Title: Full Board Review of New Research Study Protocols

SOP Code: SOP 07A/V2
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SOP Constitution and Approval:

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the members of Institutional Human Ethics Committee (IHEC), will perform an initial review on a new research study protocol using the assessment Form.

2. Scope

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the IHEC. All research studies presented with more than minimal risk and which do not qualify for exemption, expedited review, proposals submitted after major revision, proposals that need termination of a study are covered in this SOP.

3. Responsibility

- After categorization, the new proposal (as per SOP 7/V2) is forwarded to the Secretariat by the three internal members, it is.
- IHEC Secretariat is responsible for creation of a study specific file, distribution of packages along with study assessment forms to IHEC members for review (If the study is categorized for Full Board review)
- IHEC members (including Member Secretary/Additional Member Secretary) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the IHEC members to fill the Assessment form along with comments and recommendation after reviewing each study protocol.
- The IHEC members are responsible for attending and participating actively in the discussion at the full Board Meeting.
- The Member Secretary/Additional Member Secretary is responsible for setting up the Full Board Meeting.
- IHEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

Member Secretary/Additional Member Secretary is responsible to sign and date the decision on each proposal in the IHEC Decision Form and communicate the decision to the PI.

4. Detailed instructions

4.1 Appointment of primary reviewers

- The Member Secretary/Additional Member Secretary/Chairperson will appoint two primary reviewers for each study on the basis of expertise in the related field and experience. They will include one clinician and one non-technical person as applicable. More than two may be appointed if necessary.

4.2 Distribute the protocol package

- Distribution of Protocol at least 4 weeks prior to Scheduled review meeting
- The Secretariat will fill in the required details in the cover letter to the IHEC Members requesting initial review along with study assessment form.
- Secretariat will send a packet *(hard or soft copy)* to the IHEC members.
    - Letter to IHEC Members requesting Initial Review
    - Study assessment form
    - Study Submission Application Form
    - Protocol and related documents

4.3 Receive the distributed protocol package

- IHEC members will receive the protocol package with the Study Application Form as hard copy or soft copy through email (if so desired).
- Designated primary reviewers will also receive Study Assessment Form for Initial review

4.4 Verify the contents of the package

- IHEC member will verify all the contents.
- IHEC member will check the meeting date to see if it is convenient to attend the meeting.
- IHEC member will notify the IHEC Secretariat if any documents are missing or if the specified date of the IHEC meeting is not convenient to attend.

4.5 Review by the IHEC members

Review of the protocol

- The protocol will be reviewed by each member as per guidelines to review study protocol.
- The IHEC member will consider the following criteria when performing the review of the study protocol and the study related documents:
    - Scientific design and conduct of the study

- Risks and potential benefits to the participants/community
- Selection of study population and recruitment of research participants
- Inducements, financial benefits and financial costs
- Protection of research participants' privacy and confidentiality
- Community considerations
- Assess the qualifications of Investigators and adequacy of study sites
- Disclosure or declaration of potential conflicts of interest
- The protocol will be sent for review by an independent consultant if decided by the primary reviewer(s)

- The IHEC member will consider the following criteria when performing the review of the Informed consent
  - Voluntary, non-coercive recruitment, participation/ withdrawal
  - Procedures for obtaining informed consent
  - Contents of the patient information sheet - title, objective, study design and procedures
  - Contents and language of the informed consent document
  - Translation of the informed consent document in the local languages
  - Language used – plain and easy to understand by general public
  - Contact persons with address and phone numbers for questions about research participants doubts or consultation regarding injury
  - Privacy and confidentiality
  - Risks and discomforts – physical / mental / social
  - Alternative treatment
  - Benefits – to participants, community, institution and society
  - Compensation for participation: (Whether it will act as undue inducement) o Involvement of vulnerable participants
  - Provisions for medical/ psychosocial support
  - Treatment for study related injuries
  - Compensation for study-related injuries: as per applicable local regulations o Use of biological material
  - Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness
  - Provision for audiovisual recording of consent process in case of regulatory drug trials
  - Use of study assessment form for reviewers
  - The assessment form is designed to standardize the review process.

- All reviewers will fill out the form (AX 01/SOP 7A/V2 - letter to IHEC members requesting initial review with study assessment form) and write their comments related to review of the research proposal.
- In addition, primary reviewers will use the study assessment form
- Ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting.
- The duly filled, signed and dated assessment forms will be returned along with the research protocols to the Secretariat 15 days prior to the meeting.

4.6 Gather the assessment reports

The IHEC Secretariat will collect the assessment forms, comments from each reviewer and file in the original study file and convert into a soft copy for discussion at the meeting. If the comments come as a soft copy these will be collated for discussion at the meeting.

4.6 IHEC meeting

- Any member, if part of investigation team of a particular proposal shall inform the chair person and disengage from discussion by leaving the meeting hall for the duration of discussion on that proposal.
- 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 on the assessment form.
- The comments of an independent consultant (if applicable) will be discussed by member secretary/Additional Member Secretary.
- The other IHEC members shall give their comments right after the presentation.
- The PI/co-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IHEC.
- The IHEC members will discuss and clarify the comments and suggestions.
- The Member secretary/Additional Member Secretary (assisted by the Secretarial staff) shall record/minute the discussion points.
- The final decision on the study will be recorded as: “Approved/ Disapproved/ Suggested recommendations or any other (as per IHEC policy” in the meeting shall be made by majority consensus or voting (as per the IHEC policy) and will be recorded in the IHEC Decision Form by the Member Secretary/Additional Member Secretary.
- A majority consensus for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study or by voting which is defined as 2/3rd of the voting members present at the meeting.

The following will not be eligible to vote

- Member(s) of the committee who is/are listed as investigator(s) on a research proposal
    - A member if he/she happens to be part of the study team.
    - An investigator or study team member invited for the meeting.
    - An independent consultant invited for the meeting to provide opinion
    - Specific patient groups invited for the meeting will not vote or participate in the decision-making procedures of the committee.
    - Member who has declare conflict of interest during the meeting.
- The Committee will decide whether the query responses and (if applicable) revised protocol will go only to Member Secretary/Additional Member Secretary, to primary reviewers or to Full Board before final approval.
- The response and changes (major revision) carried out may be considered for discussion at a future IHEC meeting.
- If the IHEC decision is 'Disapproved' or any if there is a need for major revision, the decision which shall be made on the basis of specific reasons, shall be communicated by the IHEC secretariat to the principal investigator in the letter of notification.
- The Secretariat will obtain the signature of the Chairperson on the IHEC Decision Form.
- If the study is approved, the Committee will recommend monitoring for a study if it is so determined at the meeting depending on presence of factors like risk, vulnerable population etc in the protocol, the PI has a history of protocol violations; PI has more than two protocols at a given time and any other reason so deemed by IHEC.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IHEC members.
- With the study protocol, the Assessment Form from all members and IHEC Decision Form will be filed in the study file by the Secretariat.
- The Administrative Officer will return the file and the protocol to the appropriate shelves.

4.8 Final communication of the IHEC decision taken on the study to the Principal Investigator

- The Secretariat will prepare an approval letter to be sent to the Principal Investigator when the study is approved at an IHEC meeting.
- Definition of Principal Investigator (PI): The Guide/supervising Faculty will be the PI.
- The letter shall contain:
    - Study reference number
    - Study title

- A listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the duration of the study, till completion of the same.
- The approval is provided for the one year duration of the study, which shall be extended on request after consideration by the IHEC.
- List of IHEC members present at the meeting when the study was approved.
- The Chairperson and the Member Secretary/Additional Member Secretary will sign the approval letter and the Secretariat will transmit it to the Principal Investigator within 14 days.

- If the IHEC decides that the proposal needs any minor revision the same will be intimated to the investigator and 4 weeks' time would be provided for resubmission with compliance, only after which the study can be undertaken.

The Secretariat will notify the investigator in writing about the decision on approval or the reason/s for not approving the study if any within 14 working days.

A notifying letter to the investigator should state the following:

- "If you wish to appeal to this decision, please contact the IHEC and submit your appeal in writing within twelve (12) weeks of the receipt of the committee's decision, addressed to the IHEC Chairperson with justification as to why the appeal should be granted. In absence of appeal, the study will be declared closed for the IHEC office records."
- If the Committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the IHEC.
- The Principal Investigator will be asked to respond to the letter of comments/queries within 60 days of the receipt of the letter by the investigator. In the absence of any response, the study will be declared closed for the IHEC office records.
- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 14 days after the meeting.

4.9 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the study file along with all the reviewed documents. The Administrative officer will store the file on an appropriate shelf in the designated cabinet.

5. Glossary

Vulnerable research participants	A vulnerable category of research participants includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.
Initial Review	The first time review of that protocol made by two or three individual reviewers (IHEC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.
Minimal Risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Benefit	A research benefit is considered to be something of a health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participating in research is not considered to be a benefit. A great deal of research in the social and behavioral sciences offers little potential for direct benefits to the subjects themselves. Rather, the benefits often encompass the importance of the knowledge to be gained, and/or to the contributions the research makes to science or society.

6. Annexures

Annexure 1: AX 01/SOP07A/V2 - Letter to IHEC Members requesting initial review with study assessment form
Annexure 2: AX 02/SOP07A/V2 - Study assessment form for primary reviewer
Annexure 3: AX 03/SOP07A/V2 - IHEC decision form
Annexure 4: AX 04/SOP07A/V2 - Format of study approval letter
Annexure 5: AX 05/SOP07A/V2- Guidelines for reviewing a study protocol

Annexure 1: AX 01/SOP07A/V2

Letter to IHEC Members requesting initial review with study assessment form

Dear Member,

The next meeting of the IHEC will be held on …….at…….in…….

Please note that a package of research proposal is dispatched in the following order. You are requested to review the same preferably within 7 working days of receiving the package. Please review the protocol and related documents as per the guidelines attached with Annexure 1 and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the Soft copy. Kindly confirm your availability for the meeting.

Name of Member	Date of Receipt	Signature	Attending meeting (Y/N)

1. Protocol Number (as per IHEC records):
2. Date of receipt at IHEC office after review by member (DD/MM/YY):
3. Protocol Title:

4. Name of the Reviewer:
5. Comments:

_____ _____

Signature of IHEC member Date

Reviewing the study:

Annexure 2: AX 02/SOP07A/V2

Study assessment form to be used by the primary reviewer

Protocol Number :		Date (DD/MM/YY):
Protocol Title :		
Principal Investigator:		
Department :		
No. of Participants at the site:	No. of Study site(s):	

Mark and comment on whatever items are applicable to the study.

1	Objectives of the Study Clear unclear	What should be improved?
2	Need for Human Participants Yes No	Comments:
3	Method ology: Clear unclear	What should be improved?
4a	Background Information and Data Sufficient insufficient	Comments:
4b	Risks and Benefits Assessment acceptable unacceptable	Comments:
4c	Inclusion Criteria appropriate inappropriate	Comments:
4d	Exclusion Criteria appropriate inappropriate	Comments:
4e	Discontinuation and Withdrawal Criteria appropriate inappropriate	Comments:
5	Involvement of Vulnerable Participants: Yes No	Comments:
6	Voluntary, Non-Coercive Recruitment of Participants Yes No	Comments:
7	Sufficient number of participants? Yes No	Comments:
8	Control Arms (placebo, if any) Ye s No	Comments:
9	Are Qualifications and experience of the Participating Investigators appropriate? Yes No	Comments:
10	Disclosure or Declaration of Potential Conflicts of Interest Yes No	Comments:

11	Facilities and infrastructure of Participating Sites Appropriate Inappropriate	Comments:
12	Community Consultation: Yes No NA	Comments:
13	Benefit to Local Communities Yes No	Comments:
14	Contribution to development of local capacity for research and treatment Yes No	Comments:
15	Availability of similar Study / Results: Yes No	Comments:
16	Are blood/tissue samples sent Abroad? Yes No	Comments:
17	Are procedures for obtaining Informed Consent appropriate? Yes No	Comments:
18	Contents of the Informed Consent Document: Clear unclear	Comments:
19	Language of the Informed Consent Document: Clear unclear	Comments:
20	Contact Persons for Participants Yes No	Comments:
21	Privacy & Confidentiality Yes No	Comments:
22	Inducement for Participation Unlikely Likely	Comments:
23	Provision for Compensation for Participation appropriate inappropriate	Comments:
24	Provision for Treatment for Study-Related Injuries appropriate inappropriate	Comments:
25	Provision for Compensation for Study Related Injuries appropriate inappropriate	Comments:

Reviewer's Signature with date: _____

Annexure 3: AX 03/SOP07A/V2
IHEC decision form

Date of IHEC meeting: _____
Protocol number: _____

IHEC Protocol No. and Title:	
Principal Investigator:	Department:
Final Decision at the meeting:	☐ Approved ☐Approved after modifications ☐Resubmission ☐Disapproved ☐Monitoring required Reason: _____ ☐Deferred Disapproved, Reasons: _____ _____

Recommendations:

Note: *The revised protocol to be submitted to the Member Secretary/ Additional Member Secretary at IHEC Office.*

_____ _____

Signature of the Chairperson **Date**

Annexure 4: AX 04/SOP07A/V2
Format of Study Approval Letter

Date: xxxxxxxxx

To,

Dr. xxxxxxxxxxxxxx,

Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, "xxxxxxxxxxxxxxx".

Dear Dr. xxxxxxxxx,

The following documents of the above mentioned project were reviewed and approved through a full board review process.

1. xxx 2.xxxxxxx 3.xxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at as per the submitted protocol.

The IHEC approves the above mentioned study.

This approval is valid for the one year duration of the study and shall be considered for extension by IHEC, upon request with in sufficient time by the PI.

It is the policy of IHEC that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP 12 to IHEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IHEC and the Head of the institution where the trial is been conducted within 14 days of SAE or death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IHEC of an appropriate amendment. The

IHEC expects that the investigator should promptly report to the IHEC any deviations from or changes of the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxx.

A copy of the final report should be submitted to IHEC for review.

Sincerely yours

xxxxxxxxxxx

Member Secretary/Additional Member Secretary / Chairperson

Date of approval of the study: xxxxxx

Annexure 5: AX 05/SOP07A/V2

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - Knowledge from the basic research may possibly benefit.
   - A new choice of method, drug or device that benefits the research participants during the study and others in the future.
   - Provide safety data or more competitive choices.
2. Does the study design will be able to give answers to the objectives? Whether
   - The endpoints are appropriately selected.
   - The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - The control arm is appropriately selected for best comparison.
   - The placebo is justified.
   - The number of study participants in non-treatment (or placebo) arm is minimized.
   - Unbiased assignment (e.g. randomization, etc.) is in practice.
   - Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - The sample group size appropriate with the given statistical assumptions.
   - Predictable risks are minimized.
     - The tests and procedures that are more than minimal risk are cautiously used.
     - Research participants deception is avoid.
     - Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.
     - The study participants are adequately assessed and provided follow-up care, if needed.
3. Who will be the participants in the study? Whether
   - The described population is appropriate for the study.
   - Predictable vulnerabilities are considered.
   - It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
   - There will be secondary participants.
4. Do the inclusion and exclusion criteria
   - Selectively include participants most likely to serve the objective of the study?

- Equitably include participants?
- Properly exclude participants who can predictably confound the results?
- Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?

5. Does the study design have adequate built-in safeguards for risks?
   - Appropriate screening of potential participants?
   - Use of a stepwise dose escalation with analysis of the results before proceeding?
   - Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
   - Is there minimized use of medication withdrawal and placebo whenever possible?
   - Will rescue medications and procedures be allowed when appropriate?
   - Is there a defined safety committee to perform interim assessments, when appropriate?
   - Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - The animal study and *in vitro* testing results?
   - Previous clinical results, if done?
   - Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
     - The selected dose based on adequate prior results?
     - Monitoring tests designed to detect expected possible risks and side effects?
7. Do the study and the informed consent process include issues of special concern, such as:
   - Waiver or alteration of consent?
   - Delayed consent (e.g., emergency treatment, etc.)?
   - Deception?
   - Sensitive information of participants that may require a confidentiality statement?

Guidelines to review Informed Consent Document/Patient Information Sheet

The actual process of informed consent should:

- Give the participants significant information about the study.
- Make sure the participants have enough time to carefully read and consider all options.
- Answer all questions of the participants before making decision to participate.
- Explain risks or concerns to the participants.
- Make sure that all information is understood and satisfied by the participants.
- Make sure the participants understand the study and the consent process.
- Obtain voluntary informed consent to participate.

- Make sure the participants can freely consent without coercion, pressure or other undue influences.
- Consent should be informally verified on a continuing basis.
- Continue to inform the participants throughout the study.
- Continue to re-affirm the consent to participate throughout the study.

Guidelines to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (≥85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

   If the answers of (1) to (6) are "yes", placebo is not recommended. If any one or more answers are "no", placebo may be possible.

7) Are the side effects of the standard treatment severe?
8) Does standard treatment have many uncomfortable side effects?
9) Does standard treatment have contraindications that prevent some research participants from being treated?
10) Is there substantial (≥25%) placebo response in this disease or symptom?

    If the answer of (7) *to* (10) *are "no", placebo is not recommended. If any one or more answers are "yes", placebo may be possible.*

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening?

   If yes, placebo is not acceptable.

2) Is the use of placebo instead of treatment likely to lead to permanent damage?

   If yes, placebo is not acceptable.

3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?

   If yes, placebo is not acceptable.

4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?

   If answers of (4) *to* (6) *are "yes", placebo is not acceptable unless risk management is adequate.*

III. Risk management

1) Is there benefit in the overall management of the research participants?

   Yes, consider placebo
   No, placebo not recommended.

2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?

   No, consider placebo

   Yes, placebo not recommended.

3) Are research participants at high risk for the use of placebo excluded?

   Yes, consider placebo
   No, placebo not recommended.

4) Is the duration of the study the minimum necessary in relation to the action of the drug?

   Yes, consider placebo

   No, placebo not recommended.

5) Are there clearly defined stopping rules to withdraw the research participants in case he/she does not improve?

   Yes, consider placebo

   No, placebo not recommended.

6) Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences?

   Not applicable.

   Yes, consider placebo

   No, placebo not recommended.

7) Are there clearly defined stopping rules to withdraw the research participants before the advent of severe disease progression?

   Yes, consider placebo

   No, placebo not recommended.

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

   Not applicable.

   Yes, consider placebo

   No, placebo not recommended.

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?

   Not applicable.

   Yes, consider placebo.

   No, placebo not recommended.

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

Not applicable.

Yes, consider placebo.

No, placebo not recommended.

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?

Yes, consider placebo.

2) Are the risks of the test drug disclosed?

Yes, consider placebo.

3) Are the advantages of alternative treatments explained?

Yes, consider placebo.

Conclusions:

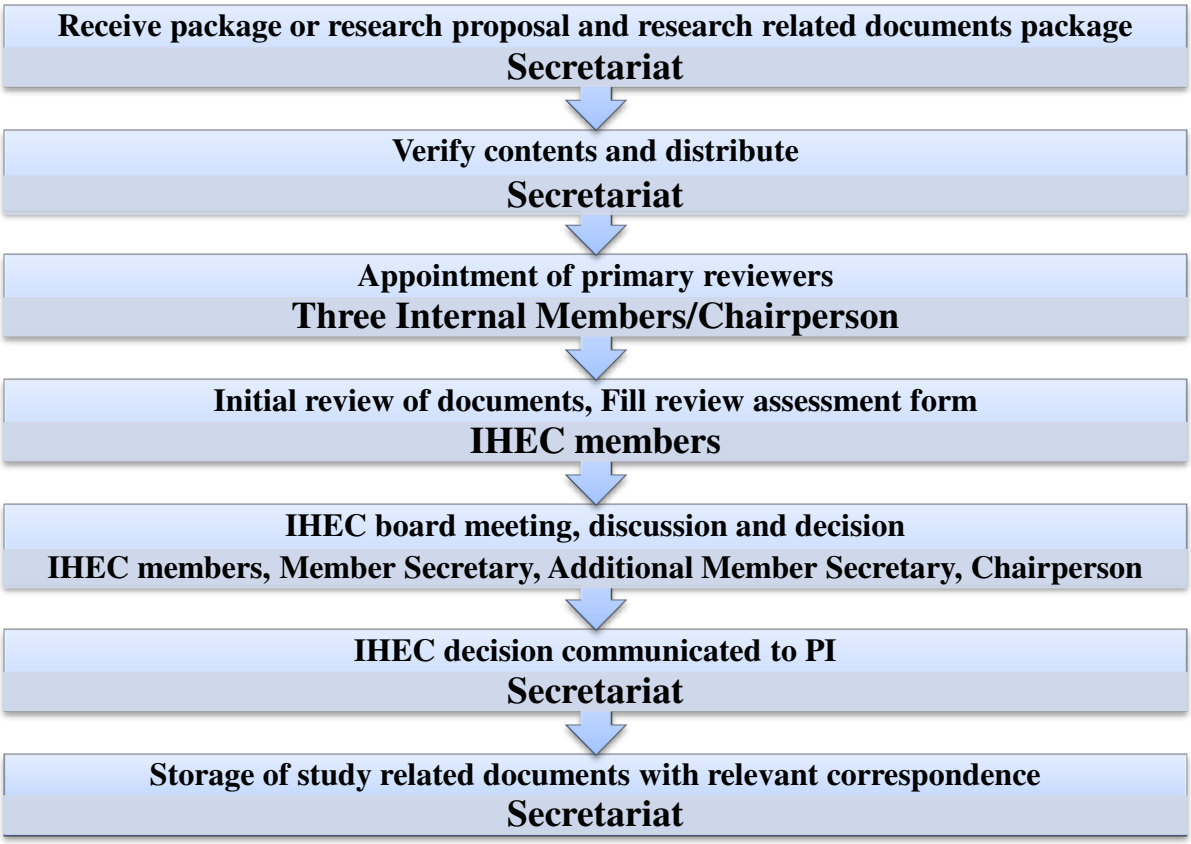
The use of placebo is ethically acceptable when

- research participants are not exposed to severe or permanent harm by the use of placebo.
- research participants under placebo will benefit from the overall treatment of the disease.
- risks of the use of placebo are minimized.
- risks are adequately disclosed in the consent form.

Guidelines to review advertisements

- Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:
  - The name and address of the researcher or research facility.
  - The purpose of the research or the condition under study.
  - In summary form, the criteria that will be used to determine eligibility for the study.
  - A brief list of benefits to participants, if any.
  - The time or other commitment required of the participants.
  - The location of the research and the person or office to contact for further information
  - The IHEC reviews advertising to ensure that advertisements **DO NOT**:
  - State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
  - Include exculpatory language.
  - Emphasize the payment or the amount to be paid, by such means as larger or bold type
  - Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

7. Flow Chart



8. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*