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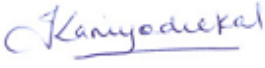
Accepted by:	**Designation:** Managing Director **Name:** Msgr. Dr. Joseph Kaniyodickal **Signature** 

AMENDMENT SHEET

Sl. No	Sec no. & page No.	Details of amendment	Signature

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the Terms of Reference (TOR), which provide the framework for constitution, selection, roles and responsibilities of the Institutional Human Ethics Committee (IHEC) and procedures for maintaining confidentiality of all activities and documents.

Scope

This SOP applies to the constitution of the IHEC, selection, roles and responsibilities of members of the IHEC and maintenance of confidentiality of all activities and documents.

Responsibility

The selection of Chairperson, Member Secretary and IHEC members will be done by the Head of the Institution. It is the responsibility of all the IHEC members and the Secretariat to read, understand, follow and respect this SOP.

Detailed Instructions

4.1 Composition of the Institutional Ethics Committee

The IHEC will be established by the **Head of the Institution (HOI)**. The Chairperson could recommend the names of potential members but the Head of the Institute will be the appointing authority.

Its hierarchical position in the organization and authority under which it is established will be clearly indicated (*ANX-02/IHEC/SOP-02/V1)*

The IHEC will be multidisciplinary and multi-sectoral in composition.

Preferably 50% of the members should be non-affiliated or from outside the institution.

The IHEC will be composed of at least 7 members upto a maximum of 15 (as per current CDSCO requirements).

Function of the Ethics Committee

The Ethics Committee for clinical trials shall perform the following functions for a person, institution or organization; namely:

(i) review and accord approval to a clinical trial, bioavailability or bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause

(B) of Table 1 of the Third Schedule and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with the rules, Good Clinical Practices Guidelines and other applicable regulations;

(ii) make at appropriate intervals, an ongoing review of the clinical trials for which it has accorded approval and such review may be based on periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites;

(iii) indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licensing Authority;

(iv) where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyze the relevant documents pertaining to such event and forward its report to the Central Licensing Authority and comply with the provisions of Chapter VI;

(v) where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licensing Authority;

(vi) allow any officer authorized by the Central Licensing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects;

(vii) comply with the requirements or conditions in addition to the requirements specified under the Act and these rules as may be specified by the Central Licensing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

The Terms of References to the Ethics Committee

- The EC should have written SOPs according to which the committee should function. The SOPs will be updated periodically to reflect changing requirements. A copy of the latest version of SOPs will be made available to each member and they will be trained on the SOPs. The SOPs will be available in the secretariat of the EC as both hard and soft copies.
- The scope, tenure and renewal policy of the EC will be stated.
- Members of the EC will not have any known record of misconduct.
- The EC will be registered with the relevant regulatory authorities.
- The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
- The EC must ensure ethical conduct of research by the investigator team.
- The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
- The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.
- Responsibilities of members should be clearly defined.
- The SOPs should be given to EC members at the time of their appointment.
- The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
- The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected
- The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
- The EC should recommend appropriate compensation for research related injury, wherever required.
- The EC should carry out monitoring visits at study sites as and when needed.

- The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
- The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

The members will:

- include a combination of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- have differing backgrounds to promote complete and adequate review of research
- have the required qualifications as prescribed by applicable regulations and guidelines from time to time
- have the expertise, time and commitment to perform all functions
- The IHEC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society.
- The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/research site.
- The IHEC may invite member(s) of specific patient groups or other special interest groups for an IHEC meeting (if required, based on the requirement of research area, e.g. HIV/AIDS, etc for eliciting their views. Such individuals will have to sign confidentiality agreement (*ANX-05/IHEC/SOP-02/V1)* and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have right to vote.

