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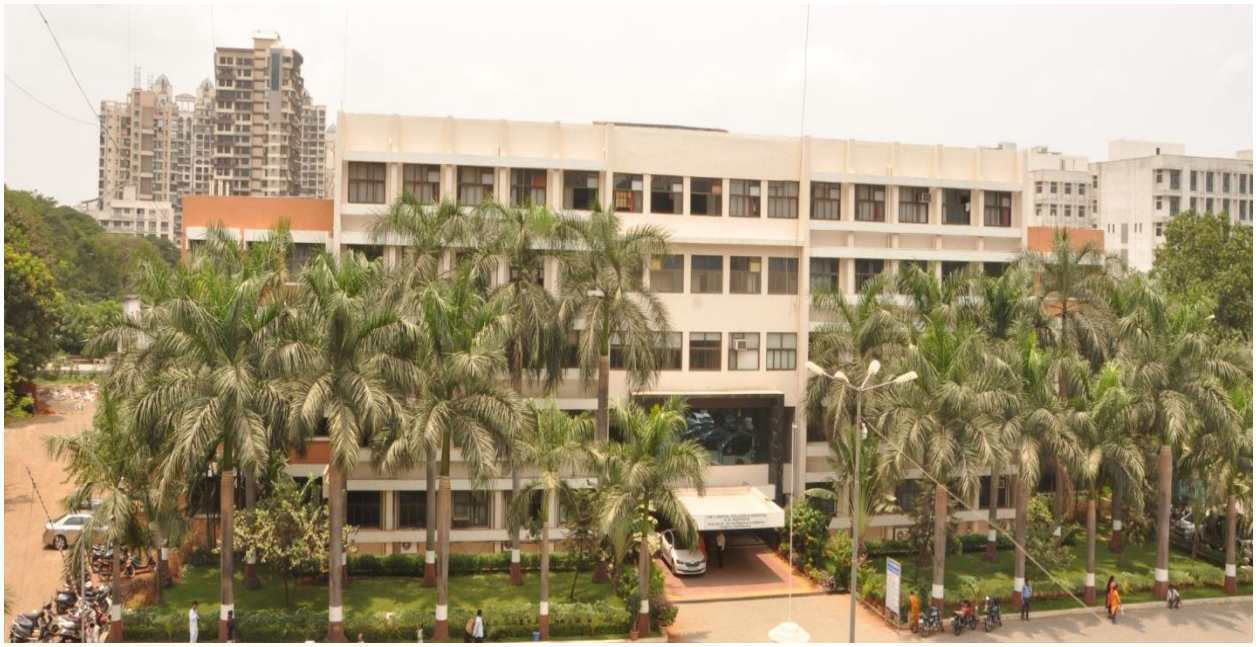

STANDARD OPERATING PROCEDURES FOR

INSTITUTIONAL ETHICS COMMITTEE (IEC)

INDEX

Year of Framing SOPs: 2018

INSTITUTIONAL ETHICS COMMITTEE (IEC)

INTRODUCTION

Short Title:
The following may be called as "Standard Operating Procedures" for the Institutional ethics committee (IEC) of Yerala Dental College and Hospital.

II. Adoption of SOP:

Yerala Dental College and Hospital has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at Yerala Dental College and Hospital.

III. Objective:
The objective of this Standard Operating Procedures of the Institutional ethics committee of Yerala Dental College and Hospital is to maintain effective functioning of the IEC to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

IV. Scope
The SOP applies to the working of the IEC

WORKING OF IEC

I. Mandate of Yerala Dental College and Hospital-IEC

Mandate of IEC is to function independently for maintaining a consistent scientific and ethical framework for patient care and research, and for integrating ethical values into practice, policy relationships, and organizational activities.

II. Role and Responsibilities of Yerala Dental College and Hospital-IEC:

The EC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects.

Responsibilities of this committee will be:

1. The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of the funding agency.
2. IEC will ascertain whether all the cardinal principles of research ethics viz., Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations.
3. IEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through IEC
4. In case an ethics committee revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator
5. In case of serious adverse event occurring to the clinical trial subject, the ethics committee shall forward its report on the serious adverse event, after due analysis, along with its opinion on the financial compensation.
6. The ethics committee shall ensure the highest scientific and ethical standards of research at Yerala Dental College and Hospital
7. IEC shall ensure the competent review and evaluation of proposals and approve, proposals for clinical or translational research projects for scientific and ethical content.

8. IEC shall improve ethical standards and issue guidelines on ethical dilemmas related to patient care services.
9. To function as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public.
10. To issue and periodically, update and revise SOPs and guidelines for effective functioning of IEC as and when necessary.
11. To initiate and commission research studies on ethical aspects of practice at Yerala Dental College and Hospital
12. Education of professional, administrative, and support staff about ethical issues.

VI. Composition of Yerala Dental College and Hospital-IEC:

Yerala Dental College and Hospital-IEC is a multidisciplinary and multisectorial body in composition and independent. The number of members of the ethics committee may range from 7 to 15. The Authority/Chairpeson under whom the IEC is constituted is Dean while other members are a mix of dental/medical/non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the differed points of view. There is representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. All Members are aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

All members will be appointed by the Director, Yerala Dental College and Hospital in consultation with the Chairperson.

Criteria for selection of members:

1. Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile.
2. Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
3. New members will be identified according to the requirement.

The following qualities are sought in IEC members:

1. Experience and education
2. Interest and motivation
3. Commitment and availability
4. Respect for divergent opinions
5. Integrity and diplomacy

The Yerala Dental College and Hospital-IEC includes

1. Chairperson
2. One - two persons from basic medical science area (One pharmacologist compulsorily, one female scientist compulsory)

3. One - two clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary agency
6. One philosopher/ ethicist/ theologian
7. One lay person from the community
8. Member Secretary

Membership requirements:

1. All members will serve for a period of 3 years on renewable basis. 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.
2. During the term, Chairman in consultation with the member secretary can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.
3. A member can tender resignation of his office of membership from the IEC to the Dean of Faculty through the Chairperson after serving one month advance notice.
4. Chairperson can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.
6. Conflict of interest should be declared by members of the IEC prior to review meeting.
7. Shall maintain the privacy and confidentiality of the study participants.

Roles and Responsibilities of the IEC members

The members' primary responsibilities will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research subjects.

1. Participate in the IEC meeting.
2. Review and discuss research proposals assigned for evaluation.
3. Review progress reports and monitor ongoing studies.
4. Monitor SAEs and recommend appropriate action(s).
5. Maintain confidentiality of the documents and deliberations of the IECs meetings.
6. Declare conflict of interest, if any.
7. Carry out work delegated by the Chairperson, Co-Chairperson and/or Member Secretary.
8. Participate in continuing education activities in biomedical ethics and biomedical research.
9. Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.

Quorum requirements:

Minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 5 members with following representations:

(a) Basic medical scientists (preferably one pharmacologist).
(b) Clinicians
(c) Legal expert
(d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(e) Lay person from the community.

Scientific and Ethical Basis

- The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project.
- The IEC evaluates protocols and ethical issues and is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.
- The IEC is guided in its reflection, advice and decision by the Ethical principles expressed in the Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004, 59th WMA general Assembly, Seoul, October 2008).
- It makes further reference to the International Ethical Guidelines for e.g. The Nuremburg Code (1945), the Council of International Organizations of Medical Sciences (CIOMS), the Belmont Report 1979, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human Rights and Biomedicine 1977.
- The IEC establishes its own Standard Operating Procedures based on the ICMR guidelines (2006), Schedule Y (Drugs and Cosmetics Act 1940., amendment 20th Jan 2005), Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000), and ICH-GCP, 1996 and the local regulations, CFR 45 (US FDA).
- IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations.

Education for IEC Members

IEC members have a need for initial and continued education regarding the science and ethics of biomedical research. All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines. IEC members will receive introductory training material in research bioethics and functioning of IEC and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.

Training of the IEC members in Research Bioethics:

1. A new member will be inducted 1 month prior to his/her appointment and will be

requested to be an 'Observer' for the first board meeting. An introductory training will be imparted by the Member Secretary.

2. The IEC members will be encouraged to receive ongoing training by attending workshops at least once every year.
3. The IEC will conduct workshops from time to time to impart training to the IEC members and Institutional faculty members.
4. The training programs should be scheduled and spread over the year.

Updating IEC members:

1. All relevant new guidelines should be brought to the attention of the members.
2. The EC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

VII. Conduct of Yerala Dental College and Hospital- IEC meetings:

The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

VIII. Review procedures:

All Research proposals shall be submitted along with the information and documents as specified in Annexures.

1. The proposals requiring IEC clearance should be sent at least 2 weeks in advance of scheduled IEC meeting.
2. All relevant documents should be enclosed with application form. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators should be submitted.
3. Every application will be allotted an IEC registration number to be used for all future correspondence and reference.
4. The Principal investigator PI/Research Scholar will present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the co-investigator will present the proposal.
5. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
6. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.

7. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
8. PI should inform IEC regarding funding/sponsorship of the research by pharmaceutical companies, Agencies, Multinationals etc.

Aspects considered during review of research proposal.

1. Scientific design and conduct of the study.

2. Approval by appropriate scientific review committees / Research committee (IEC).

3. Examination of predictable risks/harms

4. Examination of potential benefits.

5. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.

6. Management of research related injuries, adverse events.

7. Compensation provisions.

8. Availability of products, benefits to subjects after the study is completed if applicable.

9. Patient information sheet, informed consent form in English and in local languages.

10. Protection of privacy and confidentiality.

11. Involvement of the community, wherever necessary

12. Plans for data analysis and reporting.

13. Adherence to all regulatory requirements and applicable guidelines.

14. Competence of investigators, research and supporting staff.

15. Facilities and infrastructure of study sites.

16. Criteria for withdrawal of patients, suspending or premature termination of the study in Yerala Dental College and Hospital.

Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve:

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:

Clinical studies of drugs and medical devices only when -

i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4.Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be included** in the clinical trial that may be initiated later based on the findings of the pilot study.
a. Research on interventions in emergency situation
When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical/dental care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -
i. when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;
b. Research on disaster management

6.Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

Full Review
All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.
While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:
a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;

Iii.from neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
2. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
3. Mucosal cells collected by buccal scraping or swab, skin swab, or mouth washings;
4. Sputum collected

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance
i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
ii. Weighing or testing sensory acuity;
Iii. Magnetic resonance imaging;
iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,
v. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

IX. Decision-making:

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.

2. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

3. Decision will be made only in meetings where quorum is complete.

4. Only member can make the decision. The expert consultants will only offer their opinions.

5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given

In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.

7. Modified proposals will be reviewed by an expedited review through identified members.

8. Procedures for appeal by the researchers will be clearly defined.

Special considerations / protection of vulnerable population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population

Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary in writing to the PI / Research Scholar within 10 working days after the meeting at which the decision was taken in the specified format.

X. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.

2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.

3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.

4. Final report should be submitted at the end of study.

5. Following instances and events will require the follow-up review/ Renewed Approval:

a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.

b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.

c. Any event or information that may affect the benefit/risk ratio of the study.

6. Protocol deviation, if any, should be informed with adequate justifications.

7. Any new information related to the study should be communicated.

8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.

9. Change of investigators/sites must be informed to the office of IEC.

10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.

11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

XI. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

(i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.
(ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.
(iii) In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be
submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions, if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;
(iv) Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee and chairman of the expert committee constituted by the licensing authority as defined under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.
(V). IN case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for

medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.
(VI) The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

XII. Responsibilities of the Investigator(s)

(1) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B)of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.
(2) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death**.**

XIII. ADMINISTRATION AND MANAGEMENT OF IEC
A full-time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by YMTDC) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

Record keeping and archiving at the office of IEC:
1. All the documents and communications of IEC will be dated, filed and archived in a secure place.

2. Only persons, who are authorized by the Chairman of IEC will have the access to the various documents.

3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.

4. No document (except agenda) will be retained by any IEC member.

5. At the end of each meeting, every member must return the CD containing all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.

6. Following documents will be filed and archived with proper label on the top of file for easy identification

a. Constitution and composition of IEC

b. Curriculum Vitae (CV) of all members of IEC with records of training in Human ethics if any.

c. Standard Operating Procedures of IEC.

d. Annual reports

e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;

f. The published guidelines for submission established by the EC.

g. Copy of all study protocols with enclosed documents, progress reports
and SAEs.
h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.

j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.

k. Record of all notification issued for premature termination of a study with a summary of the reasons;

l. Final report of the approved projects, including microfilms, CDs and Video recordings.

Terms of reference
This includes
A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

Annual activity report

The Member Secretary in Consultation with the Chairperson shall prepare an annual activity report of the IEC for submission to the Director, YMTDC. This
shall include:

1. A quantitative evaluation of the activities of the committee in a year.
2. List of the research proposals reviewed in a year.
3. Status of research proposals.

Standard Operating Procedure (SOP) for IEC

Abbreviations:

SOP:	Standard Operating Procedure
IEC:	Institutional Ethics Committee
IEC:	Institutional Ethics Committee
PI:	Principal Investigator
Project:	Research project

The SOP consists of 4 parts:

1. General functioning of IEC.
2. Decision-making cycle.
3. Monitoring research projects.
4. Termination/suspension of research projects.
5.

Part I: SOP for General Functioning of the Core Committee, IEC

1. Mission of IEC

   To foster research for advancement of dental practice and community well-being.

2. Scope of IEC
   - 2.1. To establish, review, and revise the Standard Operating Procedure (SOP) for the functioning of the IEC.
   - 2.2. To approve projects in compliance to the aforementioned standards and guidelines.
   - 2.3. The IEC shall decide the date for Review committee meeting for reviewing research proposals.
   - 2.4. To periodically review and monitor research in the institution by obtaining reports from the PI.
   - 2.5. To identify priority areas of research in each specialty and encourage research in these areas.
   - 2.6. To provide training to foster relevant, systematic, and ethical research.
   - 2.7. To compile and disseminate a resource database to foster research.
   - 2.8. Termination/suspension of research projects.

3. Meetings of the IEC
   - 3.1. IEC shall meet at least once in 4 months (3 times in a year).
   - 3.2. Additional meetings can be convened based on the request to the Chairman and as deemed necessary by the chair for reviewing of projects which require urgent attention.
   - 3.3. IEC members shall be present for all the Review Committee meeting.
   - 3.4. Quorum: The minimum number of members to be present for a meeting is 50%.
   - 3.5. If there are less than 50% of members, the chairman can adjourn the meeting, and reconvene after a specific duration. Such reconvened meeting could be held as valid even if less than 50% members are present.
   - 3.6. A member absent for 3 consecutive meeting without prior intimation to the Chairman would forfeit his membership.
   - 3.7. Only the IEC member shall attend the meeting and proxy attendance is not permissible.

3.8. The notice of intimation for the meeting and minutes of previous meeting with all enclosures have to be circulated to the members 7 days in advance by the Member-Secretary.
3.9. Members should carry a copy of the Notice and Minutes of Meeting to the meeting for her/his reference.
3.10. Cancellation or change of date of the meeting shall be intimated to all the members by the Member-Secretary sufficiently in advance.

Part II: SOP for the Decision making cycle

4. Guidelines for forwarding studies for approval to other committee/s
   4.1. The IEC shall give final approval to the conduct of the project after the PI obtains approval of any other relevant committees.
   4.2. Exemptions from forwarding to IEC include research involving:
      4.2.1. Regular and special educational strategies, comparison among various educational instructional techniques, curriculum development projects, etc, which are deemed not to cause adverse impact on students' performance, or undue stress or hardships to students, or put students at a disadvantage.
      4.2.2. Use of educational tests, surveys, interviews, etc. without disclosure of student's identity.
5. Decision-making cycle of IEC
   5.1. IEC shall schedule its meetings based on requirements of PIs from the institution within 1 months from the date of submission.
   5.2. Final decision on exemption shall be made by the IEC after reviewing of Project.
   5.3. Decision outcome of the proposals could be one of the following:
      5.3.1. Approved and favorable opinion.
      5.3.2. Modification required prior to approval.
      5.3.3. Approval required from other committees before IEC approval.
      5.3.4. Disapproval and unfavorable opinion.
      5.3.5. Termination/ suspension of approved Project.
   5.4. Decision outcome shall be communicated in writing by the Member-Secretary to the PI in the prescribed format (Annexure).

Part III: SOP for monitoring the progress of projects by IEC

6. Monitoring the progress of Projects

6.1 Projects of duration more than1 year shall submit progress reports once every six months to IEC.

6.2 If any unanticipated adverse events are reported by the PI during the course of the study then the matter should be immediately reported to IEC regardless of the study duration.

Part IV: SOP for termination or suspension of projects

7. PIs who receive written notification to suspend or terminate a research study must cease immediately all research activities of that project.
   7.1 Suspension is the temporary withholding of the Project for a duration specified by the IEC until further intimation.
   7.2 Suspended research is still subject to Continuing Review. Eventually, a notice of suspension is withdrawn by the IEC or the suspended protocol becomes subject to termination procedures by IEC.

7.3 A project may be terminated or suspended based on the following observations:

7.3.1 A Project may be temporarily suspended by the Chairman till the next meeting of the IEC in case of reporting of any unanticipated adverse events by the PI.

