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1. Purpose and Application:

The purpose of this section is to provide a form of Confidentiality/Conflict of Interest Agreement and identify who should read, understand, accept, sign and date the form. The procedure provides details when and where to sign as well as how the signed document should be kept.

The policy principles and procedures contained in this SOPs applies to:

- Institutional Ethics Committee members
- Permanent, temporary and part time employees of Ethics Committee

2. Scope:

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Ethics Committee of KLE Academy of Higher Education and Research, Belagavi.

3. Responsibility:

As it is mandatory to maintain the confidentiality of study protocols, IEC documents, and correspondence with experts, it is the responsibility of all newly appointed Ethics Committee, KLE University members to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form, before beginning their ethical review tasks to protect the rights and safety of study participants. If non-members of the IEC need copies of documents, it is the responsibility of the IEC member/staff to take confidentiality and conflict of interest agreement forms duly signed and dated.

4. Flow chart:

Sl.No.	Activity	Responsibility
1.	Read the text carefully and thoroughly ↓	IEC members
2.	Ask questions, if any ↓	IEC members
3.	Sign to indicate consent ↓	IEC members
4.	Keep the Agreement in mind ↓	IEC members
5.	Copy Confidential documents ↓	IEC Secretariat
6.	File log of Copies	IEC Secretariat

5. Detailed instructions:

It will be the policy of the Ethics Committee of KAHER, which every member including the Chairperson, the alternate Chairperson and the alternate members to sign the Confidentiality/Conflict of Interest Agreement with date. Even though the member discontinues being a part of the IEC of KLE University for Clinical Studies, He/she will have to maintain confidentiality which will be valid for all the protocol related information for which he/she had access to Observation of IEC, KLE University for Clinical Studies meetings / Departmental visit by Guest Attendees.

- Permission to observe the Institutional Ethics Committee, KLE University meetings/ visit to the Office of Ethics Committee, KLE University will be given only after a formal written request addressed to the Chairman/ Member Secretary.
- Permission will be granted for academic purposes and other reasons at the discretion of the Chairman / Member Secretary.
- They will be requested to sign a Confidentiality Agreement Form for Guest Attendees to Ethics Committee, KLE University Meetings/ Departmental visit.
- They will be escorted by staff of the Ethics Committee, KLE University for Clinical Studies.
- Care will be taken to see only the necessary documents are given access to while proposals will be stored under lock and key.

5.1 Read the text carefully and thoroughly

- Newly appointed members obtain two copies of the Agreement Form AF/IEC/01/03/V-8.0
- The member is expected to read through the text of the form very carefully.

5.2 Ask questions, if any

- Direct questions to the Secretariat, if any part or sentences is not clear.
- Let the Member Secretary explain or clarify the contents of the document.

5.3 Sign with consent

- Sign and date both copies of the document before a member of the Secretariat.
- Give the forms back to a Member Secretary/ Secretariat to sign and date.
- The members have to keep a copy for their records

6. Glossary:

Confidentiality: The nonoccurrence of unauthorized disclosure of information:

Confidentiality Agreement: (Secrecy or Nondisclosure agreements). An agreement designed to protect, information, data and expertise from being misused by those who have learned

about them. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

Conflict of Interest: A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

Conflict of interest is present and interferes with ability to make an objective evaluation in cases of:

- Member of IEC have their own research projects under review by the Ethics Committee, when they are an investigator, co-investigator, or when they are in a supervisory or mentoring relationship with a Principal Investigator.
- A member whose spouse is a Principal Investigator, co-investigator, for any project under review is also considered to have conflict of interest.
- Members may also be in a conflict of interest situation when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, organization that may be the sponsor of the research project, or that may be substantially affected by the research.
- To maintain the independence and integrity of research ethics review, members must identify, eliminate, minimize or otherwise manage real, potential or perceived conflicts of interest. If a member has a personal or financial conflict of interest then he/she must disclose the nature of the conflict and absent themselves from any discussion or decision regarding that research project. In the event that a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the Committee can ensure that an alternate member be in attendance to maintain quorum.

Strategies to manage Conflict of Interest:

- Disclose conflict of interest
- Document the conflict of interest in attendance register /minutes of the meeting
- Refrain from taking part in any discussion/review/ debate about the proposal;
- Refrain from participating in the review process of project proposal by leaving the meeting room.

7. References:

- ✓ International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.

