



**IHEC – MGMCRI SOPs**  
**Constitution of Institutional Human Ethics**  
**Committee(IHEC) Selection, Roles and**  
**Responsibilities of Members of the IHEC,**

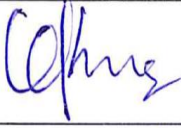

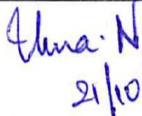


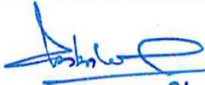


**SOP Code: SOP 02/V2**  
**Effective from 21/10/2019**


**Title: Constitution of Institutional Human Ethics Committee (IHEC), Selection, Roles and Responsibilities of Members of the IHEC**

**SOP Code: SOP 02/V2**

**Effective Date: 21-10-2019**

**SOP Constitution and Approval:**

<b>Prepared by:</b>	<b>Signature and Date:</b>
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<b>Reviewed by:</b>	<b>Signature and Date:</b>
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Dr. Sivagnanam G, IHEC Co-Chairperson	 21/10/19
<b>Approved by:</b>	<b>Signature and Date:</b>
Dr. Jambulingam, P IHEC Chairperson	 21.10.19
Dr. Adithan C, Dean Research, SBV	 21/10/19
Dr. Ravishankar M, Dean, MGMCRI	 21/10

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## 1. 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.

## 2. Scope

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


## 3. Responsibility

The selection of Chairperson, Co-Chairperson, Member Secretary, Additional Member Secretary and IHEC Members will be done by the Dean of the institute. It is the responsibility of all IHEC members and Secretariat to read, understand, follow and respect this SOP.

## 4. Detailed Instructions

### 4.1 Composition of the Institutional Human Ethics Committee (IHEC)

- IHEC will be established by the Dean. Chairperson and IHEC members can suggest names of potential members but final decision will remain with the Dean.
- Its hierarchical position in the organization and authority under which it is established will be clearly indicated (AX 02/SOP 02/V2).
- IHEC will be multidisciplinary and multi - sectoral in composition.
- It will be composed of at least 7 members to a maximum of 15 (as per current CDSCO requirements).

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The IHEC members will

- be 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 required qualifications as prescribed by applicable regulations and guidelines from time to time.
- have the expertise, time and commitment to perform all functions.
- 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 IHEC meeting (if required, based on requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (AX 05/SOP 02/V2) 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. (See SOP 05/V2)
- **The Composition of IHEC shall be as follows:**
  - ✓ Chairperson (non-affiliated to the institution)
  - ✓ Co-Chairperson (non-affiliated to the institution)
  - ✓ One Member Secretary (affiliated to the institution)
  - ✓ One Additional Member Secretary (affiliated to the institution)
  - ✓ One or two medical scientist/s(preferably a Pharmacologist, especially if overseeing drug, device, vaccine, biologics etc. research)
  - ✓ One or more clinicians (affiliated / Non-affiliated)
  - ✓ Two legal experts (Non- affiliated one academic, one practicing legal expert)



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- ✓ One social scientist(affiliated/Non-affiliated) or representative of non-governmental agency
- ✓ One philosopher, ethicist or theologian (Non-affiliated)
- ✓ One or more lay person from community

## **4.2 Criteria for selection of members of IHEC**

### **A. Chairperson**

- must be from outside the institution
- should be a person with high standing in society
- have a minimum 1 year experience of serving on an ethics committee

### **B. Co-Chairperson (optional)**


- from outside the institution
- have a minimum 1 year experience of serving on an ethics committee

### **C. Member-Secretary and Additional Member-Secretary**

- Faculty of the institution
- a medical professional
- Should have a state medical council recognized postgraduate degree
- should have research experience(Clinical/Basic) with clinical research and ethics knowledge, personal interest and capacity, good communication skills

### **D. Members**

- 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 declare a nil record of professional misconduct.
- Medical scientists and clinicians should have recognized post graduate qualifications.
- Conflict of interest should be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests. (See SOP 03/V2)

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### 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 (AX 03A/SOP 02/V2)
- The staff of the secretariat will sign confidentiality agreement which should be filed with the IHEC (AX 03B/SOP 02/V2)
- The secretariat will obtain the signature of the IHEC Chairperson on the Confidentiality form.
- The secretariat will email IHEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and IHEC Chairperson) and acknowledge the receipt of agreement with their signature.
- 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.

### 4.4 Tenure of membership

The tenure of IHEC will be for a continuous period of 3 years from the date of appointment.

