



Institutional Human Ethics Committee, BITS Pilani, Pilani Campus, Rajasthan
STANDARD OPERATING PROCEDURE

Title: General Procedure and Instruction		
Document No:		
Preparation Date: 20-05-2019	Effective Date: 31/05/19	Revision Date:

General Procedure : Instructions for preparation, and distribution of meeting agenda, minutes of IHEC Full Board Review meetings.

The Member-Secretary, IHEC and IHEC secretariat staff are responsible for the conduct of IHEC meeting.

Detailed instructions

IHEC will look into all the proposed protocols, the amendments to the ongoing study projects, and revision or continuation of the previously approved protocols during the full board meetings.

The agenda of the IHEC meeting is prepared in the prescribed format as per the different items to be discussed. The Member-Secretary will prepare the agenda with the help of the IHEC staff and send them to the members before the meeting or circulate them before the meeting is initiated.

Distribution of Protocol/Documents to the IHEC Members

- The IHEC secretariat distributes copies of the protocols by electronic mail to members and hard copies to primary Reviewers 7 days in advance before the meeting.
- The IHEC secretariat confirms the received protocol.
- It is the responsibility of the IHEC members to verify items of the protocol documents on receipt and in the event of any missing items.

Preparation for the meeting

- i. The Full Board Review Meeting of IHEC shall take place once or twice in a year. Emergency IHEC full board meeting may be conducted on any other day if any protocol requires an urgent review.
- ii. The IHEC secretariat will reserve the meeting room for the scheduled date and time for the IHEC meeting.
- iii. IHEC secretariat will ensure that all the required facilities are available.
- iv. The secretariat will keep all the original files of protocols listed in the agenda in the meeting room for ready reference.

Conduction of Meeting

- The members will assemble in the IHEC meeting room at the scheduled time.
- The meeting proceeds in the sequential order of the agenda.
- Member secretary will begin the meeting with a welcome speech.
- Independent consultants will sign agreement of confidentiality.
- IHEC members will sign in the attendance sheet.
- Participants or their representative (in case of emergency) can be allowed to be a part of the meeting.
- Observers will sign the confidentiality agreement.
- The Member-Secretary will give a list for expected approval.



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- PI will give the proposal to all IHEC members during the meeting.
- Member secretary will ask Primary reviewers to give their analysis of the proposal. After this all the members will give their inputs.
- The meeting proceeding will be recorded by the Member-Secretary.

Decision Making Process

- i. Decisions will only be made at meetings when all the members of quorum are present.
- ii. The documents of proposal under review should be complete.
- iii. Decision will be taken only after sufficient time and consideration is given to all the aspects of the proposal.
- iv. Only IHEC members who attend the meeting will participate in the decision making process. Decision will be made unanimously or may be by voting.

The possible decisions may be

- ✓ Approved
- ✓ Approval pending for minor modifications
- ✓ Resubmission
- ✓ Disapproved

The board will approve the proposal if no or only minor modifications are required.

If major changes are required, the updated proposal will be discussed in the next meeting.

If the study is found to have major risk involved before or after its approval, the IHEC may disapprove the proposal. The minutes of the meeting will be prepared by the Member-Secretary.

This will apply to review the statistical report of study protocols once in 12 months. Factors to be considered are: (i) the degree of risk to the participants, (ii) the nature of the studies and (iii) the possible harm of the study participants and duration of the study. This SOP also covers the process for auto-renewal of the approval of projects to multiyear. IHEC Secretariat is responsible to scheduled date for statistical report review with application form for renewal of approval and send reminder to the PIs for submitting status reports.

It is the duty of IHEC to review the progress made in the study protocol.



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Title: Review of Resubmitted Protocol		
Document No:		
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The PI can submit research process details to the IHEC secretariat for review and approval according to section provided below within the specified period of time given below:

Re-submission of Protocols with corrections as per IHEC suggestions:

- Within 15 days from the date of decision letter received from IHEC.
- For re-submitted protocol, the PI will submit three hard copies and one soft copy of the amended Protocol and related documents clearly highlighted/marked sections which have undergone amendment (two copies to the Primary Reviewers and the other for records purposes in the IHEC Secretariat).
- The IHEC Secretariat will verify the completeness as per following process:
 - i. The checklist attached to the Study Protocol Submission Forms. The secretariat must check the re-submitted protocols according to the checklist to make sure that all required forms and materials are submitted.
 - ii. Verification includes:
 - Properly filled and updated and signed Study Protocol Submission Forms.
 - Study protocols.
 - Other relevant documents.
 - Return the protocol documents to the applicants, if the documents are incomplete, clearly mentioning/explaining the missing items.
 - iii. The secretariat will check the following important parameters:
 - Stamp, sign & date the received document on the front page and confirms the receipt of the documents along with fee.
 - Provide study proposition number, stamp and sign with date on the last page of the Protocol Submission Forms, make a photocopy and return a copy to the applicant for their records.



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Title: Review of Serious Adverse Events (SAE) Reports		
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The IHEC board will discuss the submitted reports of Primary Reviewers. In case of serious side effect be associated / occurred, If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IHEC discussion, some of which are listed below:

- ✓ Terminate the study;
- ✓ Suspend the study till IHEC review of the same is completed;
- ✓ Suspend the study till additional information is obtained;
- ✓ Suspend the study for a fixed duration of time;
- ✓ Suspend the study till amendments requested for by the IHEC are accepted;
- ✓ Suspend enrolment of new research participants;
- ✓ Suspend certain activities under the protocol
- ✓ Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
- ✓ Request additional details
- ✓ Direct the PI to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary.
- ✓ Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.
- ✓ Note the SAE report in the IHEC records if information submitted is found to be adequate



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Title: Review of Study Completion Reports		
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Responsibility: It is the responsibility of the IHEC members to review the study completion report.

Before board meeting

- The secretariat will receive three hard copies and one soft copy each of Study Completion Report from the PI
- The Secretariat will follow instructions for receiving and checking the reports
- Member-Secretary, IHEC will send hard copy to primary reviewer and soft copy to all the members
- The IHEC Secretariat should keep the study completion reports on the agenda for IHEC meeting.

During the board meeting

- The members will discuss the report in the IHEC meeting.
- The Chairperson will call for consensus to accept it or request further information or take any other action as suggested by IHEC.

Responsibility: It is the responsibility of the IHEC to suspend/terminate any previously approved study when there is high benefit to risk ratio.

Receive recommendation for study Termination/ Suspension/Discontinuation

- ✓ The Secretariat will receive comments from the site monitoring team, PI, or other authorized bodies for premature termination of study protocol.
- ✓ The IHEC can prematurely termination occurs due to any violation.
- ✓ Occurring SAE at site may need the study to be prematurely terminated for the safety of the patients.
- ✓ The termination decision will be informed to the PI. Also the PI was requested to submit a protocol premature suspension/termination report in the prescribed format
- ✓ The Secretariat will verify the documents for completion and it is signed and dated by PI.
- ✓ The Secretariat should also sign and date the report and the copy is provided to PI.
- ✓ Hard copies are send to of the Primary reviewers and soft copies to other members for review.

At Full board meeting

- IHEC will review the study Termination/Suspension/Discontinuation report at full board meeting.
- After the board meeting
- The study will be considered as terminated/ suspended/discontinued, if the document is accepted.
- The secretariat will write the conclude decision in meeting minutes.
- In case further information/action is required, the same should be communicated to the IHEC Secretariat within 30 days.
- The IHEC decision is communicated to the investigator within 14 days

Filing the documents

- The Secretariat will place the corresponding report and decision letter in the study file.
- Post-review activities:
- Suspension:
- In case of suspension, IHEC will stop the suspension after receipt of correct report from the PI.

Termination / Discontinuation:

- In case of termination/discontinuation, IHEC Secretariat will archive the entire study protocol and the report for a period of five years from the date of termination/discontinuation of the project.