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1. Purpose:

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation and circulation of meeting agenda, Meeting proceedings, action taken, invitation, and notification letters of institutional Ethics Committee Ethics Committee.

2. Scope:

This SOP applies to administrative processes concerning the preparation of the agenda for all regular IEC meetings, divided into three stages: before, during and after the meeting.

3. Responsibility:

It is the responsibility of the Secretariat staff to prepare the agenda for the IEC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson/Member Secretary should review and approve the agenda and the minutes sent to him/her.

4. Detailed Instructions:

4.1 Before each Ethics Committee meeting:

4.1.1 Check for filled up forms for completeness - Secretariat

- Reviews the new study application for completeness
- Documents the review by completing the appropriate Checklist (AF/IEC/01/06/V-8.0) if incomplete, the secretariat staff attempts to obtain the information from the investigators who submitted the application package and gets rectification done.

4.1.2 Consider the appropriate review channel of each protocol

- Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel-
- SOP for Expedited Review - SOP/07/V-8.0
- SOP for Initial Review of Submitted Protocols – SOP/08/V-8.0
- The protocol will be checked by IEC members and Member Secretary with the help of Checklist (see Annex 1 AF/EC/01/06/V-8.0) in which they will assess whether the project will be considered for Review of submitted Protocols, Review of Protocol Amendments, Continuing Review of Study Protocols, Review of Final Reports and Management of Study Termination. The Principal Investigator will mention the type of review in the covering letter and will submit the documents accordingly. Principal Investigator will incorporate the suggestions given by IEC members and submit multiple copies as required to the secretariat.
- The Dossier will be sent to the IEC Members for their comments and suggestions will be discussed in the IEC meeting

4.1.3 Prepare meeting agenda

- Schedule the review as soon as possible after submission, at the time of the next scheduled meeting.
- Consult the Chairperson and other IEC members to schedule the meeting date.
- Prepare the meeting agenda, according to the format shown in ANNEX 1 (AF/EC/01/20/V-8.0).
- Schedule protocols in the agenda on a first-come first-serve basis.
- Inform to the IEC members regarding the meeting for confirmation purpose
- Allow at least 2 weeks for the review process.
- Specify the due date for the return of comments.
- Include a Study Assessment Form see Annex 2 (AF/EC/02/06/V-8.0).with the protocol package along with the invitation letter and the meeting agenda.
- Write down the running number of the protocol in the square boxes at the bottom right corner of the form Annex 1 AF/EC/01/20/V-8.0
- Sign the second page of the form Annex1 AF/EC/01/20/V-8.0
- Prepare the package for delivery.
- Record the name of the IEC Members in the agenda for each protocol to be reviewed.
  Distribution of Protocol Packages (IEC Dossiers) to the IEC Members
- Keep in mind Procedure for Maintaining Confidentiality of IEC documents when preparing and distributing documents.
- Distribute copies of the protocol submission packages to the IEC members personally 8 days prior to IEC meeting by post/ hand given materials in the Correspondence section of the respective protocol file.
- Verify verbally with the members whether the Dossiers are received.

4.2 During the Ethics Committee meeting:

- The IEC may allow investigators, clinical collaborators, and guest attendees etc., to attend the portion of the EC meeting related to their studies.
- At the discretion of the Chairman, guest attendees (potential client, students, etc.) may be allowed to observe the Board meetings.
- Guest Attendees are required to sign a confidentiality agreement form (AF/IEC/03/04/V-8.0)
- The Secretariat reports on the minutes of the previous meeting and presents the agenda for discussion.
- The Secretariat records the discussions and the decisions made during the meeting.
- The Chairperson may inform members and attendees of the rules being followed during meetings.

- The meeting proceeds in the order organized in the agenda; however, the Chairperson may allow some switching depending on the situation.
- The IEC Members give their comments right after the presentation and the discussion about the study takes place.
- Investigators may be allowed to present their Protocols in brief and clarify any questions the IEC members may have.