- ✓ Forum for Ethical Review Committees in Asia and the Western Pacific OPs 2006
- ✓ Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- ✓ New Drugs and Clinical Trial Rules, 2019

8. ANNEXURES:

AF/IEC/ 01/03/V-8.0 Confidentiality Agreement Form for IEC members

AF/IEC/ 02/03/V-8.0 Conflict of Interest Agreement Form for IEC members

AF/IEC/ 03/03/V-8.0 Confidentiality Agreement Form for Guest Attendees to IEC- KLE Meetings

AF/IEC/ 04/03/V-8.0 Confidentiality Agreement Form for Independent consultants

AF/IEC/ 05/03/V-8.0 Confidentiality Agreement for Non-members Requesting Copy of IEC Documents

AF/IEC/ 06/03/V-8.0 Log of Requests for Copies of IEC Documents

AF/IEC/ 07/03/V-8.0 Log of Requests for Original Documents

ANNEXURE: 01

AF/IEC/01/03/V-8.0

Confidentiality Agreement Form for Ethics Committee Member

In recognition of the fact, that I _____ herein referred to as the “Undersigned”, have been appointed as a member of the Institutional Ethics Committee KLE University, has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the fundamental duty of an Ethics Committee KLE University member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the Ethics Committee KLE University for Clinical Studies must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the Ethics Committee KLE University. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

The undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute’s policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

In the course of my activities as a member of the Committee, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

I also understand that as a member I will be given copies of the study proposals/necessary documents to be evaluated. I also understand that these documents are confidential; hence every effort will be taken to prevent access to any other person other than me or the office staff of the Ethics Committee. At times documents/proposals in format will be given/send to me.

I have read and accepted the aforementioned terms and conditions as explained in this Agreement

Undersigned Signature	Date
EC chairperson/Member secretary	Date

ANNEXURE: 02

AF/IEC/02/03/V-8.0

Conflict of Interest Agreement Form for Ethics Committee Members

It is recognized that the potential for conflict of interest will always exist but has faith in the Ethics Committee and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the Ethics Committee University that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the Ethics Committee KLE University for Clinical Studies.

The Undersigned will immediately disclose to the Chairperson of the Ethics Committee any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the Ethics Committee KLE University review or approval except to provide information requested by the Committee.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the KLE Ethics Committee. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ----- have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals.

Undersigned Signature	Date
EC chairperson/Member secretary	Date

ANNEXURE: 03

AF/IEC/03/03/V-8.0

Confidentiality Agreement Form

For Guest Attendees to Institutional Ethics Committee, KLE University for Clinical Studies Meetings

Ifromunderstand that I am allowed to attend the Institutional Ethics Committee of KLE University Full board/or SAE Review meeting as a guest or an observer. In the course of the meeting of the KLE Ethics Committee, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.

Indicate the details (date and number) of **the Institutional Ethics Committee KLE University Meeting** attended:

.....
.....
.....

Signature of the Guest or Observer	Date
Member Secretary	Date
EC chairperson/Member secretary	Date

ANNEXURE: 04

AF/IEC/04/03/V-8.0

Confidentiality Agreement Form for independent Consultants

I from.....as a non-member of Institutional Ethics Committee, KLE University for Clinical Studies, understand that the copy(ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Institutional Ethics Committee, KLE University and shall not duplicate, give or distribute these documents to any person(s) without permission from the Institutional Ethics Committee, KLE University. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the Ethics Committee. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

Signature of the Independent consultant	Date
Member Secretary	Date
EC chairperson/Member secretary	Date

ANNEXURE: 05

AF/IEC/05/03/V-8.0

Confidentiality Agreement Form for Non-members Requesting Copies of IEC Documents

I from.....as a non-member of Institutional Ethics Committee KLE University for Clinical Studies, understand that the copy (i.es) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Institutional Ethics Committee and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IEC documents:

.....

Signature of the recipient	Date
Member Secretary	Date
EC chairperson/Member secretary	Date

*ANNEXURE: 06***AF/IEC/06/03/V-8.0****Log of Requests for Copies of IEC Documents**

Sr. No	Date	Name of the Receiver	Documents Requested	Signature of the Receiver	Reason for Request

ANNEXURE: 07

AF/IEC/07/03/V-8.0

Log of Requests for Original Documents

Sr. No	Date	Name of the Receiver	Documents Requested	Signature of the Receiver	Reason for Request