1. **Purpose:**

   This procedure describes how an IEC proceeds and manages the termination of IEC Approval of research study. Protocols are usually terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. **Scope:**

   This SOP applies to any study approved by IEC of KAHER (Formerly known as KLE University) that is being recommended for termination of IEC approval before its scheduled completion.

3. **Responsibility:**

   It is the responsibility of the IEC Chairperson/Member-secretary to terminate IEC approval of any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

4. **Flow chart:**

Sl.No.	Activity	Responsibility
1.	Receive recommendation for study termination ↓	IEC Secretariat
2.	Review and Discuss the Termination Package ↓	IEC Secretariat and Chairperson
3.	Notify the Principal Investigator ↓	IEC Secretariat
4.	Store the Protocol Documents ↓	IEC Secretariat
5.	Inactivate the Protocol Document	IEC Secretariat

5. **Detailed instructions:**

   5.1 Receive recommendation for study approval termination.

   - Receive recommendation and comments from IEC members, Scientific Director, Sponsor or other authorized bodies for study protocol termination.
   - Inform the principal investigator to prepare and submit a protocol termination package.

- Receive the study protocol termination package prepared and submitted by the principal investigator.
- The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data as listed below:

* Original Continuing Review Application Form (AF/IEC/03/06/V-8.0) of SOP/06/V-8.0.
* Termination is indicated under "Action Request".
* Completeness of the information, including accrual data since the time of the last continuing review.
* Presence of the required signatures (Principal Investigator) - Initial and date the package upon receipt. Find the Termination form in SOP/06/V-8.0.

5.2 Review and discuss the Termination Package.

- Notify the Chairperson regarding the recommendation for study protocol termination.
- Send a copy of the termination package to the Chairperson within 07 working days upon receipt.
- The Chairperson reviews the results, reasons and accrual data.
- The Chairperson calls for an emergency meeting of full board to discuss about the recommendation. If needed
- The Chairperson signs and dates the Protocol Termination Application Form in acknowledgment and approval of the termination.
- The Chairperson returns the form back to the Secretariat within 07 working days of receipt of the package.
- The Secretariat reviews, signs, and dates the Protocol Termination Application Form indicating that the termination process is complete.

5.3 Notify the Principal Investigator:

- Make a copy of the completed Review Application Form
- Send the copy to the principal investigator for their records within 7 working days.

5.4 Store the protocol documents:

- Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.
- Send the file to archive.
- Store the protocol documents for five years.

6. References:

✓ International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
✓ Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
✓ WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
✓ Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
✓ New Drugs and Clinical trial Rules, 2019