Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

SOP Code: SOP 13/ V5 dated 26th July 2017

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation and notification letters of Institutional Ethics Committee (IEC) meetings.

2. Scope

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

3. Responsibility

It is the responsibility of the Secretariat to prepare the agenda for the IEC meeting and to ensure proper recording and dissemination of the minutes after the meeting is over. The Chairperson will review and approve the agenda and the minutes sent to him/her.

4. Flow chart

No.	Activity	Responsibility
1	Preparation of meeting agenda prior to a board meeting	IEC Secretariat
2	During the Meeting	IEC Secretariat, Members and Chairperson
3	After the Board Meeting and Preparing the minutes	IEC Secretariat/ Member Secretary
4	Approval of minutes	IEC members / Chairperson
5	Filing the minutes	IEC Secretariat

5. Detailed instructions

5.1 Before each Board meeting

5.1.1 Preparation of meeting agenda

- The Secretariat will prepare the agenda to include:

Meeting no.:
Date : -
Venue : -
Time : -

Period 1

1. Confirmation of quorum by the chairperson
2. Welcoming members by chairperson Roll call and apologies from absent IEC member:
3. Discussion of points, if any arising from minutes of the last meeting
4. Declaration of Conflict of interest

Period 2 **Issues to be discussed**

A. New protocol presentation, review, discussion and reaching a consensus to approve/raise queries

B. Review the responses forwarded by the Principal Investigator to the query letter /resubmitted protocols

C. To discuss protocol/ICD amendments and other project related documents
D. To discuss continuing review report, Completion, Termination

- **To discuss continuing review report**
- **Reminders already sent to PI for continuing review report not yet received**
- **To discuss Completion report**
- **To discuss termination report**

E. To discuss Deviation report

F. To discuss other letters related to the projects
G. IEC Site monitoring reports

H. To inform about the SAE Subcommittee meeting and to read out minutes of the SAE Subcommittee meeting.

Period 3:

1] ISSUES TO BE REPORTED FOR CONSIDERATION:

A] i) Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed and approved by the Primary reviewers /member Secretary / Chairperson (n =00)

ii) Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed by the Primary reviewers / member Secretary / Chairperson query for which needs to be communicated to the PI (n =00)

B] Projects Exempted from review: (n =NIL)

C] Expedite review process done for the following projects and query letter / approval given: (n =NIL)

D] Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson (n =NIL)

E] Continuing review report/ completion report/ final clinical trial report reviewed and approved by The IEC member Secretary and Chairperson.

- **Continuing review report (n=NIL)**

- **Completion report:- (n=NIL)**

- **Termination report:- (n =NIL)**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson (n =NIL)

G] IEC Site monitoring reports (n = NIL)

H] Other letters reviewed and noted by the IEC member Secretary / Chairperson (n = NIL)

2] ISSUES TO BE INFORMED TO THE MEMBERS AT FULL BOARD which are reviewed / approved by the IEC member Secretary / Chairperson and letters already sent to the principal investigators

A. Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols(n =NIL)

B. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson (n =NIL)

C. Continuing review report/ completion report/ final clinical trial report reviewed and approved by the IEC member Secretary and Chairperson.

- **Continuing review report (n=NIL)**

- **Completion report:- (n=NIL)**

- **Termination report:- (n =NIL)**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson (n =NIL)

G] IEC Site monitoring reports (n = NIL)

Period 5:

A. Other points for discussion (n =0)

e.g

1. Policy decisions of the meeting of IEC-I /II.
2. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

B. Other issues of interest to the members with permission of chairperson

C. Next Meeting to be scheduled on xxxxxx 2017(19, 20, reserved for staff society)

- The Secretariat will collect and verify all forms/documents for completeness to keep all these papers in the meeting.
- The Secretariat will prepare the meeting agenda, according to the above mentioned format.
- The Secretariat will schedule protocols in the agenda on a first-come first-serve basis.
- Both IEC-I / IEC-II will preferably meet every month. Duration of meeting between two committees should not be more than 2 weeks.
- Answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) from the investigators received 7 days before and other types of documents received 3 days prior to the date of full board IEC meeting will be included in the agenda.
- Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting, any study-related document received within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next month's meeting for discussion EXCEPT where in the opinion of the IEC Secretary or Chairperson has direct bearing on the safety of the research participants (such as SAE report, major protocol violation). Such important matters will be taken up at the imminent meeting.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC members telephonically and/ or via e-mail.
- The Secretariat will send the agenda of the meeting to members via e-mail at least 1 day in advance of the scheduled meeting.
- The Secretariat will make a meeting room reservation for the scheduled meeting date and time.
- The Secretariat will make sure that the room, equipment and facilities are available in good running conditions and cleaned for the meeting day.

