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YENEPOYA ETHICS COMMITTEE 2
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Review of protocol violation and deviation

YEC2/SOP011/v2

Effective Date: 25.02.2023



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Title: Review of Protocol violation/deviation
SOP Code: YEC2/SOP011/v2

Prepared by:

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Approved by:

Dr. Animesh Jain Chairperson, YEC2	Signature with Date <i>Animesh</i> 25/02/23
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Notified by:

Registrar, Yencpoya (Decmed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>Basu</i> 29/02/23
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Details of superseded SOP 11/v1

Subcommittee Convenor name	Version no	Effective date (dd/mm/yy)	Describe the main changes
Dr.H.Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

Details of Current SOP 11/v2

SOP subcommittee convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. H. Hari Kishore Bhat	v1	25.02.2023	Added Definition Added Responsibility Added detailed instruction



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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe action to be taken by the YEC 2 when the investigator/ trial site fail to do any of the following

Follow the procedures written in the approved protocol

Comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the YEC2 for the conduct of human research

Respond to the YEC 2 requests regarding statutory, ethical, scientific or administrative matter

2. Scope:

This SOP applies to all research protocols involving human research participants approved by the YEC 2

The SOP applies to any deviation or violation of the protocol as reported by the principal investigator/ sponsor/ participant/ others

3. Definition

Non-compliance: A NC is noted when the investigator or the trial site fails to

Respond to YEC2 requests

Comply with the applicable national or international guidelines

Comply with the national regulatory requirements

Comply with the University/institutional rules and regulations

Protocol Deviation: A PD is any change, divergence, or departure from the study team, design or procedures of a research protocol that is under the investigator's control and that has not been approved by YEC2.



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Protocol Violation: A PV is a deviation from the YEC2 approved protocol that may affect the subject's rights, safety, or well being and/or the completeness, accuracy and reliability of the study data. If a PD meets any of the following criteria, it is considered a PV.

The deviation has harmed or posed a significant or substantial risk of harm to the research subject.

For example

A research subject received the wrong treatment or incorrect dose.

A research subject met discontinuation criteria during the study but was not discontinued.

A research subject received an excluded concomitant medication.

The deviation compromises the scientific integrity of the data collected for the study. For example

A research subject was enrolled despite not meeting the protocol's eligibility criteria (inclusion/exclusion criteria).

Failure to treat research subjects as per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)

Inadvertent loss of samples or data.

The deviation is a wilful act and a breach of human subject protection regulations, policies, or procedures on the part of the investigator(s). For example

Failure to obtain a valid, informed consent prior to initiation of study-related procedures

Falsifying research or medical records.

Performing tests or procedures beyond the scope of the research question



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The deviation involves a serious or continuing noncompliance with national, state, local or institutional human subject protection regulations, policies, or procedures.

For example

Working under an expired professional license or certification

Failure to follow national regulations, and Yenepoya deemed to be University or YEC2 policies.

Repeated deviations.

The deviation is inconsistent with the current national guidelines on research, medical, and ethical principles.

For example

A breach of confidentiality.

Inadequate or improper informed consent procedure.

Any other act from any research team member that significantly increases the risk to participants, causes harm to participants, alters the reliability and credibility of the data

Responsibility:

The YEC2 Chairperson will

Lead the discussion in the YEC2 meeting so that suitable action is taken in case of NC/PD/PVs.

Approve Member-Secretary's recommendation to convene an emergency meeting and assign two or more members to attend the emergency meeting in cases where an urgent decision is required.



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The Member-Secretary will

It is the responsibility of the Member-Secretary to place the report of protocol deviation or violation in the agenda of the next YEC 2 meeting

It is the responsibility of the Member-Secretary to initiate the process of discussion and decision making on an urgent basis

The YEC2 member(s) will:

Review the NC/PD/PV report

Attend the emergency meeting, if nominated

Discuss and deliberate on the report in the YEC2 meeting

The Secretariat:

It is the responsibility of the secretariat to receive any report of deviation or violation of protocol by the principal investigator or any other person

The secretariat will ensure that the report is submitted in the prescribed format (YEC2/Ann01/SOP11/v2)

It is the responsibility of the secretariat to bring this report to the notice of the Member-Secretary

5. Detailed instructions:

Detection of Protocol deviation/ violation:

Protocol deviation/ violation may be detected in one the following ways (but not limited to those listed below):

Protocol deviation/ violation may be reported by Investigator/ study site/ sponsor/Contract-Research Organization to the YEC 2.



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The YEC 2 members performing monitoring of the project at trial site may detect protocol deviation/violation if the project is not been conducted as per protocol/ national/ international regulations.

The Secretariat may detect protocol deviation/ violation from failure to comply with statutory requirements/ failure to respond to requests from YEC 2 within reasonable time limit/ failure to respond to communication made by YEC 2.

The YEC 2 members may detect protocol deviation/ violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization

5.1.5 The YEC 2 Secretariat and/ or YEC 2 members may become aware of a protocol deviation/ violation while reviewing study-related documents including reports filed in by the Principal Investigator (PI).

Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrolment.

Any report/ communication brought to the notice of Member Secretary/ Chairperson of YEC 2 by an independent person.

Communication received from the Head of the Institution informing YEC 2 about an alleged protocol violation/ protocol deviation.

.Receipt of protocol deviation / violation report by the Secretariat

The PI will report the protocol deviation/violation as per Annexure YEC2/Ann01/SOP11/v1.

In case protocol deviation/violation is detected by any other person (See Section 5.1) and reported to the YEC 2 (there is no format for this), the Member- Secretary will write to the PI to submit a protocol deviation/violation as per Annexure 1 YEC2/Ann 01/SOP11/v1

The Secretariat will notify the Member-Secretary of any protocol deviation/violation report received from the PI/ from any source within 2 workingdays of receipt of the notification.



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Actions to be taken:

The action of the YEC 2 will be based on:

- The nature and seriousness of the deviation / violation.
- Frequency of deviation/ violation in the study in the past.
- Frequency of deviation/ violation in previous studies conducted by the same
- PI/ Co-PI or in the same department.

Member-Secretary will decide on the impact of the protocol deviation / violation and act accordingly. Depending upon the seriousness, the YEC 2 shall do the following (not limited to these actions)

- Ask PI for written clarification as soon as the report of deviation is received
- If the impact is serious, this report will be shared with the Chairperson and two or more YEC 2 members designated by the Chairperson.
- If the impact of the protocol deviation is serious enough, the Member-Secretary will instruct the Secretariat to call for an emergency YEC 2 meeting specifically to discuss the issue within 7 working days of the initial scrutiny
- The Secretariat will put up the information and communication at the next YEC 2 meeting for discussion.

The Member-Secretary in consultation with YEC 2 members will review the information available and deliberate on it.

The Chairperson will take a final decision depending on the seriousness of the violation.

The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by voting. A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the voting members present at the meeting.

The decision taken by YEC 2 could include one or more of the following:

- Determine that no further action is required, or take other actions as appropriate.



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- Inform the PI that the YEC 2 has noted the violation / deviation, and instruct the PI to ensure that deviations/ violations do not occur in future and to follow YEC 2 recommendations.
- Enlist measures that the PI would undertake to ensure that such deviations / violations do not occur in future.
- Observe the research or consent process (depending on the nature and frequency of the deviation).
- Suggest modifications to the protocol
- Alter the interval for submission of the continuing review/ annual project status.
- Ask for additional training of the investigator and study team
- Reprimand the PI.
- Seek additional information from the PI.
- Conduct audit of trial by the YEC 2.
- Suspend the study till additional information is made available and scrutinized.
- Suspend the study till recommendations made by the YEC 2 are implemented by the PI and found to be satisfactory by the YEC 2.
- Suspend the study for a fixed duration of time.
- Suspension or termination of the study.
- Revoke approval of the current study.
- Inform DCGI/ other relevant regulatory authorities.
- Keep other research proposals from the PI/ Co-PI under abeyance. Review and/ or inspect other studies undertaken by PI/Co-PI.

5.3.7 This final decision will be recorded on YEC2/Ann01/SOP11/v1 by the Member-Secretary

Procedure for notifying the PI and other concerned authorities

The Member-Secretary will draft the notification letter.

The notification signed letter by Member-Secretary will be sent to

- The PI



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- The Department Head (if required on case to case basis)
- The Institutional Officials (if required on case to case basis).
- The relevant national authorities (if required on case to case basis)
- The other institutes (if required on case to case basis in case of multi-centric trials)

6. Records and follow up to be kept by YEC 2 secretariat:

The Secretariat will keep a copy of the notification letter in the respective project file
respective project file

7. Annexures:

7.1 YEC2/Ann01/SOP11/v1 - Deviation/ Violation Record

YEC2/Ann01/SOP11/v2

Deviation / Violation Record

Deviation / Violation Report by the Principal Investigator
YEC 2 Protocol no.:
Study Title:
Principal Investigator:
Department:
<input type="checkbox"/> Deviation from protocol <input type="checkbox"/> Violation
Description of deviation (s)/violation(s):



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Corrective Actions Taken by the Principal Investigator (If any):
Reported by (Name of Principal Investigator/ Study Team Member):
Signature with date:
II. Provisional Decision by the Reviewer (Member-Secretary and/or Chairperson and/or YEC 2 Member/s)
<input type="checkbox"/> Noted <input type="checkbox"/> Request the PI not to perform such deviations/ non compliances/ violations in future <input type="checkbox"/> Specific recommendations state below to be followed (to be listed) <input type="checkbox"/> Suspend the study till the YEC 2 recommendations are implemented <input type="checkbox"/> Suspend the study till information available <input type="checkbox"/> Terminate approval of the current study (with reasons) <input type="checkbox"/> Refuse subsequent applications from PI <input type="checkbox"/> To discuss at the full Board meeting <input type="checkbox"/> Any other
Reviewed by Name/s:
Signature/s with date:
III. Final decision by the YEC 2
<input type="checkbox"/> At the emergency meeting on _____ <input type="checkbox"/> At the YEC 2 meeting on _____ Final decision: Any recommendation: Signature of the Member-Secretary/Chairperson Date:



8. Flow chart:

