



Pune District Education Association's

College of Ayurved & Research Centre

(I.D.No. P.U./P.N./AYU./081/1990)

Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.

Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in

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Strategic Plan/SOP for Institutional Ethics Committee-I & II

1. Introduction

For the sake of accessibility and smooth functioning IEC of PDEA is separated as IEC-I meant for review of M.D. student's research work and IEC-II for the review of research proposals of Ph.D. students, sponsored clinical research projects as well as funded projects. This SOP is adopted by the Institutional Ethics Committee-I & II(IEC) of Pune District Education Association's, College of Ayurved & Research Centre, Pune (CARC) to ensure reliability, consistency, quality and ethicality in the research involving human beings.

2. Aim :-

The aim of IEC-I & IEC-II is to follow ethical issues prescribed by Indian Council of Medical Research (ICMR) and national ethical guidelines for bio-medical clinical research on human subjects. In addition to this to follow the Declaration of Helsinki - Ethical Principles for Medical Research involving Human Subjects.

3. Objectives:

- 1) To ensure that following of ethical issues prescribed by ICMR & National ethical guidelines/principles for bio-medical clinical research is done properly.
- 2) Function & comply with regulatory requirements of ICMR without deviating cardinal principles of ethics in research.
- 3) To review & approve all MD/MS/Ph.D./ students clinical/other research proposals with funded/non funded as per requirement with a view to safeguard the dignity, rights, safety & well-being irrespective of the source of funding.

4. Name - P.D.E. A's, C.A.R.C.'s, Institutional Ethics Committee-I&II for Human Research.

Address of the IEC-I&II

Office: -

Pune District Education Association's,

College of Ayurved & Research Centre,

Sector No. 25, Pradhikaran, Near Vitthal Rukmini Temple,

Nigdi, Pune-411 044, Maharashtra State.

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5. Policy of IEC-I &II: -

- A. IEC-I is constituted to function independently to review ethics involved in proposed clinical studies of MD students before initiation, monitor and review the ongoing project regularly following Good Clinical Practices (GCP) in planning, execution and reporting in the study and to study final outcome of research.
IEC-II is constituted to function independently to review ethics involved in proposed clinical studies of Ph.D. students & sponsored clinical research projects as well as funded projects before initiation, monitor and review the ongoing project regularly following Good Clinical Practices (GCP) in planning, execution and reporting in the study and to study final outcome of research.
- B. IEC -I&II is functioning and complying with the regulatory requirements of ICMR, DCGI and/or national ethical guidelines for clinical studies without deviating cardinal principles of ethics in research.
- C. The functions of IEC-I& II are to review and approve all clinical research proposals of MD, Ph.D students & research projects respectively, involving human participants with a view to safeguard the dignity, rights, safety and wellbeing irrespective of the source of funding. It will also take care that the objectives of the research, however, important, should never be permitted to override the health and wellbeing of the subjects under study.
- D. The IEC-I II ensures that all the cardinal principles of research ethics viz, autonomy, beneficence; non-maleficence, plagiarism and justice are taken care of in planning, conduct and reporting of the proposed study. It looks into the aspects of inclusion as well as exclusion criteria, informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required. It reviews the clinical research of M.D. & Ph.D. students affiliated to M.U.H.S.& research projects. The proposals are being reviewed before start of the study as well as monitored at certain time interval throughout the study and after completion of the study through periodic reports, final report and site visits to verify the documentation etc. For that purpose, review of necessary steps is followed of protocol, presentation to guide-department-pre-IEC & research approval – final IEC in the institution before approval.
- E. In general IEC ensures compliance with all regulatory requirements, applicable guidelines and laws.

6. Composition of IEC-I

The composition of IEC-I is odd in number, and ensures gender, age, community representation, experts from different disciplines as per ICMR guidelines. The Chairperson of the committee is not Head / former Head of Pune District Education Association's, College of Ayurved & Research Centre. However, Member Secretary is from Pune District Education





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Association's, College of Ayurved & Research Centre, who is responsible to conduct the functioning of IEC.

The composition of IEC-I is as follows:

1. Chairperson
2. Basic medical scientist (2)
3. Clinician (2)
4. Legal expert (2)
5. Social scientist / representative of non-governmental voluntary agency (1)
6. Educated person from the community (1)
7. Member-Secretary.
8. Alternate member secretary (1)

The composition of IEC-II is as follows:

1. Chairperson
2. Basic medical scientist (2)
3. Clinician (3)
4. Legal expert (1)
5. Social scientist / representative of non-governmental voluntary agency (1)
6. Educated person from the community/Lay person (1)
7. Member-Secretary. (1)
8. Alternate member secretary (1)

The committee is normally constituted every after 3 to 5 years by changing some members.

4. Membership duration and responsibilities

- A. Duration of the membership is 3- 5 years, if necessary, this may be extended for additional period.
- B. About one to two members are replaced at the end of the term those are continuously absent for successive 3 meetings. In the event of long-term absence of member(s), the authorities of Pune District Education Association's, College of Ayurved & Research Centre suggests replacement for the same.
- C. All members provide their bio-data and sign confidentiality form.
- D. Member declares any conflict of interest for any project at the beginning of IEC-I & II meeting in writing for documentation.
- E. Members of committee are encouraged to attend national and international training programs / conferences / seminars concerned with research ethics; this helps and improves the quality of research protocols, review procedures and / or functions of the IEC.

7. Conduct of the Meeting

The Chairperson conducts all meetings of the IEC-I & II. In the absence of Chairperson, chairperson nominates one of the members as a chairperson. The Member Secretary organizes the meetings, prepare agenda in consultation with the Chairperson,





circulate the proposals, prepare minutes of the meeting and get approval for the same by the Chairperson. The Secretary maintains the records of the meetings in the archives, and communicates with all members.

The minimum quorum for the meeting is kept five. For some exceptional situations like Covid-19 with due permission of chairman meetings are conducted through mail circulation/ ONLINE.

8. Submission and processing of the proposal

- Principal investigator (PI)/Student submits 10 copies of the proposal with soft copies through head of departments of Pune District Education Association's, College of Ayurved & Research Centre to the Member Secretary. If the proposal is in collaboration with other institution, then it is signed by Co-principal investigator (CO-PI) and forwarded through the head of the respective institute along with the IEC approval of concern institute.
- The Member Secretary & PG Director acknowledges the same immediately and indicates any deficiency in proposal using the Check List as per MUHS guidelines within one week after the receipt of the proposal. The compliance for the same is done by PI/student as early as possible.
- The Member Secretary circulates the final proposal to all members as early as possible. At least one or two weeks prior to the meeting of IEC-I & II.
- The Member Secretary informs the date and time of the meeting to PIs/students and respective guides for their availability for the same for any clarification, if any.

9. Review Procedure

- The IEC-I & II meeting are held at least twice in a year (as per MUHS schedule). If necessary, additional meeting is arranged physically or through mail circulation/online.
- The proposals are circulated to all IEC-I&II members at least one-two weeks in advance along with the minutes of the previous meeting to confirm them at the time of meeting.
- Discussions on proposal are done in presence of students, guides in the meeting. The guide may be invited to offer Clarifications, if necessary. However, the decisions are taken in the absence of investigator / co-investigator / sponsor/student. Usually, decisions are taken after the consensus (after discussions), otherwise voting is resorted for the decision.
- In case of conflict of interest a member informs IEC-I & II, prior to review of the proposal and withdraw from the meeting and the same is recorded in the minutes of the meeting.
- For approved proposals the following standard conditions are mandatory. PI/student should inform Serious Adverse Event (SAE), if any, and action taken within 48 hours to Chairman/ Secretary of IEC -I & II. In addition, PI/student should submit annual report of ongoing project, and final report after the completion of the project, any amendments in the protocols, premature termination of project to IEC-I & II.
- The decisions of the meeting are recorded in the minute's document and is confirmed after final version of corrected synopsis/proposal submitted to the secretary with signature of





the Chairperson on appendix B page of MUHS and all signatures of members on the final page of minutes of meeting is preserved.

7) Usually for minor review the expedited review is carried out by Chairman, if necessary, he/she may appoint a sub-committee in consultation with member secretary to review such proposal, and based on their recommendations, the decision is given by the Chairperson. Member Secretary reports such decision in next IEC-I/II meeting. The revised form of proposal requiring major changes are reviewed at the next / additional IEC-I /II meeting.

8) Following points are important while reviewing the proposals-Design and conduct, assessment of risk / benefit from the study, inclusion / exclusion / withdrawal criteria for subjects, sample size, patient information sheet, consent form in bilingual English / Hindi / Local language including confidentiality of subject, handling of the medicine, data analysis and reporting, handling of the adverse events and provision for compensation, competence of investigator students and research as well as supporting staff, facilities / infrastructure at site.

9) The committee conducts work of scientific review committee as well as to check ethical issues.

10. Submission of Application: -

The researcher /students submit an application in a prescribed format along with the study protocol.

11. Decision Making Process: -

The following points are considered while decision making

1) The decision is taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The member secretary communicates the decision in writing to the PI/student.

2) A negative decision is always being supported by clearly defined reason.

3) An IEC -I /II may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk / benefit ratio.

4) The following circumstances require the matter to be brought to the attention of IEC-I /II

a. Any amendment to the protocol from the originally approved protocol with proper justification.

b. Serious and unexpected adverse events and remedial steps taken to tackle them.

c. Any new information that may influence the conduct of the study.

5) If necessary, the applicant / investigator may be invited to present the protocol or offer clarifications in the meeting.

6) Minutes of the meeting are approved and signed by the Chairman / designated member of the committee.

12. Review Process: -

Review is done by all reviewers and then finally by & Chairman in which case a brief summary of the project with informed consent and patient information sheet, is circulated to all the other members.





13. Periodic Review -

The ongoing research is reviewed at regular intervals of 6 months as per guidelines of MUHS.

Continuing Reviews: -

The IEC-I&II has the responsibility to continue reviewing approved projects for continuation, new information, adverse event monitoring, follow up and later after completion if needed.

14. Monitoring: -

Once IEC gives a certificate of approval it is the duty of the IEC-I &II to monitor the approved studies, therefore an oversight mechanism is conducted in place.

Actual site visits are made especially in the event of reporting of adverse events or violation of human rights.

Periodic/monthly status reports are asked for an appropriate interval based on the safety concerns and the record is maintained in form of KPIs for NABH.

SAE reports/Protocol deviation if received from the site as well as other sites are reviewed by IEC-I &II and appropriate action is taken when required.

15. Record Keeping: -

All documentation and communication of an IEC-I &II are dated, filed and preserved according to written procedures. Strict confidentiality is maintained during access and retrieval procedures. The following records are maintained -

- I) The constitution and composition of the IEC-I &II
- ii) Signed and dated copies of the synopsis/proposals (3 years).
- iii) Standing operating procedures of the IEC-I &II.
- iv) National and International guidelines.
- v) All correspondence with IEC-I &II members and investigators/students regarding application, decision and follow up.
- vii) Agenda of all IEC-I &II meetings.
- viii) Minutes of all IEC-I&II meetings with signature of the Chairperson/ Secretary.
- vi) Copies of suggestions communicated to the applicants.
- x) Record of all notification issued for premature termination of a study (if reported) with a summary of the reasons.
- xi) Final completion report of the study.

All records are safely maintained after the completion of the study for a period of 3 years.





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P.D.E.A'S College of Ayurved& Research Centre, Akurdi,Nigdi, Pune-44, EC-1 composition, specific role-(from Jan 2022 onwards)

Sr No	ICMR Guidelines	CARC-IEC members Current existing
1	Chairperson Non affiliated (Experience of having serving in an EC)	Dr V.V.Doiphode
2	Vice Chairperson(optional) Non affiliated (Experience of having serving in an EC)	Dr R.R.Patil
3	Member Secretary Affiliated (Staff member having experience in clinical research & good communication skills)	Dr IlaBhor
4	Basic Medical Scientists-1Pharmacologist& 1 Dravyaguna/research field Affiliated/Non affiliated With qualification in basic medical sciences	Mr Sunil Bakliwal Pharmacologist
5	Research & legal expert	Dr Vishnu Joglekar
6	Research experts from ASU	Dr Yogini Kulkarni
7	Physiologist	Dr R.R.Deshpande
8	Statistician	Mrs Namrata Jain
9	Clinicians-2 Affiliated/Non affiliated (Expert in clinical trials research)	Dr Jayant Mahajan
10	Clinician-1	Dr HrushikeshRangn ekar
11	Legal expert Affiliated/Non affiliated Basic degree law/Training in medical law	Dr MohanraoDeshm ukh
12	Social Scientist /Philosopher/ Lay person	Dr Sudhir Kate
13	Assistant Secretary	Dr Vijaya Nyahalse

P.D.E.A'S College of Ayurved& Research Centre, Akurdi,Nigdi, Pune-44, EC-2 composition, specific role-(from Jan 2022 onwards)





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Sr No	ICMR Guidelines	CARC-IEC members Current existing
1.	Chairperson	Dr.Supriya Bhalerao
2.	Member Secretary	Dr. Yogita Jamdade
	Alternate Member Secretary	Dr.D.B.Naik
3.	Basic Medical scientists	Dr. Ashish Kulkarni Dr.Meenal Lad
4.	Clinicians	Dr. Abhishek Karmalkar Dr.Medha Joshi Dr.Ajit Kolhatkar
5.	Legal Expert	Mrs.Pratibha Dalal
6.	Social Scientist/Philosopher	Mrs.Anjali Oak
7.	Lay Person	Mr.Sanjiv Alurkar

CARC



Principal

P.D.E.A.S

College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

