

Code of Ethics for research:-



**DR. M. L. DHAWALE MEMORIAL
HOMEOPATHIC INSTITUTE**

Title:

**Constitution of Institutional Ethics Committee (IEC), Selection, Roles
and Responsibilities of Members of the IEC**

INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures – Human Studies

Dr. M. L. Dhawale Memorial Homoeopathic Institute,
Palghar – 401404



Title :


Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC

SOP Code: SOP 02 - Version 1



Effective Date: 22nd March 2019

Page Nos.: 17

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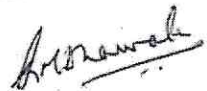
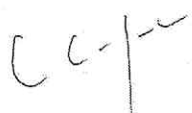

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1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the framework for a constitution, selection, roles, and responsibilities of the Institutional Ethics Committee (IEC) and procedures for maintaining the confidentiality of all activities and documents

2. Scope:

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

3. Responsibility: Authority for constructing MLDMHI – IEC:

The Director of the MLD trust in consultation with the Principal of MLDMHI will appoint the Chairperson and Member secretary. Member secretary in consultation with the Director of Institutes and Chairperson will appoint the rest of the committee members based on their competency, experience, and integrity by sending the official request letters (AX1A / SOP 02 – V1&AX 1B / SOP 02 – V1). Members will confirm their acceptance to the MLD trust Director and Member secretary by providing all the required information about membership (AX 02 / SOP 02 – V1). The Chairperson will furnish any information or report to the Director of MLD Trust, Principal of MLDMHI and/or Member secretary of IEC when required.

It is the responsibility of all the IEC members to read, understand, follow and respect this SOP.

4. Detailed instructions:

4.1. Composition of Institutional Ethics Committee:

The Head of the Institution (HOI) will establish the IEC. The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the Head of the Institute (Director of MLDT and Principal of MLDMHI).

- Its hierarchical position in the organization and authority under which it is established will be clearly indicated (AX 03/SOP 02 - V1)
- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7 members up to a maximum of 15 (as per current CDSCO requirements).
- 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 a 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 IEC 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.
- Independent consultants - The MLDMHI IEC may call upon subject experts as independent consultants who may provide a special review of selected research protocols if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups, or special interest groups e.g. cancer patients, HIV/AIDS-positive persons, or ethnic minorities. They will be required to give their specialized views but should not take part in the decision-making process which will be made by the members of the MLDMHI IEC. Such individuals will have to sign a confidentiality agreement (AX 05/SOP 02 - V1) and declare in writing, conflicts of interest if any before attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have the right to vote. (See SOP 05 - V1)
- The Composition shall be as follows:
 - Chairperson (non-affiliated to the institution)
 - Co-Chairperson (non-affiliated to the institution, optional)
 - One Member Secretary (institutional)
 - One Joint Member Secretary (institutional, optional)
 - One or more persons from basic medical science (preferably a pharmacologist, especially if overseeing drug, device, vaccine, biologics, etc. research)
 - One or more clinicians (Medical and Homoeopathy stream) from various institutes
 - One legal expert
 - One social scientist/ representative of a non-governmental agency
 - One philosopher, ethicist, or theologian
 - One or more lay person from the community

4.2. Criteria for selection of Members of IEC:

Chairperson:

- From outside the institution.
- Have at the minimum 1-3 years experience serving on an ethics committee
- Should have sound knowledge of Homoeopathy as well as Ethics in Research
- Should have a state medical council-recognized postgraduate degree

Co-Chairperson (if applicable)

- From outside the institution (preferably)
- Have at the minimum 1-3 years experience serving on an ethics committee
- Should have a state medical council recognized postgraduate degree

Member-Secretary (and Joint Member-Secretary, if applicable)

- Will be a faculty (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, and good communication skills.

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 IEC.
- They should not have any known record of professional misconduct,
- Medical scientists and clinicians should have post graduate qualifications.
- Clinicians from Medical and Homoeopathy stream should have minimum 10 years of clinical experiences. They should be working as a clinician in Institute or Hospital.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests (See SOP 03 - V1).

4.3. Agreement regarding the Maintenance of Confidentiality:

- It is the responsibility of each IEC member, reviewing research project or attending IEC meetings, to read, understand, accept and sign the agreement contained in the confidentiality Form (AX 03A/SOP 02/V1).
- The Member secretary will provide IEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement with their signature.
- The Member Secretary will keep the original copies of the signed Agreements in the IEC office in the file entitled 'Confidentiality Agreement file for members and photocopies of the agreement in the individual members files

4.4. Tenure of the Membership:

- The tenure of IEC will be for a continuous period of 3 years (this can be extended up to 5 years depending upon institutional policy) from the date of appointment

4.5. Appointment of New Members

- a) The IEC members will be appointed by the HOI.
- 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 as stated in this SOP
 5. During the term, the Dean of the Faculty in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is a long period of non-availability.
- c) New members will be included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
- d) 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 fulfills the conditions of appointment) after discussion by the IEC. The names of new members to be appointed may be suggested by the IEC members and the Chairperson of the HOI. The final decision regarding the appointment of members will be taken by the HOI.

4.6. Conditions to be fulfilled by a member after appointment:

Members to be appointed to the IEC will need to fulfill the following conditions:

- Members must submit
 - a recently signed CV
 - Preferably, if available training certificates in Ethics and/ or GCP [if not available at time of induction as member in the IEC, the member must submit these within a year of appointment
- Members must be willing to publicize his/her full name, profession, and affiliation.
- sign the Confidentiality Agreement (as per Annexure 3A/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 SOP 03/V1).
- Conflict of interest should be declared by members of the MLDMHI-IEC prior to review meeting

4.7. Resignation and Disqualification of Members:

- Resignation: A member can tender resignation of his office of membership from the IEC to the HOI through the Chairperson after serving one month advance notice. 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 IEC member: A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate of an IEC member.
 - The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.
 - 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 IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.
 - The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules.
 - of quorum. The allegation will be discussed at the IEC 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 IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation or if the contribution is inadequate. The process conducted will be as follows:
 - The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC without prior intimation to the IEC.
 - 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 IEC meeting.
 - A written communication will be sent to the concerned IEC 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 IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson

- The matter will be discussed and reviewed at the IEC 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 IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC.

4.8. Training of the IEC Members in Ethics:

- An individual selected as a new member of the IEC will be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC.
- Member Secretary or an IEC 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 a year.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a online courses, workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- The IEC will circulate the available materials / literature (GCP and SOPs) on ethics in clinical research from time to time to impart training and update the IEC Members and Institutional faculty members.
- The IEC may nominate and / or sponsor the expenses of (as applicable) an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

4.9. Hierarchy:

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

5. Functioning of IEC Members:

5.1.1. Functions of Chairperson

- The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- 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 IEC at various meetings and forums.
- The Chairperson will sign documents and communications related to IEC functioning.

- The Chairperson will delegate his/ her responsibilities to the Co-Chairperson in accordance with IEC SOPs.
- In case of anticipated absence of both Chairperson and Co-Chairperson at a planned meeting, the Chairperson will nominate a committee member as Acting Chairperson or the members present may elect the chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

5.1.2. Functions of Co- Chairperson

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

5.1.3. 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 IEC meetings
- Prepare and maintain meeting agenda and minutes.
- Maintain IEC documentation and to archive them.
- Sign documents and communications related to IEC functioning.
- Communicate with the IEC members and applicants/ investigators.
- Notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- Arrange for training of personnel and IEC members.
- Organize the preparations, review, revision and distribution of SOPs and guidelines.
- Provide necessary administrative support for IEC 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 IEC 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 IEC.

5.1.4. 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.

5.1.5. Functions of IEC members

- Attend IEC 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 IEC 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 IEC Member Secretary
- Provide an updated CV when requested for by the IEC Member Secretary
- Carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary
- Assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs
- Be updated on relevant laws and regulations

6. Types of projects reviewed by IEC:

The IEC 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 organisations/universities, all internship projects (Homoeopathy), dissertation projects (postgraduate students :MD – Homoeopathy) and PhD thesis (Homoeopathy), education research projects (under the guidance of IMETTT – Advanced education technology workshop) and investigator initiated research studies which are self-funded / funded by institutional funding bodies.

7. Quorum Requirements :

- The full board meeting will be held as scheduled provided there is quorum.
- Minimum of 50% of committee strength and not less than 4 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender.

- Without satisfying this condition, any decision taken by the committee shall remain null and void.
- All decisions will be taken in meetings and not by circulation of project proposals
- In absence of the Chairperson, Co-Chairperson will chair the meeting.

8. Honorarium to the Members:

Reimbursement of travelling expense for attending the IEC meetings may be given to the IEC members.

