

**CODE OF ETHICS**  
**BY**  
**INSTITUTION**

# MALABAR DENTAL COLLEGE & RESEARCH CENTRE

Manoor, chekannur Road, Mudur (PO), Edappal, Malappuram Dt, Pin-679578

Phone: 0494 - 2697020, 21,22,23,24.

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## CODE OF ETHICS BY INSTITUTION

### COMMITTEE MEMBERS

The institution ethics committee of Malabar Dental College and research center has been constituted with effect from 05.10.2016, with the following as the members:

1. Dr. Toms c. Joseph (Chairperson)
2. Dr.Vinod Kumar R.B
3. Dr.joby peter
4. Dr.Justin Mathew
5. Dr.Bejoy p
6. Dr. Mahesh N
7. Dr.Lijo Isaac
8. Dr.Sunil M.Eraly
9. Dr.Deepak Daryani
10. Dr.Civy Pulayath
11. Adv.Shehab Mechery
12. Mr.Hassan Kutty
13. Theologian/social scientist/NGO activist
14. Dr.priya (member secretary)

### FORMAL MEETINGS

The ethics review of the proposals will be strictly done in the formal meetings by the Malabar Dental College and Research Center not by circulation of files

As far as possible, an annual calendar of the meetings of the Malabar dental college for the next year will be announced in advance at the last meeting of each calendar year so that members can ensure their presence for the meetings and

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unnecessary delays in the process of scientific and ethics clearance of the proposals can be avoided. The Malabar dental college will normally meet once in three months on a fixed date, which should be notified through appropriate mechanisms. Frequency of the meetings will be decided by the Chairperson depending on the volume of review work and other requirements that may arise from time to time. Extraordinary or special meetings may be convened depending on exigencies.

At least three weeks prior to the meeting of the Malabar dental college, Ethics committee secretariat shall inform all members about the date and venue of the meeting, the agenda and provide copies of the protocols for review.

All members are expected to allocate time for the meeting as per the agreed annual calendar of the meeting.

If for some unavoidable reasons a member is not able to attend the meeting, she/he should inform the Member Secretary at the earliest. However, the member shall be bound to hand over to the Secretary the review report and connected papers available with her/him in respect of the proposals allocated to her/him for review.

All members, irrespective of whether they are appointed as primary or secondary reviewers for specific proposals, are required to read all protocols sent to them and participate in the discussion during the meeting for their ethics review to ensure that they conform to the guidelines used by the Malabar dental college

## **DECISION MAKING:**

In order to evolve or attain consensus of views of the members, the Malabar dental college would promote extensive discussion among members. As far as possible, the decisions in the Malabar dental college will be taken by arriving at consensus. But in the event of the members not being able to reach a consensus, the decision will be taken on the basis of the majority of those present and voting.

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All members of the Malabar dental college, including the Chairperson, will be reimbursed for travel costs and other secretarial expenses treating them as First Class Officials as per University norms. If supporting documents like vouchers or tickets are asked for, the member shall be bound to provide them to the office.

## **CONFIDENTIALITY AND CONFLICT OF INTEREST**

Subject to statutory exceptions, the Malabar dental college members will maintain confidentiality with regard to the identifiable research information to which they have access to as a part of their work on the Malabar dental college, and will sign a statement or agreement to that effect.

Any member having a pecuniary or other conflict of interest as in the case of investment in Health Industry will declare it in writing to the Chairperson at the time of appointment to the Malabar dental college.

If an Malabar dental college member submits a project proposal as an Investigator or is associated as a consultant or in any other way significantly involved in a research proposal submitted to Malabar dental college, the member should declare her/his conflict of interest to the Chair. He/she will not participate in the review and withdraw from the meeting when this proposal is discussed and decided upon in the Malabar dental college meeting.

## **REVIEW AND AUDIT OF WORK OF MALABAR DENTAL COLLEGE**

The Malabar dental college may review its functioning, the work accomplished and the challenges faced in ethics review at the end of every year and formulate its goals and plans for the following year.

The Member Secretary, under the direction of the Chairperson will draft the annual report of the Malabar dental college and present it for discussion in the Malabar dental college meeting. All care will be taken to ensure that no information identifiable with the researcher(s), project(s), Malabar dental college

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member(s) etc. is given in such report. The Annual report, so approved by the Malabar dental college, should thereafter be submitted to the Governing Council.

The Malabar dental college may decide to publish or display the full or part of the report on the KUHS website.

In order to improve the functioning and quality of its ethics review, the Malabar dental college may commission an internal or external audit of its work, as and when needed.