5.2 Conduct of the meeting

- The committee will endeavor to hold regular meetings at least once every month. The gap between any two meetings will not exceed 60 days. Even if there are no research proposals for review, the gap between two meetings will not exceed 12 (twelve) weeks. Regular meetings may not be held in the months of May and October/ November, when the college closes for vacation. Meeting will be held as scheduled provided there is quorum. For the IEC meeting, a quorum will consist of:
  - One basic medical scientist (preferably a pharmacologist),
  - One social worker (or a social scientist, theologian, ethicist, Philosopher, member or representative of a non-governmental voluntary agency or a similar person),
  - A clinician,
  - A lay person from the community and
  - A legal expert

    besides the Member Secretary and the Chairperson.
- At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, student, inspectors, auditors, members of other Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc. and are required to sign a confidentiality agreement *AX 03/SOP 03/V5*prior to attending the meeting.
- The Secretariat will obtain signatures on the Confidentiality /Conflict of Interest Agreement Form *AX 03/SOP03/V5* from newly appointed members/ Guests/ observers/ Subject Expert prior to the start of the meeting.
- The Secretariat will obtain the signatures of all the IEC members on the attendance register.
- The Secretariat will obtain from members the written conflict of interest *AX 01/SOP13/V5* prior to the start of meeting
- The Chairperson will initiate the meeting after ensuring that the quorum has been met. The Chairperson at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict.
- The Chairperson will decide if the Conflict of Interest is potentially significant enough to cloud the member's judgment. If yes, the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.

- In case of projects submitted for initial review; the detailed instructions given in SOP 05-A/V5 – are followed.
- Investigators who have been asked by the IEC secretariat to provide additional information or clarifications related to their project may do so by attending the IEC meeting. The discussion amongst IEC members will not be done while the investigator is in the meeting room.
- For other points on the agenda, the member secretary will present the gist of the matter/ read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.

During the discussion at the meeting

The primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided. The comments of subject expert (if applicable) will be discussed by the member secretary. The other IEC members shall give their comments right after the presentation.

- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IEC.
- The IEC members will discuss and clarify the comments and suggestions. The Member secretary (assisted by the Secretarial staff) shall record the discussions

Decision making

- The final decision on the project as: "Approved/ Approved with minor modification/ approved with major modification/Disapproved or any other/Monitoring required ----" in the meeting shall be by consensus and will be recorded in the IEC Decision Form *AX 01/SOP 05-A/V5 by the Member Secretary*.
- In case no consensus reached, voting will be taken. A majority vote for approval, disapproval, request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.
- The following will not vote at the meeting:
  a. Member(s) of the committee who is/are listed as investigator(s) on a research proposal
  b. An investigator or study team member invited for the meeting
  c. An independent consultant invited for the meeting to provide opinion Specific patient groups invited for the meeting
- If the IEC decision is '*Approved***'**, it implies the approval of the study as it is presented with no modifications and the study can be initiated.
- If the IEC decision is *'Approved with minor modification*, the IEC Chairperson may authorize the Secretary/Primary reviewer + secretary to determine if the response and changes are satisfactory and to decide if letter of permission can be issued to the Principal Investigator.
- If the IEC decision is '*Approved with major modification*, the IEC Chairperson may authorize the Primary reviewer + secretary to determine to review the responses which will be discussed in

next full board meeting. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.

- If the IEC decision is '*Disapproved*' or any other, the decision should be made on the basis of specific reasons which are communicated by the IEC to the principal investigator in the letter of notification.
- The Secretariat will obtain the signature of all the members and of the Chairperson of the IEC on the IEC Decision Form *AX 01/SOP 05-A/V5*.
- If the study is approved, the Committee will determine the frequency of Continuing Review from each investigator.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.

5.3 After the Board meeting and preparing the Minutes

- The Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.
- The Secretariat will make sure to cover all contents in each particular category to include the following as in annexure 2

5.4 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and forward the minutes to the IEC members/Chairperson for review within 7 working days of the meeting day.
- After obtaining approval from the Chairperson via email. The minutes will be approved and signed by the chairperson in upcoming full board meeting.

5.5 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Administrative Officer will file the IEC Decision Forms in the project files and place all correspondence in the appropriate files.

6. Glossary

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 votes in its favor.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (last accessed 31st July 2017).

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st July 2017).