9. Preparing an annual activity report of the IEC 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:

- Number and dates of the IEC meetings occurred in the campus of MLDMHI
- Number and type of proposals (Pharma/ Government sponsored/ Dissertations/ thesis / investigator initiated) reviewed in a year, status of each study proposal whether completed / ongoing / terminated
- Number of approvals for full board review/ expedited review with decisions
- Any other matter

10. Reference to other applicable SOPs:

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

SOP 05/V1 - Procedures for allowing Guest/ Observer to visit IEC or attend IEC meeting

SOP 08/V1 - Agenda Preparation, Meeting Procedures and Recording of Minutes

11. Annexures:

Annexure 1A: AX 1A / SOP 02 – V1: Invitation letter for IEC member

Annexure 1B: AX 1B / SOP 02 – V1: Appointment Order

Annexure 2: AX 02 / SOP 02 – V1: Acceptance Letter

Annexure 3: AX 03 A/SOP 02 - V1 - Confidentiality Agreement Form for IEC members

Annexure1A: AX 1A/ SOP 01 – V1

Letter Ref. No:

Date:

From
Principal, MLDMHI
Palghar

To,

Sub: Constitution of Institute Ethics Committee (Human studies)

Dear Sir / Madam,

On behalf of Dr. M. L. Dhawale Memorial Homoeopathic Institute, Palghar an Autonomous Institute under Maharashtra University Health Science, I request your concurrence for possible appointment as a member of Institute Ethics Committee of MLDMHI, Palghar.

Kindly send your written acceptance in the enclosed format and provide short curriculum vitae along with the acceptance letter.

On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

Signature:

Name:

APPOINTMENT ORDER

Dr/ Mr. / Mrs.: _____ Date: _____

I am pleased to appoint you as _____ of the Institutional Ethics Committee (IEC) (Human research) at Dr. M. L. Dhawale Memorial Homoeopathic Institute, Palghar (MLDMHI) w.e.f. _____ for a term of _____ year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, MLDMHI.

You will be paid travelling expenses against attending the MLDMHI IEC meetings held at MLDMHI campus at Palghar as per the guidelines given in Terms of Reference-IEC, MLDMHI.

We sincerely hope your association with IEC, MLDMHI will be fruitful to the Institute & the Community we serve.

Chairperson
(Name/Seal)
IEC, MUHS
Palghar – 401404

Signature of Appointee
(Name & Date)

From,

To,

The Principal
MLDMHI
Palghar - 401404

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) - Reg. Ref:
Your Letter No: _____ dated: _____

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of MLDMHI. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature

Name of the Member:	
Date:	
Address:	
Telephone No. (Res.):	
Mobile No.:	
E - Mail	

Confidentiality Agreement Form for IEC Members

In recognition of the fact, that I, _____

(Member’s name, his/her position on IEC and affiliation)

herein referred to as the “undersigned”, have been appointed as a member of the IEC 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 IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization. The IEC 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 IEC, is expected to meet the same high standards of ethical behaviour 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 IEC. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC. 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 IEC 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 the IEC. A copy will be given to the Undersigned.]

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

Signature

Date

12. Flow Chart:

No.	Activity	Responsibility
1	Composition of Institutional Ethics Committee	Head of Institute (Director MLDT & Principal MLDMHI)
2	Selection and Appointment of Chairperson and Member Secretary	Head of Institute (Principal of MLDMHI)
3	Appointment of the rest of IEC Members	HOI, Chairperson and Member secretary
4	Appointment of New Members	Head of Institute (Director MLDT & Principal MLDMHI)
5	Conditions of appointment	Head of Institute (Director MLDT & Principal MLDMHI)
6	Initiation of process of appointment and sending the appointment letters	Head of Institute (Research Department MLDMHI)
7	Tenure of Membership	Chairperson and IEC Members
8	Resignation and Disqualification of members	IEC Members
9	Quorum requirements	IEC Members

13. References:

- <file:///F:/Research%20Dept/Ethical%20Committee/New%20folder/AIIMSP%20IEC%20SOP%20v1.0%20.pdf> accessed on 15th March 2019
- <file:///F:/Research%20Dept/Ethical%20Committee/SOP%20Formats/1.-Preparation-of-Standard-Operating-Procedures-for-Institutional-Ethics-Committee2.pdf> accessed on 16th March 2019
- [https://icmr.nic.in/sites/default/files/guidelines/ICMR Ethical Guidelines 2017.pdf](https://icmr.nic.in/sites/default/files/guidelines/ICMR%20Ethical%20Guidelines%2017.pdf) accessed on 20th March 2019
- <http://www.cdsco.nic.in/html/GCP1.html> accessed on 20th March 2019