- The Composition shall be as follows:
  - Chairperson
  - One Member Secretary
  - One or more persons from basic medical science (preferably a pharmacologist, especially if overseeing drug, device, vaccine, biologics etc. research
  - One or more clinicians

- One or more legal expert
- One Biostatistician if required
- One or more social scientist/ representative of non-governmental agency
- One or more lay person from community

4.2 Criteria for selection of members of IHEC

4.2.1. Chairperson

- From outside the institution
- A person with high standing in society
- Preferably have at the minimum 1-3 years experience of serving on an ethics committee

4.2.2. Member-Secretary

- Will be a staff member of the institution.
- Preferably be a medical professional for institutions doing biomedical research.
- Should have a state medical council recognized postgraduate degree
- Should have domain specialty experience, clinical research and ethics knowledge, personal interest and capacity, good communication skills

4.2.3. Basic Medical Scientist(s)

- Affiliated/ non-affiliated
- Medical person with qualifications in basic medical sciences
- In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist

4.2.4. Clinician(s)

- Affiliated/ non-affiliated
- Should be individual/s with recognized medical qualification, expertise and training

4.2.5. Legal expert/s

- Affiliated/ non-affiliated
- Should have a basic degree in Law from a recognized university, with experience
- Desirable: Training in medical law.

4.2.6. Social scientist/ philosopher/ethicist/theologian

- Non-affiliated
- Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values.
- Can be from an NGO involved in health-related activities

4.2.7. Biostatistician

- Affiliated or non- affiliated
- Should have a PG/PhD in Biostatistics

4.2.8. Lay person(s)

- Non-affiliated
- Literate person from the public or community
- Has not pursued a medical science/ health-related career in the last 5 years
- May be a representative of the community from which the participants are to be drawn
- Is aware of the local language, cultural and moral values of the community
- Desirable: involved in social and community welfare activities

4.2.9. Other common criteria

- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IHEC.
- They should not have any known record of professional misconduct.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests (See IHEC/SOP-03/V1).

4.3. Agreement regarding Maintenance of Confidentiality

- It is the responsibility of each IHEC member, reviewing research project or attending IHEC meetings to read, understand, accept and sign the agreement contained in the confidentiality Form (*ANX-03A/IHEC/SOP-02/V1*).
- The staff of the secretariat will also sign confidentiality agreement which should be filed with the IHEC (*ANX-03B/IHEC/SOP-02/V1).*
- The Secretariat will obtain the signature of the IHEC Chairperson on the Confidentiality form
- The secretariat could provide IHEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and countersigned IHEC Chairperson) and acknowledge the receipt of agreement with their signature if required.
- The Secretariat will keep the original copies of the signed Agreements in the IHEC office in the file entitled 'Confidentiality Agreement file for members and photocopies of the agreement in the individual member's files.
- The confidentiality agreement will be signed by every members and secretariat of the EC before reviewing the projects in every meeting.

4.4 Tenure of Membership

- The tenure of IHEC will be for a continuous period of 3 years from the date of appointment and if necessary reappoint

4.5 Appointment of New Members

a) The IHEC members will be appointed by the Head of the Institution (HOI) on recommendations of the EC chairman .
The HOI will issue an official appointment letter to the members with the roles and responsibilities/functions to be fulfilled by the members in addition to duration of appointment and conditions.

b) New members will be appointed under the following circumstances:

1. When a regular member completes his/ her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements in number as stated in this SOP
5. As per the recommendations of accrediting bodies like NABH
6. On the basis of changes in the existing rules
7. Additional members may be added if the Ethics Committee has difficulty in meeting the quorum.

c). The HOI will issue an official appointment letter to the members with the roles and responsibilities/functions to be fulfilled by the members.
d). The members will give a notice of acceptance for the appointment either in writing or via email.

4.6 Conditions to be fulfilled by a member after appointment

Members to be appointed on the IHEC will need to fulfill the following conditions:

- Members must submit:
  - A recent signed Curriculum Vitae
  - Preferably, if available training certificates in Ethics and/ or GCP
- Members must be willing to:
  - Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
  - be willing to undergo training or update their skills/knowledge during their tenure as an EC member; be aware of relevant guidelines and regulations;
  - Publicize his/her full name, profession and affiliation to any Institution or agency as per the relevant rules and guidelines.

➢ sign the Confidentiality Agreement (as per ANX-3A/IHEC/SOP-02/V1) and maintain confidentiality regarding meetings, deliberations, research proposals, information on□□□research participants and related matters

➢ Read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement/form (See IHEC/SOP-03/V1).

4.7 Resignation / Disqualification / Death of Members.

- Resignation: An IHEC member may resign from membership by submitting a letter of resignation to the Chairperson of IHEC. The member may or may not assign reasons for resignation.
  The resignation will become effective from the day it is accepted by the Chairperson.

- Disqualification for conduct unsuitable of an IHEC member: A member may be disqualified from continuance should IHEC determine by a 2/3rd majority specifically called for the purpose that the member's conduct has been inappropriate as an IHEC member.

  (i) The process will be initiated if IHEC Chairperson of IHEC or Member-secretary receives a communication in writing (provided by IHEC member or a member of the public) alleging misconduct by a member.

  (ii) The Chairperson of IHEC will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IHEC could be questioned, the Chairperson may suspend the membership of the concerned IHEC member till final decision is taken by IHEC.

  During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IHEC member and will not perform any duties of IHEC member.

  (iii) The Chairperson may call for a meeting of the IHEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules.

(iv) The allegation will be discussed at the IHEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.

The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.

- Disqualification for not attending IHEC meetings: A member may be disqualified from IHEC membership if the member fails to attend more than 3 regular consecutive IHEC meetings without prior intimation. The process conducted will be as follows:

(i) The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IHEC without prior intimation to the IHEC.

(ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IHEC meeting.

(iii) A written communication will be sent to the concerned IHEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned

IHEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.

(iv) The matter will be discussed and reviewed at the IHEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

- The Chairperson or Member-Secretary will inform the IHEC members about the cessation of membership by a confidential written communication to other members of IHEC or at the next meeting of IHEC.
- Death: The Head of the Institution will appoint a new member as per the provisions of this SOP in the event of death of a member and same will be notified to Drug Controller General of India (DCGI) by the member-secretary of the IHEC.

- Any change in the composition in the EC will be notified to the central Licensing Authority within 30 working days.

4.8 Training of the IHEC Members in Research Ethics

- Member Secretary or a designated IHEC member will provide introductory training in Research Ethics, GCP and SOPs to the new member and a certificate will be issued if deemed necessary.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- The IHEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update the IHEC Members.
- The Institution may nominate *and / or sponsor the expenses of (as applicable)* an IHEC member for attending conference, continuing education session workshop and/ or training program etc.

4.9 Hierarchy

- There will be one Chairperson, one Member Secretary (Wherever applicable) may be appointed amongst the members.
- The Chairperson will head the committee.
- The Member Secretary will be the guardian of all documents and funds in the possession of the committee.
- Other IHEC members will be regular committee members with equal ranking

4.10 a. Functions of Chairperson

- The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations.
- Ratify minutes of the previous meetings

- The Chairperson will preside over all elections as well as administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the IHEC at various meetings and forums.
- The Chairperson will sign documents and communications related to IHEC functioning.
- Seek COI declaration from members and ensure quorum and fair decision making.
- The Chairperson will delegate his/ her responsibilities to the Co-Chairperson in accordance with IHEC SOPs.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
- In case of Chairperson at a planned meeting, the members present may elect the non-affiliated member chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

4.11 Functions of the Member secretary

- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files
- Schedule and organize IHEC meetings
- Prepare and maintain meeting agenda and minutes
- Maintain IHEC documentation and to archive them
- Sign documents and communications related to IHEC functioning.
- Communicate with the IHEC members and applicants/ investigators.
- Notify the Principal Investigator regarding IHEC decisions related to the submitted research proposal and further action thereof / after the meeting.
- Arrange for training of personnel and IHEC members.
- Organize the preparations, review, revision and distribution of SOPs and guidelines
- Provide necessary administrative support for IHEC related activities to the Chairperson.
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members
- Receive ethics committee review processing fees and issue official receipts for the same
- Delegate various responsibilities to appropriate and authorized individuals

- Ensure adherence of IHEC functioning as per SOPs
- Prepare for audits and inspections
- Prepare and make available for scrutiny by auditors/ inspectors annual reports/ annual financial statements of the IHEC.

4.12 Functions of the Joint/ Associate/ Alternate Member Secretary **(**whenever appointed)

- The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.

4.13 Functions of Basic Medical Scientist

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4.14 Functions of Clinician/s

- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report).

4.15 Functions of Legal expert/s

- Ethical review of the proposal, ICD along with translations, Memorandum of Understanding(MOU), Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, Health Ministry's Screening Committee (HMSC) for international collaboration, compliance with guidelines etc.

- Interpret and inform EC members about new regulations if any

4.16Functions of **Social scientist/ philosopher/ethicist/theologian**

- Ethical review of the proposal, Informed Consent Documents (ICD) along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal /community representative and bring in ethical and societal concerns.

4.17.**Functions of Biostatistician**

- Sample review of proposal including the sample size calculated research design, methodology and proposed analysis.

4.18.Functions of **Lay person(s)**

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

4.19. Functions of IHEC members

- Attend IHEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- Review, discuss and consider research proposals submitted for evaluation.
- Monitor Serious Adverse Event reports and recommend appropriate action(s).
- Review the progress reports and monitor ongoing studies as appropriate. Do onsite visits wherever needed.
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of IHEC meetings. Declare any conflict of interest in writing to the Chairperson, if any, at each meeting.

- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC secretariat.
- Provide an updated CV when requested for by the IHEC secretariat.
- Carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary.
- Assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IHEC work as per SOPs.
- Be updated on relevant laws and regulations.

4.20 Secretariat

- The Academic Manager will function as the administrator and other members of the Academics will function as other administrative staff . The staff will be appointed by the HOI.
- The Secretariat will support the Member Secretary in all their functions
- All the staff of the Secretariat will sign confidentiality agreement which should be filed with the IHEC (*ANX-03-B/IHEC/SOP-02/V).*
- The working rules for the Secretariat are stated in (ANX-01/IHEC/SOP-02/*V1*)
- The Secretariat staff members being on MSMP pay roll or on contract basis will be have no additional payment for serving in the IHEC

4.21 Types of projects reviewed by IHEC

- Clinical trials of new drugs, vaccines, biologicals, and medical devices as per the *New Drugs and Clinical Trials Rules, 2019 (NDCTR)*; Bioavailability and bioequivalence studies involving human participants; Post-marketing surveillance or Phase IV studies, and Academic clinical trials and investigator-initiated studies involving approved drugs for new indications, dosages, or populations.
- Epidemiological, social, and behavioural health studies involving human participants or identifiable data; Public health or community-based intervention studies; Biomedical research involving human biological materials (blood, tissues, cells, DNA, etc.) or linked data; Genetic and genomic research, biobanking, and data repository studies; Research involving medical records or digital health data, and any collaborative, multi-centric, or sponsored research involving human participants, where any component is conducted within or through the institution.
- All dissertation projects (postgraduate students: DNB, PhD and any other course run by Institution as applicable), research projects of undergraduate students carried out under guidance of teachers (e.g. Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self-funded/ funded by institutional funding bodies.

Provision for review of the proposal outside the organisation

- The IEC may, under exceptional circumstances, undertake the review of research proposals originating from outside institutions. Such external reviews shall be limited to biomedical and health research proposals that fall within the purview of DHR-recognised activities and **shall not include studies regulated under the CDSCO framework**, such as clinical trials, bioavailability/bioequivalence studies, or any research governed by the New Drugs and Clinical Trials Rules, 2019. External reviews shall be considered

only when requested by institutions that do not have a registered IEC and shall be carried out based on a valid Memorandum of Understanding (MoU) or written agreement specifying respective roles and responsibilities. The IEC shall ensure that all such reviews comply with DHR and ICMR ethical guidelines, and complete documentation of the review process shall be maintained.

4.20 Quorum Requirements

- A minimum of five members present in the meeting room.
- The quorum should include both medical, non-medical or technical or/and non-technical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the lay person should be part of the quorum.
- No decision is valid without fulfilment of the quorum.
- The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.
- The quorum for reviewing regulatory clinical trials should be in accordance with current the New Drugs and Clinical Trial Rules 2019 (For the IHEC meeting, a quorum will consist of at least 5 members for regulatory clinical trials with the following representation: one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community, **apart from** Member Secretary and Chairperson)

4.23 Honorarium to the Members

- Reimbursement of travelling expense if required and /or reasonable honorarium for attending the IHEC meetings may be given to the IHEC members

4.24 Preparing an annual activity report of the IHEC for submission to the Head of the Institute

- The Member Secretary will make a yearly activity report for submission to the Head of the Institute
- Which will include the following elements:

a. Number and dates of the IHEC meetings of full board

b. Number of SAE subcommittee and any other subcommittee, as applicable

c. Number and type of proposals (Pharma/ Government sponsored/ Dissertations/ investigator initiated) reviewed in a year, status of each study proposal whether completed / ongoing / terminated

d. Number of approvals for full board review/ expedited review with decisions

e. Brief details about workshops, training programmes and other activities undertaken by the IHEC and those attended by IHEC members

f. Any other matter

4.25 Appointment of Secondary/Additional members

- The Head of the Institute can appoint secondary/additional members along with the other members or as and when required to meet situations wherein a primary member is unable to attend the meeting and the quorum is not fulfilled.
- The same rules as in the case of primary members will be applicable to the appointment, training and all other procedures of secondary members
- They will be called in for the meeting only when the primary member is absent and will have the same voting rights.

4.26. Financial Transaction of IHEC

- All financial transactions relating to the EC will be maintained in a separate ledger under the finance Department of MSMP.
- Sitting fees to members will be given by cheque or electronic transfer.
- All EC review fees will be received either in cheque/ DD or through electronic transfer
- All financial transactions of IHEC will be audited annually.

4.27. Constitution of subcommittee

- The EC may constitute one or more sub-committees of its members and other members or experts for assisting the EC in its functions.
- A separate scientific committee should review proposal before it is referred to EC.

5. Reference to other applicable SOPs

MSMP/SOP-03/V1 - *Conflict of Interest Policy for Institutional Ethics Committee*

MSMP/SOP-09/V1 - *Agenda Preparation, Meeting Procedures and Recording of Minutes*

6. Annexures

Annexure 1 *ANX-01/IHEC/SOP-02/V1* - IHEC Administrative Staff: Working rules

Annexure 2 *ANX-02/IHEC/SOP-02/V1* - Organizational Chart of the Institution

Annexure 3A *ANX 03/IHEC /SOP 02/V1* - Confidentiality Agreement Form for IHEC members

Annexure 3B *ANX 03B/IHEC/SOP 02/V1* - Confidentiality Agreement Form for Staff of the Secretariat

Annexure 1: ANX-01/SOP-02/V1

The IHEC Administrative Staff: Working Rules

- AGM Academics along with other staff of Academics will help the IHEC Chairperson and Member-Secretary in executing functions of the IHEC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IHEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The administrative staff will function as per MSMP staff policy.

- The administrative staff will report to the Chairperson and/or Member Secretary in matters related to Ethics committee.

Duties of Administrator- in-charge

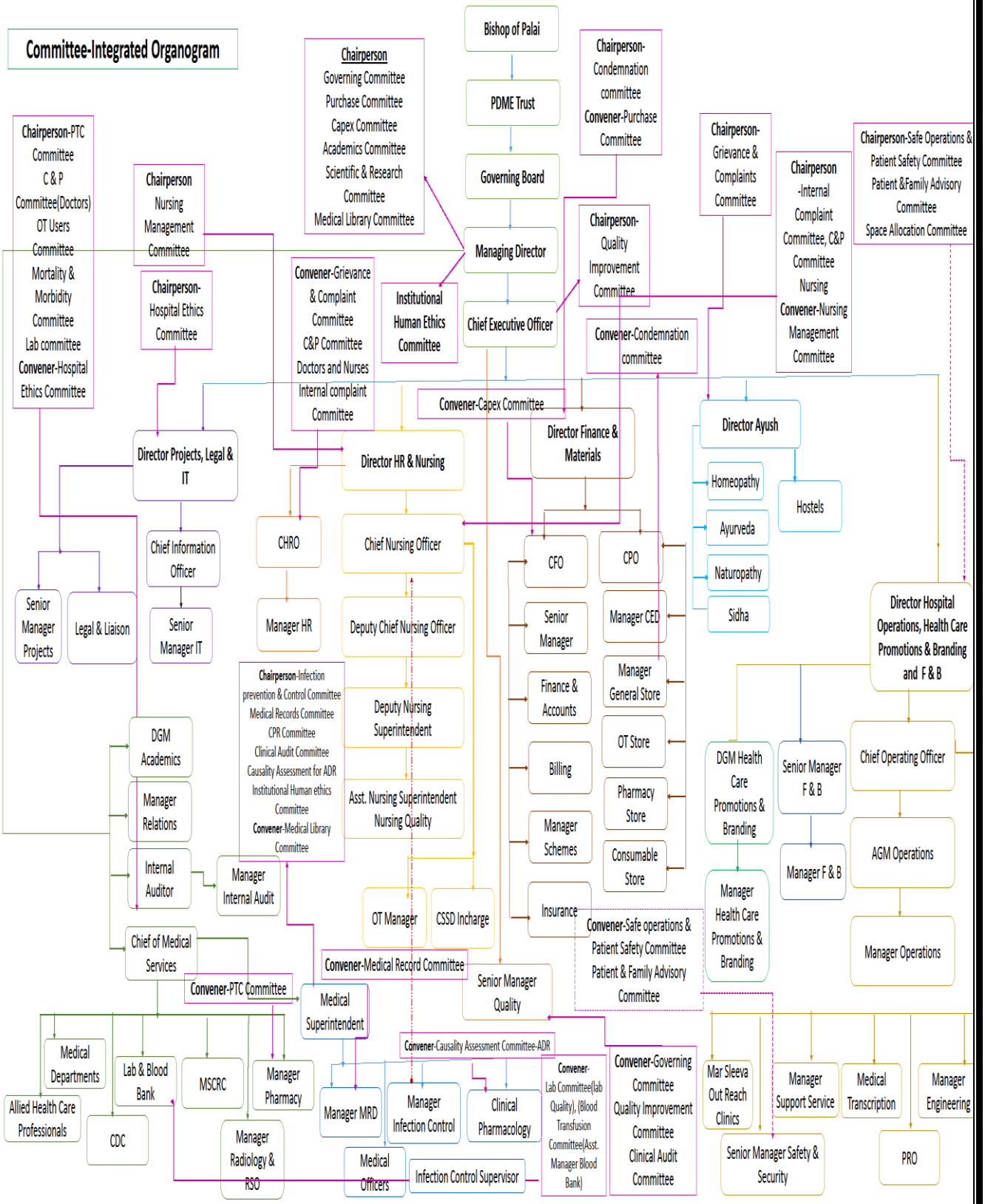
- Correspondence with IHEC members and external experts
- Correspondence with the investigators
- Preparing agenda a and minutes of the IHEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files, SOPs, all correspondences
- Maintaining electronic database of the IHEC records

Duties of the attendant

- Assisting the secretariat in arranging the IHEC meetings
- Dispatching sets of study documents to IHEC members and external experts

- Receiving the study related documents from and dispatching the IHEC letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Assisting the Secretariat during the meetings

Annexure 2: ANX 02/SOP 02/V1


Committee-Integrated Organogram
Bishop of Palai
PDME Trust
Governing Board
Managing Director
Chief Executive Officer
Institutional Human Ethics Committee
Chairperson
Governing Committee
Purchase Committee
Capex Committee
Academics Committee
Scientific & Research Committee
Medical Library Committee
Chairperson-Condemnation committee
Convener-Purchase Committee
Chairperson-Quality Improvement Committee
Convener-Condemnation committee
Chairperson-Grievance & Complaints Committee
Chairperson -Internal Complaint Committee, C&P Committee Nursing
Convener-Nursing Management Committee
Chairperson-Safe Operations & Patient Safety Committee Patient &Family Advisory Committee Space Allocation Committee
Chairperson-PTC Committee C & P Committee(Doctors) OT Users Committee Mortality & Morbidity Committee Lab committee
Convener-Hospital Ethics Committee
Chairperson Nursing Management Committee
Chairperson-Hospital Ethics Committee
Convener-Grievance & Complaint Committee C&P Committee Doctors and Nurses Internal complaint Committee
Convener-Capex Committee
Director Projects, Legal & IT
Director HR & Nursing
Director Finance & Materials
Director Ayush
Homeopathy
Ayurveda
Naturopathy
Sidha
Hostels
Chief Information Officer
Senior Manager Projects
Legal & Liaison
Senior Manager IT
CHRO
Manager HR
Chief Nursing Officer
Deputy Chief Nursing Officer
Deputy Nursing Superintendent
Asst. Nursing Superintendent Nursing Quality
CFO
CPO
Senior Manager
Manager CED
Finance & Accounts
Manager General Store
Billing
OT Store
Manager Schemes
Pharmacy Store
Insurance
Consumable Store
Director Hospital Operations, Health Care Promotions & Branding and F & B
Chief Operating Officer
DGM Health Care Promotions & Branding
Senior Manager F & B
Manager F & B
AGM Operations
Manager Health Care Promotions & Branding
Manager Operations
Chairperson-Infection prevention & Control Committee Medical Records Committee CPR Committee Clinical Audit Committee Causality Assessment for ADR Institutional Human ethics Committee
Convener-Medical Library Committee
DGM Academics
Manager Relations
Internal Auditor
Manager Internal Audit
OT Manager
CSSD Incharge
Convener-Safe operations & Patient Safety Committee Patient & Family Advisory Committee
Chief of Medical Services
Convener-PTC Committee
Convener-Medical Record Committee
Senior Manager Quality
Medical Superintendent
Convener-Causality Assessment Committee-ADR
Medical Departments
Lab & Blood Bank
MSCRC
Manager Pharmacy
Allied Health Care Professionals
CDC
Manager Radiology & RSO
Manager MRD
Manager Infection Control
Clinical Pharmacology
Medical Officers
Infection Control Supervisor
Convener-Lab Committee(lab Quality), (Blood Transfusion Committee(Asst. Manager Blood Bank)
Convener-Governing Committee Quality Improvement Committee Clinical Audit Committee
Mar Sleeva Out Reach Clinics
Manager Support Service
Medical Transcription
Manager Engineering
Senior Manager Safety & Security
PRO

Annexure 3A: ANX-03A/SOP-02/V1

Confidentiality Agreement Form for IHEC Members

In recognition of the fact, that I, _____
_____
(*Member's name, his/her position on IHEC and affiliation)* herein referred to as the "undersigned", have been appointed as a member of the IHEC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines.

The appointment of the undersigned as a member of the IHEC is based on individual merits and not as an advocate or representative of a home province, territory or community or as a delegate of any organization.

The IHEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants and the undersigned, as a member of the IHEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the IHEC. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IHEC. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review will not be copied or retained.

I, _____ (name of the IHEC member) have read and accept the aforementioned conditions as explained in this Agreement.

_____ _____

Signature Date

Chairperson's Signature Date

Annexure 3B: ANX-03B/SOP 02/V1

Confidentiality Agreement Form for Staff of the Secretariat

I, _____

_____

(*Staff's name and designation)* herein referred to as the "undersigned", have been appointed as a staff of the IHEC office. This agreement encompasses any information deemed confidential provided to the Undersigned in conjunction with the duties as a staff of the IHEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the IHEC.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him /her during his/her tenure of service.

I, _____ (name of the IHEC office staff) have read and I accept the conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Chairperson's Signature Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the **IHEC**. A copy will be given to the signatory.]*

7. Flow Chart