### 4.5 Appointment of new members

- a) The IHEC members will be appointed by the Dean.
- b) New members will be appointed under the following circumstances:
  - When a regular member completes his/ her tenure.
  - If a regular member resigns before the tenure is completed.
  - If a regular member ceases to be a member for any reason including death or disqualification.
  - To fulfill the membership requirements as stated in this SOP.
- c) New members will be identified by the Chairperson according to the membership requirement (i.e. as per the composition specified in Section 4.1 of this SOP and provided the potential member fulfils the conditions of appointment) after discussion in the IHEC. The names of new

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members to be appointed may be suggested by the IHEC members and the Chairperson to the Dean. The final decision regarding appointment of members will be taken by the Dean.

#### 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 CV
  - ✓ preferably, if available training certificates in Ethics and/ or GCP [if not available at time of induction as member in the IHEC, the member must submit these within *6 months* of appointment]
- Members must be willing to
  - ✓ Publicize his/her full name, profession and affiliation.
  - ✓ Sign the Confidentiality Agreement (as per 3A/SOP 02/V2) and maintain confidentiality regarding meetings, deliberations, research proposals, information on research participants and related matters.
  - ✓ Read, understand, accept and follow the conflict of interest (COI) policy and sign the Conflict of interest agreement/form (See SOP 03/V2).

#### 4.7 Resignation and Disqualification of Members

- **Resignation:** An IHEC member may resign from membership by submitting a letter of resignation to the Chairperson. 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 if IHEC decides by a 2/3<sup>rd</sup> majority specifically called for the purpose that the member's conduct has been inappropriate to be considered as an IHEC member.



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- i. The process will be initiated if IHEC Chairperson 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 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 during one of the regular IHEC meetings. The meeting convened will follow the general rules of quorum.
  - 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). 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/Additional 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.



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- 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.

#### **4.8 Training of the IHEC Members in Research Ethics**

- An individual selected as a new member of the IHEC will be required to attend one meeting as an ‘Observer’ before being inducted as a member of the IHEC.
- Member Secretary/Additional Member Secretary or an IHEC member will provide introductory training in research Ethics, GCP and SOPs to the new member.
- A newly inducted member should submit certificate of training in 6 months.
- All members including Chairperson and Member Secretary/ Additional 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.
- IHEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update the IHEC Members and Institutional faculty members.





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- IHEC may nominate *and / or sponsor the expenses of (as applicable)* an IHEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

#### **4.9 Hierarchy**

- One Chairperson, Co-Chairperson, one Member Secretary and one Additional Member Secretary (wherever applicable) appointed amongst the members.
- The Chairperson will head the committee.
- The Member Secretary and the Additional Member Secretary (whenever applicable) will be the guardian of all documents in the possession of the committee.
- Other IHEC members will be regular committee members with equal ranking.

#### **4.10a Functions of Chairperson**

The Chairperson will

- be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- preside over all elections as well as administrative matters pertinent to the committee's functions.
- represent the IHEC at various meetings and forums.
- sign documents and communications related to IHEC functioning.
- delegate his/ her responsibilities to the Co-Chairperson in accordance with IHEC SOPs.

In case of anticipated absence of both Chairperson and Co-Chairperson at a planned meeting, the Chairperson will nominate a committee member as an Acting Chairperson or the members present may elect the chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

#### **4.10b Functions of Co-Chairperson**

- To act as Chair in the absence of Chairperson and to perform all functions of Chairperson.




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#### **4.11 Functions of the Member secretary**

- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received
- Prepare, maintain and distribute 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
- Prepare and sign the IHEC approval certificates with prior permission from the Chairperson
- Communicate with the IHEC members and applicants/ investigators
- Notify Principal Investigator regarding IHEC decisions related to submitted research proposal
- Report the AEs and SAEs to the Chairperson of SAE committee
- 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
- To get the annual report of the approved proposals
- To inform the committee regarding the proposals to be monitored periodically.

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#### 4.12 Functions of the Additional Member Secretary


- The Additional Member Secretary will perform the same functions of Member Secretary in his/her absence and assist the Member Secretary in his regular responsibilities.

#### 4.13 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
- Conduct 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/Co-Chairperson, if any, at each meeting
- Participate in continuing education activities in biomedical ethics and 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 work delegated by Chairperson/ Co-Chairperson, Member-secretary and Additional Member-secretary
- Assist Chairperson/Co-Chairperson, Member-secretary and Additional Member-secretary in carrying out IHEC work as per SOPs
- Be updated on relevant laws and regulations

#### 4.14 Secretariat

- The Secretariat will be composed of the scientific officer/s, the administrative Officer/s and other administrative supporting staff.
- The Secretariat will support the Member Secretary and Additional Member Secretary (if applicable) in all their functions.