## SUBMISSION AND CONSIDERATION OF MATERIALS FOR REVIEW

The PI must fill up the ethics review application form in simple non-jargonized language taking care that each point is adequately explained; and submit it with enclosures to the Member Secretary of the Malabar dental college Coordinator at least THREE WEEKS prior to the scheduled date of the Malabar dental college meeting.

Details regarding all insurance coverage for the study, including certificates should be submitted wherever necessary.

It is mandatory that all clinical trials should be registered online at Clinical Trial Registry - India (CTRI) ([www.ctri.in](http://www.ctri.in)) and the registration number should be submitted to the Malabar dental college before initiation of the study.

A processing fee of Rs 10,000 will be charged for all new submissions of proposals. This fee is applicable to all sponsored projects other than that of internal projects of KUHS, and other Government initiated projects. Student

Projects are also exempted from payment of processing fee. There will not be any additional fee for amendments and adverse event report submissions to the Malabar dental college. Once the project is approved, 5% of the total amount collected will be deducted as a part of the over-head and credited to the Malabar dental college corpus fund.

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The applicant of a proposal is required to submit his / her application online through the university website. But secretary can request for electronic /offline submission/ or hard copy submission (upto 12 copies) through post if:

- i. The online system is not optimally functional,
- ii. or one of the members /experts is not able to handle online documents or
- iii. any other justifying situations exist.

The submission should be supported by production of

- i. Evidence for payment of the prescribed processing fee, if any, necessary.
- ii. Research Protocol
- iii. Information as desired in the "Format for Submission"
- iv. Investigator's Brochure( if relevant)
- v. Patient information sheet,
- vi. Informed consent form in English and translated language in a simple layman's language that is non-technical and understandable by the study subject.
- vii. Statement from the PI stating the provisions for audiovisual recording of consent process and relating to safe archiving (if applicable) that will be carried out during the study.
- viii. Undertaking by the PI and co investigators signed in every page in the case of hard copies, or under proper authentication in the case of online submissions,.

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- ix. Copy of the questionnaire / tools used
- x. Permission to use copyrighted questionnaire and proforma if applicable
- xii. Updated brief Curriculum Vitae of Principal Investigator/s
- xiii. Other statutory permissions required if any
- xiv. Signature or online authentication by the head of the institution and/or head of the department .
- xv. Signature or online authentication of the Guide/co guide
- xvi. Documents to assure insurance and compensation if applicable

## MONITORING OF RESEARCH FOR ITS ETHICAL CONDUCT

The Malabar dental college is empowered to make visits to the research sites of units owned by the KUHS, and verify research materials, data collected or records maintained and review progress of actual conduct of the study to ensure that approved study proceeds strictly in accordance with the conditions on which it is approved. It may also appoint a Data and Safety Monitoring Board (DSMB) for continuing review of the research and take any other appropriate measure to ensure that the research is conducted according to the approved proposal/protocol. The powers of the Malabar dental college in this regard will be akin to that available to the CDSCO with regard to verifications. If DSMB is asked to make any such verification, it shall provide recommendations to Malabar dental college as and when called upon to do so.

## RECORD KEEPING

The KUHS should assist in making the following records of the Malabar dental college available in the public domain:

- (a) Governing Body's Terms of Reference (including constitution and composition) for the Malabar dental college

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- (b) The names and the curriculum vitae of all Malabar dental college members,
- (c) The Standard Operating Procedures (SOP) of the Malabar dental college,
- (d) International, National and Local guidelines and any other criteria normally used by the Malabar dental college in reviewing proposals.
- (e) All Forms prescribed by the Malabar dental college.
- (f) Annual calendar of meetings of the Malabar dental college.
- (g) Plans for training/education in the area of research ethics being conducted by the Malabar dental college or in other institutions where it is proposed to be given.
- (h) Annual reports of the work of the Malabar dental college, and audit reports
- (i) of the Malabar dental college. If any

All other documents and communications relating to the functions of the Malabar dental college are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. All such confidential records will be carefully and systematically stored in the form of electronic or hard copies in a separate room or cupboards/or with proper security measures in the secretariat by the Member-Secretary, who will be the custodian. Such confidential documents include, among others:



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- (a) Copies of protocols submitted for review and requests for advice received for consideration;
- (b) All correspondence with Malabar dental college members and investigators regarding application, decision and follow up;
- (c) Agenda of all Malabar dental college meetings;
- (d) Minutes of all Malabar dental college meetings with signature of the Chairperson;
- (e) Copies of decisions communicated to the applicants;
- (f) Record of all notifications issued for premature termination of a study with a summary of the reasons;
- (g) Final report of the study including microfilms, CDs and Video recordings.

All records will be maintained for at least 5 years in the form of electronic or hard copies, if it is not possible to maintain the same permanently.

The Member-Secretary must hand over full custody of such records to her/his successor, and the handing over must be documented.

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