8. Annexure

Annexure 1 *AX 01/SOP 13/V5* Conflict of Interest form
Annexure 2 *AX 01/SOP 13/V5* Sample format for minutes of the meeting

Annexure 1
AX 01/SOP 13/V5
Conflict of Interest form

Date:

To,

The Chairperson,

IEC-I / IEC-II,

I hereby declare the conflict of interest for the project no. EC/ /

entitled,_____

as :

1. I am the investigator / co-investigator/Author/study team
2. I have Financial interest
3. _____
4. _____

in the project which will be discussed in today's meeting i.e. xxx.

Dr. _____

Member, IEC-I / IEC-II.

_____
Chairperson,
IEC-I / IEC-II.

Annexure 2
AX 01/SOP 13/V5
Sample format for minutes of the meeting

Institutional Ethics Committee-I/II
Seth GS Medical College and KEM Hospital
Meeting number xx/xxxx

Minutes of the Meeting held on xxxxxx

The minutes of the meeting no. *xxxx* of the Institutional Ethics Committee (IEC) –I*/II*, Seth GS Medical College and KEMHospital held on *xxxxx* have been prepared by _____, Member Secretary of the IEC-I*/II*.

The meeting of the IEC-I/II was **held on xxxat xxx pm in the xxx Venue____**.

___ chaired the meeting. After making sure that the quorum was duly constituted, ____ initiated the meeting by welcoming all the members. _____ asked the members whether anyone has any conflict of interest in the projects to be discussed and if so, to declare the conflict.

Roll call

The following IEC-I/II members attended the meeting:

1. Chairperson
2. Member Secretary
3. Legal Expert
4. Social scientist
5. Lay person
6. Basic medical scientist
7. Physician
8. Member
9. Member

Apologies were received _____

- **Discussion of points, if any arising from minutes of the last meeting held on xxxxx circulated by email to the members.**

  Decision:

- **Agenda of the present meeting**

Period 2 **Issues to be discussed**

A. New protocol presentation, review, discussion and reaching a consensus to approve/raise queries (n=xx)

1. EC/PHARMA-xx/xxxxSponsored By _____
Name of the Principal Investigator: _____Dept. of _____
Name of the Co-Investigators: _____, _____
Title: "_____".

Primary reviewers	
Non-scientific members	
Documents reviewed	
Summary by	
Administrative issues	
Scientific issues	
Ethical issues	
Risk Benefit Assessment	**Risk Categories** ❑ The research involves less than minimal risk to subjects. ❑ The research involves minimal risk to subjects. ❑ The research involves more than minimal risk to subjects. **Benefits Categories** ❑ The research provides no prospect of direct benefit to individual subjects, but likely will yield generalizable knowledge about subject's disorder or condition. ❑ The research provides no prospect of direct benefits to individual subjects, but likely will yield generalizable knowledge to further society's understanding of the disorder or condition under study. ❑ The research provides the prospect of direct benefits to individual subjects. ❑ The research provides no prospect of direct benefits to individual subjects, to science, or to society.
Vulnerability	

Final Decision at the meeting:	Approved		
	Minor modification	MS	
		MS + PR	
	Major modification	MS + PR	
		MS + PR+ FB	
	Disapproved (Reason)		
	Monitoring required (Reason)		

B. Review the responses forwarded by the Principal Investigator to the query letter /resubmitted protocols

C. To discuss protocol/ICD amendments and other project related documents

D. To discuss continuing review report, Completion, Termination

- **<u>To discuss continuing review report</u>**
- **<u>Reminders already sent to PI for continuing review report not yet received</u>**
- **<u>To discuss Completion report</u>**
- **<u>To discuss termination report</u>**

E. To discuss Deviation report

F. To discuss other letters related to the projects

G. IEC Site monitoring reports

H. To inform about the SAE Subcommittee meeting and to read out minutes of the SAE Subcommittee meeting.

<u>Period 3:</u>

1] <u>ISSUES TO BE REPORTED FOR CONSIDERATION</u>:

A] i) <u>Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed and approved by the Primary reviewers /member Secretary / Chairperson (n =00)</u>

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2] ISSUES TO BE INFORMED TO THE MEMBERS AT FULL BOARD which are reviewed / approved by the IEC member Secretary / Chairperson and letters already sent to the principal investigators

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Period 5:

D. Other points for discussion (n =0)

e.g

3. Policy decisions of the meeting of IEC-I /II.
4. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

E. Next Meeting to be scheduled on xxxxxx 2017(19, 20, reserved for staff society)

F. Other issues of interest to the members with permission of chairperson

Since there was no other business, chairperson concluded the meeting by thanking all the members.

_____ _____

Member Secretary **Chairperson**