**DR. M. L. DHAWALE MEMORIAL
HOMEOPATHIC INSTITUTE**

Title:

Handling Conflict of Interest among Ethics Committee Members

INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures – Human Studies

Dr. M. L. Dhawale Memorial Homoeopathic Institute,
Palghar – 401404



Title :


Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC

SOP Code: SOP 03 - Version 1

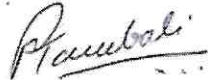

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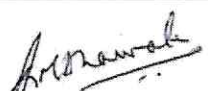
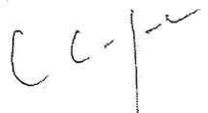

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1. Purpose:

The purpose of this SOP is to describe the process to identify and manage conflict of interest among Institutional Ethics Committee (IEC) members

2. Scope:

This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all IEC members.

3. Responsibility:

All IEC members (regular and alternate) are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

4. Definitions:

Conflict of interest (COI) is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain.

COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.

[https://icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf] accessed on 20th March 2019

Types of COI:

A personal COI is said to exist when -

- There is immediate family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent -who resides with an IEC member or consultant or who receives 50% or more support from an IEC member, regardless of age) or other close personal relationship ("step" relationships included, "Alumni" of MLDMHI) with the investigator, or with co-investigators.
- IEC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financier.
- Research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)

A professional COI means

- IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

A financial COI

- IEC members and immediate family exists the IEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and

intellectual property rights (e.g., patents, copyrights, product or service being evaluated)

The secondary interest may be financial or non-financial, personal, academic or political. This is not inherently wrong, but COI can influence the choice of research questions and methods, recruitment and retention of participants, interpretation and publication of data and the ethical review of research. It is, therefore, necessary to develop and implement policies and procedures to identify, mitigate and manage such COI which can be at the level of researcher, ethics committee or at the level of institution.

There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

[<http://www.cdsc.nic.in/html/GCP1.html>] accessed on 19th March 2019

5. Detailed Instructions:

- Voluntary disclosure regarding COI by IEC member - The IEC member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.
- IEC members should not participate in discussing, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.
 - a) If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC Chairperson and Member secretary and return the documents.
 - b) If an IEC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC Chairperson and Member Secretary so that the review is reassigned to other members.
 - c) If an IEC member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.
 - d) Recusal - IEC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.
 - e) If an IEC member finds that he/she has a COI during the conduct of a research project approved by IEC, he/she shall report the conflict to the IEC at the next IEC meeting.

- At the beginning of each meeting, the IEC Chairperson asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, IEC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
- If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair should be appointed for discussion on such a project.
- When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by IEC member with the help of IEC Chairperson / Member Secretary or by IEC Chairperson (as applicable)
- The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The IEC shall not approve a research study proposal where a COI is not managed or eliminated
- Management of CO – In case of a COI:
 - IEC members will disclose the COI as discussed above
 - IEC members will not serve as reviewers
 - IEC members will not influence the discussion and decision making of the concerned study by staying away during the IEC meeting.
 - IEC Member Secretary will record the points related to disclosure and management of COI of IEC members in the IEC minutes.

6. Annexures:

Annexure 1: AX 01 / SOP 03 – V1: Conflict of Interest Form/ Declaration for IEC Members

Conflict of Interest Form/ Declaration for IEC Members

I am aware of the policy of the IEC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the IEC.

I declare _____ (actual or potential COI) in relation to the proposal entitled

“ _____

_____”

submitted for review to the IEC.

The reason for COI is _____

I will refrain from the review process and /or discussion at the IEC meeting / and also will not take part in ongoing and periodic review and monitoring of this study.

Signature of IEC Member

Date

Chairperson's Signature

Date

7. Flow Chart:

No.	Activity	Responsibility
1	Determination of Conflict of Interest	IEC Member
2	Disclosure and Management of COI	IEC Member
3	Ensuring declaration and management of COI during review process	IEC Chairperson
4	Recording of COI in minutes of IEC Meeting	IEC Member Secretary

8. References:

- <file:///F:/Research%20Dept/Ethical%20Committee/SOP%20Formats/SOP-3-Handling-Conflict-of-Interest-among-Ethics-Committee-Members.pdf> accessed on 16th March 2019
- [https://icmr.nic.in/sites/default/files/guidelines/ICMR Ethical Guidelines 2017.pdf](https://icmr.nic.in/sites/default/files/guidelines/ICMR%20Ethical%20Guidelines%202017.pdf) accessed on 20th March 2019
- <http://www.cdsco.nic.in/html/GCP1.html> accessed on 20th March 2019