7.3.2 Project may also be suspended in the event of any shortcoming or protocol deviations noticed during periodic report or during internal audit.

7.3.3 Termination: Termination is a permanent halt to all research activity. A study can be terminated if:

7.3.3.1 Projects involving plagiarism reported to or noted by IEC shall be terminated after an enquiry.

7.3.3.2 Projects reporting serious adverse events greater than minimal risk to the human participants

REFERENCES

1. ICMR Ethical Guidelines for Biomedical Research on Human Participants, ICMR,2017. Retrieved from- https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
2. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. Retrieved from- *http://www.cioms.ch/frame guidelines nov 2002.htm* accessed 13th September 2008
3. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005*)* Retrieved from - *http://www.cdsco.nic.in/html/Schedule-Y 20(Amended 20Version-* 2005).
4. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000) Retrieved from *www.who.int/tdr/publications/publications/*
5. Code of Federal Regulations 45 CFR 46.108 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Annexure I

Yerala Dental College and Hospital
Institutional Ethics Committee (IEC)

Format for Review Submission Form for Research Proposal

1. Title of the research proposal

2. Name of the Principal Investigator with qualification and designation

3. Name of the Co-Investigator(s) with qualifications and designation

4. Name of the Institute / Hospital / Field area where research will be conducted

5. Forwarding letter from the Head of the Department / Institution / Guide.

6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.

7. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances. Source of funding and financial requirements for the project.

8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available.

9. Usefulness of the project / trial

10. Expected ‘benefits’ to volunteers / community. ‘Benefits’ to other categories if any

11. Explain all anticipated ‘risks’ (adverse events, injury, discomfort) of the project. Efforts taken to minimize the ‘risks’. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
12. Agreement to report all Serious Adverse Events (SAE) to IEC.

Other financial issues including those related to insurance.

14. An account of storage and maintenance of all data collected during the trial.

15. Research proposals approval by scientific advisory committee

16. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee (HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)

17. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.

18. Statement of conflicts of interest, if any.

19. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.

20. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided

21. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.

22. Curriculum vitae of all the investigators with relevant publications in last five years.

23. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.

24. Any other information relevant to the study.

25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

Annexure II

Yerala Dental College and Hospital
Institutional Ethics Committee (IEC)

Six monthly progress of project

Institute Ethics Committee Reference No._____

Study title:_____

Name of the Principal Investigator _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: From _____To _____

Progress/Interim Results:

Side Effect if any:

Amendments if any:

Discontinuation/Termination reasons:

Signature of Principal Investigator _____

Date:_____

Annexure III

Yerala Dental College and Hospital
Institutional Ethics Committee (IEC)

Format for Communication of Decision of the Institutional Ethics Committee

IEC No: **Date:**

Protocol title:
Principal Investigator:
Name & Address of Institution: Y.M.T. Dental College & Hospital, Kharghar, Navi Mumbai
☐ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): Date of previous review, if revised application:
Decision of the IEC: (tick where appropriate) Recommended Recommended with suggestions Revision Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of:

Please note *

- Inform IEC/ immediately in case of any adverse events and serious adverse events.
- Inform IEC in case of any change of study procedure, site and investigator.
- This permission is only for period mentioned above.
- Annual report to be submitted to IEC.
- Members of IEC have right to monitor the trial with prior intimation.

Signature of Member Secretary IEC

Annexure IV

Yerala Dental College and Hospital
Institutional Ethics Committee (IEC)

Format for Confidentiality and Conflict of Interest Agreement form for IEC Members

In recognition of the fact, that I, Dr…… herein referred to as the "Undersigned", have been appointed as a member of the Institutional Ethics Committee and would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane, scientific and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines.

Whereas, 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/ community nor as the delegate of any organization or private interest; whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review; whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities with respect to the protection of the rights and well-being of human subjects.

The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, 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. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his performance of this agreement is consistent with Yerala Dental College and Hosptial’s policies and any contractual obligations it may have to third parties.

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Undersigned Name and Signature Date

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but there is faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The IEC may elect to investigate the applicant's claim of the potential conflict. When a member has a conflict of interest, the member should notify the Chairperson IEC and may not participate in the IEC review or approval except to provide information requested by the Committee.

Example of conflict of interest cases may be any of the following:

1. A member is involved in a potentially competing research program.
2. Access to funding or intellectual information may provide an unfair competitive advantage.
3. A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the IEC 's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

_____

Undersigned Signature with Date

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr. …….. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

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Undersigned Signature Date