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- All the staff of the Secretariat will sign confidentiality agreement which should be filed with the IHEC (AX 03-B/SOP 02/V2)
- The working rules for the Secretariat are stated in (AX 01/SOP 02/V2)

#### **4.15 Types of projects reviewed by IHEC**

The IHEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations / universities, all dissertation projects (postgraduate students :MD, MS, MCh, DM, Mch, DNB, PhD, MSc, MPTh, MOTh 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.

#### **4.16 Quorum Requirements**

- The full board meeting will be held as scheduled provided there is quorum.
- 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/Additional Member Secretary and Chairperson as mandated by Schedule Y.
- Without satisfying this condition, any decision taken by the committee shall remain null and void
- In absence of the Chairperson, Co-Chairperson will chair the meeting.

#### **4.17 Honorarium to the members**

Reimbursement of travelling expense and /or reasonable honorarium for attending the IHEC meetings will be given to the IHEC members.

#### **4.18 Preparing an annual activity report of the IHEC for submission to the Dean**

The Member Secretary/Additional Member Secretary will make an annual report to brief the yearly activity report for submission to the Dean with the following elements:



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- 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
- d) status of each study proposal whether completed / ongoing / terminated
- e) number of approvals for full board review/ expedited review with decisions
- f) brief details about workshops, training programmes and other activities undertaken by the IHEC and those attended by IHEC members
- g) Miscellaneous activities, if any

**5. Reference to other applicable SOPs**

*SOP 03/V2 Conflict of Interest Policy for Institutional Human Ethics Committee*

*SOP 08/V2 Agenda Preparation, Meeting Procedures and Recording of Minutes*

**6. Glossary**

<b>Confidentiality</b>	Prevention of disclosure, to other than authorized individuals, of IHEC/ information and documents
<b>IHEC</b>	Institutional Human Ethics Committee independent body whose responsibilities are to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial (at sites which do not have EC/EC not functional as per New Drugs and Clinical Trial Rules, 2019 and to provide public assurance of that protection.

**7. Annexures**

Annexure 1: AX01/SOP 02/V2– IHEC Administrative staff: Working rules

Annexure 2: AX02/SOP 02/V2 – Organizational chart of the Institution

Annexure 3A: AX03A/SOP 02/V2 – Confidentiality Agreement Form for IHEC members

Annexure 3B: AX03B/SOP 02/V2 – Confidentiality Agreement Form for staff of IHEC

Secretariat



### **Annexure 1: AX01/SOP 02/V2**

#### **The IHEC Administrative Staff: Working Rules**

- There will be administrative assistant who will help the IHEC Chairperson/ Co-Chairperson and Member-Secretary/ Additional Member Secretary in executing functions of the IHEC. Additional staff may be appointed and duties can be assigned as and when required by the IHEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile, qualifications and office timing may be recommended by IHEC members during regular IHEC meeting and the same will be recorded in minutes.
- The administrative staff will report to the Member Secretary/Additional Member Secretary.
- The administrative staff will be appointed by the Dean, MGMCRI.

#### **Duties of administrative officer/assistant**

- Correspondence with IHEC members and external experts
- Correspondence with the investigators
- Preparing agenda 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 attendants /helpers**