4.2.1 Decision Making:

- Voting will be held only in cases where there is a lack of consensus on an issue/protocol.
- Voting will be by hand rising.
- In order to avoid conflict of interest, only those IEC members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
- All voting will take place after the observers / presenters / IEC members with a conflict of interest leave the meeting room.
- The Chairman determines if the number of voting Board members is sufficient to constitute a quorum and proceeds accordingly.
- If quorum is not met then the meeting will be deferred
- An IEC member makes a motion to recommend action on a protocol or issue being discussed.

4.3 After the Ethics Committee Meeting:

- As soon as possible after each meeting, a copy of the minutes is sent to IEC members for quality control and review.
- The EC members indicate review by signing and dating the minutes.
- Following staff review, the minutes are given to the Chairperson for review and approval.
- The Chairperson/M.S indicates approval by signing and dating the minutes.
- The Secretariat maintains the official copies of the minutes in accordance with the archiving procedures.

4.4 Preparing of Meeting Proceedings and action taken:

- IEC secretariat prepares the meeting proceeding and action taken report after completion of meeting of the PI presented protocols.
- Meeting proceeding and action will be ready by the member secretary/chairmen in next IEC meeting**.**

4.5 Preparing the Minutes and the Approval letters:

4.5.1 Assembling the meeting minutes and the decision form

- Use the format as shown in (Form AF/IEC/02/20/V-8.0) to write the minutes.
- Compose the summary of each meeting discussion and decision in a concise and easy-to-read style.
- Make sure to cover all contents in each particular category.
- Check spelling, grammar, and context of the written minutes.
- Finish the minutes within two weeks after the meeting.

4.5.2 Contents of the IEC Meeting Minutes:

The official minutes of the Board meeting consist of, but are not limited to, the following:

- ❑ Name of person preparing the minutes
- ❑ Location where the meeting was held (city, state)
- ❑ Meeting date
- ❑ Attending Ethics Committee members and guests if
- ❑ Agenda items
- ❑ Individual serving as Chairperson of the meeting
- ❑ Determination of a duly constituted quorum by the Chairperson to proceed With the meeting

- *Requirements for each study or activity requesting Approval:*
  - ❑ Principal Investigator's Name;
  - ❑ Protocol number/date/version of protocol, when available;
  - ❑ Name of EC Members for each protocol
  - ❑ Discussion as deemed appropriate by the Chairperson
  - ❑ Number of members voting 'yes', 'no', or 'abstention' only wherever applicable
  - ❑ Number of abstentions and the reason for the abstention;
  - ❑ Reference to the investigator approval letter that lists all changes requested by the EC members
  - ❑ Determination of the next requested continuing review.

- *Requirements for each study or activity requesting Expedited Review:*
  - ❑ Principal Investigator's Name
  - ❑ Protocol number
  - ❑ Justification by Principal Investigator for consideration of expedited review

- *Required for each continuing Review Report:*
  - ❑ Principal Investigator's name;
  - ❑ Protocol number /title
  - ❑ Approval letter for the project
  - ❑ Lists of recommendations or actions to be taken up with the investigator, if applicable

- *Required for each Adverse Event notification and Final Report:*
  - ❑ Principal Investigator's name;
  - ❑ Sponsor's name;
  - ❑ Protocol number/ title
  - ❑ Actions deemed appropriate by the Ethics Committee review.

Ñ11*Required for Termination of Approval:*
  - ❑ Sponsor Name's;
  - ❑ Protocol Number /title
  - ❑ Principal Investigator's name; Detail reason for termination

4.5.3 Approval of the minutes and the decision

- Check the correctness and completeness of the minutes.
- Send the minutes to the Chairperson/ Member Secretary of the EC
- Request the Chairperson/Member Secretary to approve, sign and date the minutes of the EC meeting and approval letter.

4.5.4 Filing the minutes

- Place the original version of the signed minutes by Chairperson/ Member Secretary in the EC files for the specific protocol.
- Place all correspondence in the appropriate file.
- Place a copy of the approval letter in the "minutes" file to inform the EC Members of the approval.

4.5.5 Distributing the minutes and the decision

- Send a copy of the relevant sections of the minutes and the decision form to the Principal Investigators for their records and for them to make the suggested rectifications by the EC members.
- Send the approved minutes to the EC members.

5 Glossary:

Agenda: A list of things to be done; a program of business at a meeting

Minutes: An official record of the business discussed and transacted at a meeting, conference, etc.

Quorum: Number of EC members required to act on any motion presented to the Board for action.

Majority vote: A motion is carried out if one half plus one member of the required quorum votes in its favor.

6 References:

- ✓ International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.Schedule Y 2005 and 2013.
- ✓ Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- ✓ Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

7 Annexure:

AF/IEC/01/20/V-8.0   Format of an Agenda

AF/IEC/02/20/V-8.0   Format of Meeting Proceedings and ATR

AF/IEC/03/20/V-8.0   Format for IEC meetings

ANNEXURE: 01　　　　　　　　　　　　　　　　**AF/IEC/01/20/V-8.0**

Format of an Agenda
Institutional Ethics Committee, KLE Academy of Higher Education and Research, Belagavi
Day, Date, Timing
Venue: Site management Office

The agenda will include:

I.　**Nature of Conflict of Interest [if any]**
II.　**Mention of Previous meeting minutes**
III.　**Review of New Project Proposals**:
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
IV.　**Review of Revised Project Proposals**:
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
V.　**Review of Proposals with Revision and Amendments:**
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
VI.　**Review of Annual Report**
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
VII.　**SAE reporting at site/other sites**
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
VIII.　**Protocol deviation/violation/termination**
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
IX.　**IEC member study monitoring visit**
　　　a.　Protocol title/No　　　　　　　　　　Name of the PI
X.　**Approval of project by circulation**

XI.　**The Committee will consider the following agendas which are for information**

XII.　**Any other matter with the permission of the chair**
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Member Secretary

ANNEXURE: 02   **AF/IEC/02/20/7.3**

Format of Meeting Proceedings and ATR

Date Venue Time

1. **Proceedings:**

   Protocol title/No:

   Name of the PI

   Resolution:

2. **Action taken report:**

I. **New agenda for review and approval:**

   a.   Protocol title/No   Name of the PI

   Action taken

   Discussion points

II. **Review of Proposals with Revision and Amendments:**

   a. Protocol title/No   Name of the PI

   Action taken

   Discussion points

III. **Review of Revised Project Proposals:**

   a. Protocol title/No   Name of the PI

   Action taken

   Discussion points

IV. **Review of Annual Report**

   a. Protocol title/No   Name of the PI

   Action taken

   Discussion points

V. **SAE reporting at site/other sites**

   a. Protocol title/No   Name of the PI

   Action taken

   Discussion points

VI. **Protocol deviation/violation/termination**

   a. Protocol title/No   Name of the PI

   Action taken

   Discussion points

VII. **IEC member study monitoring visit**

   a.   Protocol title/No   Name of the PI

   Action taken

   Discussion points

Member secretary/Chairperson

ANNEXURE: 03   **AF/IEC/03/20/7.3**

Format of IEC Meeting Minutes

1. Meeting, date, time from.. to..

2. Venue:

3. Mention of conflict of interest, if any :

4. Members Present :

5. If absent, justification for the same

6. Quorum requirements met?   Yes/No

7. Name of the members :

8. Review of projects as per Agenda items :

9. Type of documents reviewed

10. Vulnerability issues

11. Scientific and ethical issues

12. Minutes will be ratified in the next meeting

13. Any other matter with the permission of the chair :

14. Thanking the Chair and closure of the meeting :

15. Signature of Member Secretary / Chairperson on Final Minutes: