Sl.No	Contents	Page No
1.	Purpose	02
2.	Scope	02
3.	Responsibility a. Secretariat of Ethics Committee b. SOP Team c. Chairperson of the ethics committee	02
4.	Flow Chart	03
5.	Detailed instructions	03
5.1	Appoint the SOP Team	03
5.2	List all relevant SOPs	04
5.3	Format and layout	04
5.4	Write and approve new SOP	04
5.5	Implement, distribute and file all SOPs	04
5.6	Review and request for a revision of an existing SOP	04
5.7	Manage and archive superseded SOPs	05
6.	Glossary	05
7.	References	06
8.	ANNEXURES	06
	AF/IEC/01/01/V-8 SOP Index Page	07
	AF/IEC/01/02/V-8 Main text	09
	AF/IEC/01/03/V-8 Document History	11
	AF/IEC/01/04/V-8 Log of SOP Recipients	12
	AF/IEC/01/05/V-8 Request for Revision of an SOP	13

1. PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committees (IEC). The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with applicable national and international ethical guidelines.

2. SCOPE:

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ethics committee. The Ethics Committee SOPs will be amended when indicated or 36 months/ whichever is earlier.

The below mentioned reasons for the amendment of SOP of SOP

- Any changes in IEC membership requirements
- As per utmost CT rules and regulations
- Problems or deficiency in the SOP
- Any Regulatory authority requirements If applicable
- Any stake holders' requirements If applicable

3 RESPONSIBILITY:

It is the responsibility of the Secretariat of ethics committee to appoint the Team members for preparing, drafting or editing any SOP of the Ethics Committee.

A. <u>Secretariat of Ethics Committee:</u>

- Assist Chairperson to formulate an SOP Team
- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current Version of SOPs and maintain an up-to-date distribution list for each SOP.
- Maintain a file of all current versions of SOPs
- Maintain a file of all past SOPs of the IEC

B. SOP Team

- Assess the request(s) for SOP/s revision in consultation with the Member Secretary and Chairperson
- Propose new / modified SOP/ s as needed
- Draft the SOP/s in consultation with the IEC members and appropriate administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

C. Chairperson of the ethics committee:

- approves the SOPs
- Signs and dates the approved SOP versions

4 FLOW CHART:

Sl.No.	Activity	Responsibility
1.	Appoint the SOP Team ↓	Chairperson
2.	List all relevant SOPs ↓	SOP Team
3.	Design a format and layout ↓	SOP Team
4.	Write and approve a new/revised SOP ↓	SOP Team and Chair person
5.	Implement, distribute and file all SOPs ↓	Member Secretary
6.	Review and request for a revision of existing SOPs ↓	SOP Team / EC members/ administrative staff/chair person
7.	Manage and archive superseded SOPs	Administrative staff

5 DETAILED INSTRUCTIONS:

5.1 Chairperson of IEC

- Appoint one or more SOP Teams
- Approve the SOPs
- Sign and date the approved SOPs

5.2 List all relevant procedures

- Write down step by step all the procedures of the IEC that are to be standardized in the form of an SOP
- Organize, divide and name each process

5.3. Format and layout

- Each SOP should be given a number and a title that is self-explanatory. A unique code number with the format SOP/XX/VV.W
- XX - Two-digit numbers assigned specifically to the SOP.
- VV - version with one-digit number identifying the version of the SOP
- W is a one-digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, SOP 01/V-8.0 is the SOP number 1 version 1 with one minor revision i.e. V-8.0
- Each SOP will be prepared according to the standard template.

5.4. Write and approve new SOP

- A draft will be prepared by the member secretary/ member of the SOP team
- The draft SOP will be discussed with the other members of the SOP team
- The final version will be passed to the Chair person for review and approval.

5.5. Implement, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The approved SOPs will be distributed to the EC members and the relevant staff By the *Secretariat.* When revised version is distributed, the old version will be retrieved from the members and destroyed. However, one copy of the old version will be retained at the Secretariat.

5.6. Review and request for a revision of an existing SOP

- Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form (Annexure-2) to make a request.
- If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who made the request of the decision.

- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.4).

5.7. Manage and archive superseded SOPs

- Superseded SOPs should be retained and clearly marked "superseded" and archived in the historical file by the *secretariat***.**

6 GLOSSARY:

SOP: Detailed, written instructions, in a certain format, describe all procedures (Standard Operating activities and action undertaken by an organization to achieve Procedure) , with uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.

IEC members: Individuals serving as regular and alternate members on the Institutional Ethics Committee. These committees are constituted in Accordance with the IEC membership requirements set forth in ICH GCP and Schedule Y.

SOP Team: A selected committee of the members of KLE University Ethics Committee and administrative staff who oversee the creation, preparation, review and periodic revision of the institute SOPs.

Master SOP files: An official collection of the institute standard operating procedures (SOP) accessible to all staff, IEC members, auditors and government inspectors as a paper copy with an official stamp on first and last pages, and the approval signatures with effective date.