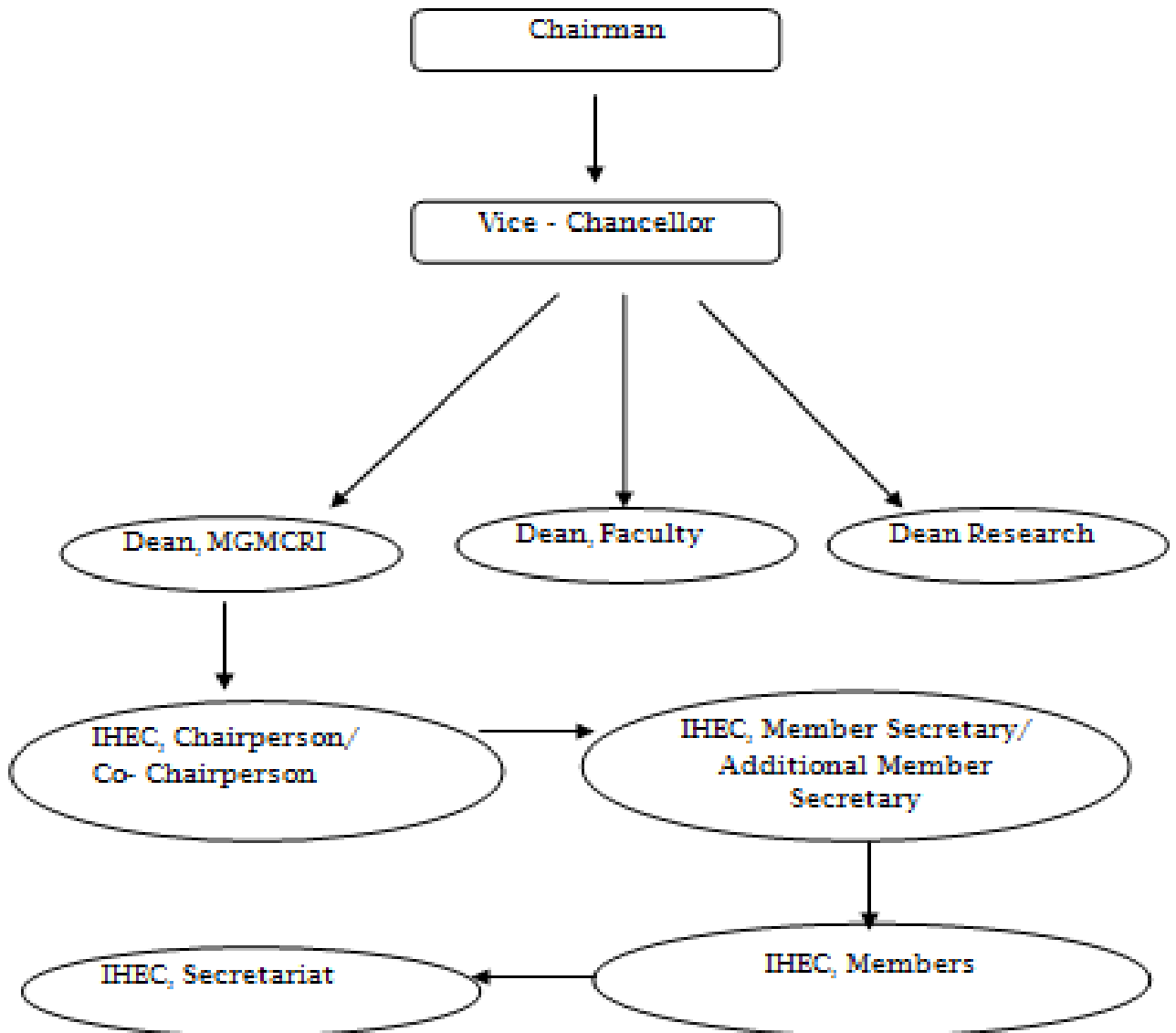
- Assisting the secretariat in arranging the IHEC meetings
- Dispatching sets of study documents to IHEC members and external experts
- Receiving study related documents from and dispatching IHEC letters to investigators
- Filing study related documents
- Archiving and maintaining the study files
- Assisting the Secretariat during the meetings

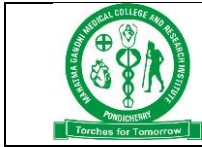


**Annexure 2: AX02/SOP 02/V2**

**Organizational flow chart of IHEC, MGMCRI**

After the Dean of MGMCRI constitute the IHEC, the newly registered body will function in the following hierarchical orders.





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**Annexure 3A: AX3A/SOP 02/V2**

**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 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 shall 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:

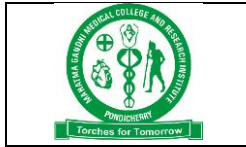
[The original (signed and dated Agreement) will be kept on file in the custody of IHEC. A copy of the same will be given to the Undersigned.]

I acknowledge that I have received a copy of this agreement signed by the IHEC Chairperson and me.

Signature:

Date





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**Annexure 3B: AX3B/SOP 02/V**

**Confidentiality Agreement Form for staff of IHEC secretariat**

In recognition of the fact, that I, \_\_\_\_\_ IHEC Secretariat’s name, Position in IHEC Office herein referred to as the “undersigned”, have been appointed as a member staff of IHEC Secretariat and have been asked to assess research study documents and other confidentiality documents involving research participants, and IHEC members 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 Staff of IHEC Secretariat is based on individual merits and not as representative of a home province, territory or community or as a delegate of any organization.

This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a Staff of IHEC Secretariat. 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 shall not be copied or retained.

I, \_\_\_\_\_ (name of Staff of IHEC Secretariat) have read and accept the aforementioned 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 soft copy of the same will be sent by email to the Undersigned.]*

I acknowledge that I have received a copy of this agreement signed by IHEC Chairperson and me.

Signature:

Date:

	<b>IHEC – MGMCRI SOPs</b> <b>Constitution of Institutional Human Ethics</b> <b>Committee(IHEC) Selection, Roles and</b> <b>Responsibilities of Members of the IHEC,</b>	<b>SOP Code: SOP 02/V2</b> <b>Effective from 21/10/2019</b>
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## 8. Flow Chart



## 9. References:

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5<sup>th</sup> 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 6<sup>th</sup> October 2019) available from: [http://www.icmr.nic.in/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf)*