Title: Agenda Preparation, Meeting Procedures and Minutes

SOP Code: SOP/20/V1.3

Effective date : 07/11/2017

Table of Contents

1. Purpose

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of NIRRH Ethics Committee for Clinical Studies.

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 should review and approve the agenda and the minutes sent to him/her.

4. Flow chart

No.	**Activity**	**Responsibility**
1	Before each Ethics Committee Meeting ↓	IEC Secretariat
2	During the Meeting ↓	IEC Secretariat, Members and Chairperson
3	Voting ↓	IEC Members without Conflict of Interest/ Chairperson
4	After the Meeting ↓	IEC Secretariat/ Chairperson
5	Preparing the Minutes	IEC Secretariat/ Chairperson

5. Detailed Instructions

5.1 Before each Ethics Committee meeting

5.1.1 Check for filled up forms for completeness - Secretariat

- Reviews the new study application for completeness.
- Documents the review by completing the appropriate Checklist (see Annex1 AF/EC/01/06/V1.5) If incomplete, the secretariat staff attempts to obtain the information from the investigators who submitted the application package and gets rectification done.

5.1.2 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/V3.2
- ❖ SOP for Initial Review of Submitted Protocols – SOP/08/V1.7

The protocol will be checked by secretariat and Member Secretary with the help of Checklist (see Annex 1 AF/EC/01/06/V1.5) in which they will assess whether the project will be considered for Review of Resubmitted 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 member secretary and submit multiple copies as required to the secretariat.

The copies will be sent to the primary reviewers for their comments and suggestions. At least three reviewers will be assigned for initial review of each submitted protocol by the IEC Secretariat.

5.1.3 Prepare meeting agenda

- Schedule the review as soon as possible after submission, at the time of the next scheduled meeting.
- Consult the Chairperson to schedule the meeting date.
- Prepare the meeting agenda, according to the format shown in ANNEX 1 (AF/EC/01/20/V1.3).
- Schedule protocols in the agenda on a first-come first-serve basis.
- Inform to the EC members regarding the meeting for confirmation purpose.
- Allow at least 2-3 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/V1.5) 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/V1.3.
- Sign the second page of the form Annex1 AF/EC/01/20/V1.3
- Prepare the package for delivery.
- Record the name of the assigned reviewers in the agenda for each project to be reviewed.

5.1.4 Distribution of Protocol Packages 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 assigned reviewers and IEC members by either electronic mail (if electronic submission

protocols), telefax, by post 2-3 weeks in advance of the scheduled meeting, personally at least 15 days in advance of the scheduled meeting.

- Keep copies of "sent" e-mail, letters accompanying posted/ by hand given materials in the Correspondence section of the respective protocol file.
- Verify (verbally, by e-mail, by fax or by mail) with the members whether the protocol packages are received.

5.1.5 Prepare for the meeting

- Make a room reservation on the schedule meeting date and time.
- Submit an advance form to the administrative section to meet the honorarium of external experts and refreshments for the EC members.
- Make sure that the room, equipment and facilities are available in good running condition and in place for the meeting day.
- Template of the minutes has to be prepared as per the agenda referring to earlier minutes

5.2 During the Ethics Committee meeting

- The IEC may allow investigators, clinical collaborators, 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/EC/03/04/V1.0)
- The Secretariat reports on the minutes of the previous meeting and presents the agenda for discussion.
- The chairperson ensures that the quorum is complete before initiation of the meeting.
- 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.
- Before start of the approval process, ask any member with conflict of interest to leave and join once decision is taken.
- The approval process starts when one of the reviewers gives a brief about the study and presents his/her observations and comments (specifically on protocol related issues such as ethics, informed consent, withdrawal criteria, risk benefit assessment, vulnerability, questionnaire).
- In case the reviewer cannot be present during the meeting, a member of the Secretariat or an IEC member may give the briefing about the study by reading the comments and evaluation of the reviewers.

- The other members give their comments right after the presentation and the discussion about the study takes place.
- Investigators may be allowed to present their projects in brief and clarify any questions the IEC members may have.

5.2.1 Voting

- Decision about the proposal are to be taken in absence of investigators/persons associated with project
- Voting will be held only in cases where there is a lack of consensus on an issue/protocol.

5.3 After the Ethics Committee Meeting

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

5.4 Preparing the Minutes and the Approval letters

5.4.1 Assembling the meeting minutes and the decision form

- Use the format as shown in ANNEX 2 (Form AF/EC/02/20/V1.3) 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.

5.4.2 Contents of the IEC/IRB 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
  - ❑ 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 reviewers 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
  - ❑ 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
  - ❑ Actions deemed appropriate by the Ethics Committee review.
- ***Required for Termination of Approval:***
  - ❑ Sponsor Name's;
  - ❑ Protocol Number
  - ❑ Principal Investigator's name; reason for termination

5.4.3 Approval of the minutes and the decision

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

5.4.4 Filing the minutes

- Place the original version of the signed minutes by Chairperson in the IEC 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.

5.4.5 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 IEC members.

6. 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 IEC 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 vote in its favor.

7. References

7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

7.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

8. Annexure

ANNEX 1	AF/EC/01/20/V1.3	Format of an Agenda
ANNEX 2	AF/EC/02/20/V1.3	Format of IEC Meeting Minutes
ANNEX 3	AF/EC/03/20/V1.3	Document History

ANNEX 1 **AF/EC/01/20/V1.3**

Format of an Agenda

NIRRH EHICS COMMITTEE FOR CLINICAL STUDIES

Day, Date, Timing

Venue:

The agenda will include:

1. **Compliance with Quorum**

2. **Declaration of Conflict of Interest**

3. **Mention of Previous meeting minutes**

4. **Review of New Project Proposals:**
   i. Title of the Study
   Project No.: Name of the PI
   Reviewers:

5. **Review of Resubmitted Project Proposals:**
   i. Title of the Study
   Project No.: Name of the PI
   Reviewers:

6. **Review of Proposals with Amendments:**
   i. Title of the Study
   Project No.: Name of the PI
   Reviewers:

7. **Continuing Review of study protocols:**
   i. Title of the Study
   Project No.: Name of the PI
   Reviewers:

8. **Discussion on SAE reporting**
   i. Tile of the study
   Project No.: Name of the PI
   Reviewers:

9. **Review of final/completion reports:**
   i. Tile of the study
   Project no. Name of the PI
   Reviewers

10. **Notification to Board (like decision on expedited review/approval on circulation)**

11. **Details of Site visit done**

12. **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

ANNEX 2 **AF/EC/02/20/V1.3**

Format of IEC Meeting Minutes

- Meeting, date, time from .. to ..
- Venue:
- Members Present :
- If absent, justification for the same and quorum availability
- Name of the members :
- Mention of conflict of interest, if any :
- Review of projects as per Agenda items :
- Any other matter with the permission of the chair :
- Thanking the Chair and closure of the meeting :
- Signature of Member Secretary and the Chairperson on Final Minutes:

ANNEX 3 **AF/EC/02/20/V1.3**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	• Bullet 5.1.2 and 5.1.3 the word 'Checklist' included instead of 'Project Review Report form • Inclusion of the points in Annex 1 page no. Agenda items to include : 1) Confirmation of minutes of the Previous meeting 2) SAE reporting 3) Protocol deviation/violation/ termination 4) Details of Site visit done
Dr. Ragini Kulkarni	Version 1.2	1st September 2016	Pg.10 Addition of the point no. 9. Approval of project by circulation Pg.4, point 5.1.3 Inform to the EC members regarding the meeting for confirmation purpose.
Dr. Ragini Kulkarni	Version 1.3	7th November 2017	Pg. 4, 5.1.2 Changes in paragraph Pg. 5, 5.2 addition of bullet no. 5 & bullet no. 9, modification in bullet no. 10 Pg. 6, 5.2.1 Added bullet no. 1, first point retained as bullet no. 2 Deleted other bullets related to voting Pg. 9, 10 Annex 1 modified