7. REFERENCES:

- ✓ International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.
- ✓ Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- ✓ New drugs and clinical trail rules,2019

8 ANNEXURES:

SOP Index Page	AF/IEC/01/01/V-8
Main text	AF/IEC/01/02/V-8
Document History	AF/IEC/01/03/V-8

Log of SOP Recipients	AF/IEC/01/04/V-8
Request for revision of SOP	AF/IEC/01/05/V-8

ANNEXURE: 01 AF/IEC/01/01/V-8.0

LIST OF STANDARD OPERATING PROCEDURES VERSION-8.0

INDEX

Sl.No	SOPs	SOP code	Page No.
I.	**Preparation of SOPs for Ethics committee for clinical studies**		
01	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for institutional Ethics Committees	SOP/01/V-8.0	1-13
II.	**Constituting the Ethics Committee for Research on Human Subjects**		
02	Constitution of an IEC	SOP/02/ V-8.0	14-27
03	Confidentiality/Conflict of Interest Agreement	SOP/03/ V-8.0	28-40
04	Training Personnel and Ethics Committee Members	SOP/04/ V-8.0	41-44
05	Selection and Responsibilities of Independent consultants	SOP/05/ V-8.0	44-49
III.	**Initial Review Procedures**		
06	Management of protocol submissions	SOP/06/ V-8.0	50-69
07	Expedited Review	SOP/07/ V-8.0	70-77
08	Initial Review of submitted protocol	SOP/08/ V-8.0	78-95
09	Vulnerable populations	SOP/09/ V-8.0	96-105
10	Audio Visual (AV) recording of informed consent process	SOP/10/ V-8.0	106-110
IV.	**Protocol Amendments, Continuing Review and End of Study**		
11	Review of Resubmitted protocols	SOP/11/ V-8.0	111-115

12	Review of Protocol Amendments	SOP/12/ V-8.0	116-121
13	Continuing Review of Study Protocol	SOP/13/ V-8.0	122-127
14	Review of Final report	SOP/14/ V-8.0	128-130
V.	**Monitoring and Evaluation of Adverse Events**		
15	Review of Serious Adverse Events (SAE) Reports	SOP/15/ V-8.0	131-140
VI.	**Monitoring Protocol Implementation**		
16	Intervention in Protocol Deviation/Non-Compliance/ Violation	SOP/16/ V-8.0	141-146
17	Response to Research Participants requests/Complaints	SOP/17/ V-8.0	147-154
18	Management of Study Termination	SOP/18/ V-8.0	155-157
VII.	**Site Monitoring**		
19	Site Monitoring visit	SOP/19/ V-8.0	158-163
VIII.	**Preparation of Review Meeting Agenda and Communication Records**		
20	Agenda Preparation, Meeting Procedures and Minutes	SOP/20/ V-8.0	164-173
IX.	**Managing Study Files**		
21	Maintenance of active study files	SOP/21/ V-8.0	174-176
22	Archival and retrieval of documents	SOP/22/ V-8.0	177-183
23	Maintaining Confidentiality of IEC Documents	SOP/23/ V-8.0	184-189
X.	**Evaluating an IEC**		
24	Audit and Inspection	SOP/24/ V-8.0	190-195
XI.	**Subjects/Patients recruitment strategies**		
25	Subjects/Patients recruitment strategies	SOP/25/ V-8.0	196-202

ANNEXURE: 02 **AF/IEC/01/02/V-8.0**

Page 1 of 2

Standard Operating Procedures Template

Institutional Ethics Committee, KLE Academy of Higher Education and Research (Formerly known as KLE University)

Title: Title which is self-explanatory and is easily understood

SOP/xx/vv.w Effective Date:

Page: of TITLE

Title which is self-explanatory and is easily understood

SOP/xx/vv.w

Supersedes:

Written By:

Date…

Reviewed By:

Approved by: Chairperson
(Name)
Signature with Date

Table of CONTENTS

1 Purpose
2. Scope
3. Responsibility
4. Flow chart
5. Detailed instructions
6 Glossary
7 References
8 Annex
Annex no. with title and code

Main Text:

1. **Purpose:** summarizes and explains the objectives of the procedure.
2. **Scope** – states the range of activities that the SOP applies to.
3. **Responsibility** – refers to person(s) assigned to perform the activities involved
4. **Flow chart** – simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity
5. **Detailed instructions** – describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.
6. **Glossary** – clarifies uncommon or ambiguous words or phrases by explanation.
7. **Reference** – lists sources of the information given in the SOP.
8. **Annexure-** documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.

ANNEX URE: 03 **AF/IEC/01/03/ V-8.0**

Document History

(The final version is the version after the approval by the Chairperson which is V-8)

Author –	**Version**	**Date**	**Describe the main change**
Name		dd-mm-yy	final version
Name		dd-mm-yy	Minor changes
Name		dd-mm-yy	Major changes
Name		No change	(routine review)

ANNEXURE: 04 **AF/IEC/01/04/ V-8.0**

Log of SOP Recipients

Sl.No.	Name of Recipients	SOP Code	No. of Copies	Signature	Date

ANNEX URE: 05 **AF/IEC/01/05/V-8.0**

Request for Revision of an SOP

SOP Version:

Title:

Requirements for the revision of SOPs:

- **a.** Any changes in IEC membership requirements ☐
- **b.** As per utmost CT rules and regulations ☐
- **c.** Problems or deficiency in the SOP ☐
- **d.** Any Regulatory authority requirements If applicable ☐
- **e.** Any stake holders' requirements If applicable ☐

Identified by: Date (D/M/Y):

Discussed with:

SOP revision required: Yes No

If yes, to be carried out by whom?

If no, why not?

Date SOP re-finalized:

Date SOP approved:

Date SOP becomes effective: