is the investigator's assessment for the amount of compensation to be paid?**	
26	**What is the sponsor's assessment for the amount of compensation to be paid?**	
27	**Has the participant made a claim?**	Yes/No Comment
28	**If yes for 27, then, for how much amount?**	
29	**If no, please ensure that the participant/nominee have been made aware of his/her rights regarding compensation.** *Please submit documentation regarding the same.*	
30	**Signature of the Principal Investigator with date**	

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

8. Flowchart

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