Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

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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 Ethics Committee for Research on Human Subjects (ECRHS) meetings.

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all regular ECRHS 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 ECRHS 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	ECRHS Secretariat
2	During the Meeting	ECRHS Secretariat, Members and Chairperson
3	After the Board Meeting and Preparing the minutes	ECRHS Secretariat/ Member Secretary
4	Approval of minutes	ECRHS members / Chairperson
5	Filing the minutes	ECRHS 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:
  1. All resubmitted protocols wherein decision was full board review.
  2. Review of Amended protocol or protocol-related documents, wherein decision was to put to Full Board review.
  3. Issues to be reported for consideration
     - Continuing review of study protocols
     - Review of Study Completion Reports
     - Review of premature study termination
     - Review of Site Monitoring Visit Reports
     - SAE reports/CIOMS forms/Safety letters (If forwarded by SAE Subcommittee)
  4. Issues to be discussed including emergency concerns/ ECRHS policies/ training of Members/ revising SOPs/ any other issues raised by Member(s).
  5. Any other matter referred for ECRHS opinion or issues to be informed to the members.
  6. Reading and approving minutes of the previous meeting.
  7. Minutes of the Meeting of SAE subcommittee.
  8. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

  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 format in *AX 01/SOP 16/V3.1*.
- The Administrative Officer will schedule protocols in the agenda on a first-come first-serve basis.
- The Member Secretary will schedule the next meeting at the time of the previous scheduled meeting after consulting the Chairperson and the ECRHS members.
- Answers to the ECRHS 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 ECRHS meeting will be included in the agenda.
- Agenda for the ECRHS 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 ECRHS 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 ECRHS members telephonically and/ or via e-mail.
- The Secretariat will send via e-mail to members the agenda of the meeting at least 1 day in advance of the scheduled meeting.
- The Secretariat will make a 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 During 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 ECRHS 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/SOP03/V3.1* prior to attending the meeting.
- The Secretariat will obtain signatures on the Confidentiality /Conflict of Interest Agreement Form *AX 02/SOP03/V3.1* from newly appointed members/ Guests/ observers/ Independent Consultants prior to the start of the meeting.

- The Secretariat will obtain the signatures of all the ECRHS members on the attendance register.
- 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 06/V3.1 – section 5.10 are followed.
- Investigators who have been asked by the ECRHS secretariat to provide additional information or clarifications related to their project may do so by attending the ECRHS meeting. The discussion amongst ECRHS 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.
- ***Decision making***

The final decision on each proposal/ issue discussed in the meeting shall be by voting/consensus.

  - 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.
  - Member(s) of the committee who is/are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.

- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
- An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision making procedures of the committee.
- Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.

- The schedule of the next meeting will be discussed and finalized by the 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:
  - Name of person preparing the minutes
  - Location where the meeting was held (city, state)
  - Meeting number, date/duration of the meeting (time of commencement and end)
  - Names of the ECRHS members and guests attending the meeting
  - Name of the 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:
  - Sponsor's name;
  - Protocol number/date/version of protocol, when available;
  - Investigator's name;
  - Names of the Primary Reviewers who presented their findings
  - Discussion as deemed appropriate by the Chairperson
  - Follow-up action decided upon
  - Reference to the investigator approval letter that lists all changes requested by the board;
  - Determination of the next requested continuing review.
- Requirements for each study or activity requesting Expedited Review:
  - Sponsor's name;
  - Protocol number, if applicable
  - Investigator's name;
  - Lists of expedited approval requests and outcomes.

- Requirements for each Continuing Review Report:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;
  - Indication of the Board's determination to continue, terminate, or amend the study;
  - Lists of recommendations or actions to be taken up with the investigator, if applicable.
- Requirements for each Adverse Event notification and Final Report:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;
  - Report or summary of report provided by the SAE sub-committee;
  - Actions deemed appropriate by the Board's review.
- Requirements for Termination of Approval:
  - Name of the Sponsor ;
  - Protocol number, if applicable;
  - Investigator's name; reason for termination.

5.4 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and presents the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Chairperson indicates approval by signing and dating the minutes.
- The Secretariat will email the minutes of the meeting to the ECRHS members after obtaining approval from the Chairperson.

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 ECRHS Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the ECRHS at the monthly meetings (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the ECRHS meeting.

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 ECRHS 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 24 March 2008)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 24 March 2008).

8. Annexure

Annexure 1 *AX 01/SOP 16/V3.1* Agenda format

Annexure 1

AX 01/SOP 16/V3.1

Agenda Format

Agenda of the ECRHS Meeting

Meeting No ECRHS meeting nn/yyyy

Location of the meeting

Meeting Date

Meeting time

The Board meeting will proceed in the following sequences:

Period 1: Discussion of the points arising from the minutes of the previous meeting and presentation of agenda of the day's meeting and Declaration of Conflict.

Period 2: A] New Protocol Presentation, Review, Discussion and reaching a decision by voting to approve/raise queries,

B] Review the responses forwarded by the principal investigator to the query letter/ resubmitted protocols

C] Approve protocol amendment and related documents.

D] To review the continuing review report/ completion report/ final clinical

trial report/ Annual report / Termination reports .

E] To review Protocol Deviations / Violations

F] To review other Letters related to projects

G] To review Monitoring reports

H] To inform about the SAE Subcommittee meetings and to review SAE/Safety reports.

I] Other points for discussion

Period 3: Issues reviewed and approved by the ECRHS member Secretary and Chairperson which are to be reported for Consideration

Period 4: Issues to be informed to the members at Full Board which are approved by the ECRHS member Secretary and Chairperson and letters already sent to the principal investigator

Period 5: Other issues of interest to the members