CHILDREN'S EDUCATION SOCIETY (Regd.)
THE OXFORD DENTAL COLLEGE
(Recognized by the Govt. of Karnataka, Affiliated to Rajiv Gandhi University of Health Sciences, Karnataka Bangalore, Recognised by Dental Council of India, New Delhi)
Bommanahalli, Hosur Road, Bangalore - 560 068
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Website: www.theoxford.edu

3.3.1

The Institution ensures implementation of its stated Code of Ethics for research.

Index

PRINCIPAL
The Oxford Dental College
Bommanahalli, Hosur Road,
Bangalore - 560 068.

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Institutional Code of Ethics manual

RESERACH ETHICS

THE OXFORD DENTAL COLLEGE

10th MILESTONE,

HOSUR ROAD

BOMMANAHALLI

PRINCIPAL
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Bommanahalli, Hosur Road,
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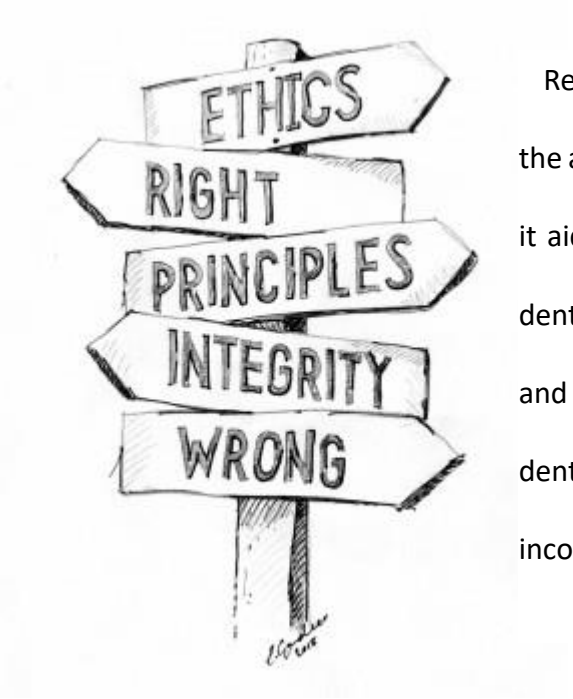
CONTENT

1. Introduction



Research is the creation of new knowledge on the basis of the already known concepts. Research forms pillar of any field, it aids in constantly evolving the field to progress further. In dentistry too, research forms an important aspect in diagnosis and treatment planning. It forms the basis of evidence based dentistry. Hence it becomes a mandatory aspect to be incorporated into academics.

Ethics in research is the most important part of conducting research. As most of the research is conducted on humans or animals, utmost care must be taken to practice ethical research. The institution hence ensures all the research conducted does undergo stringent review to be accepted and constantly follows up this research to monitor the progress. This handbook is prepared with inputs from the institutional ethical committee, institutional review board and faculty. It provides an complete insight to the protocols followed in the institution for conducting research.

2. Research Values

The outcomes of research affects the well being of the society directly. Hence the integrity of these research becomes of paramount importance. The following are the values underlying research integrity.

2.1 ETHICS:

- Research should be conducted in an ethical way so as to ascertain that the rights, safety, dignity and privacy of the ecosystem is maintained.

2.2 Rigour:

- Research ensures high quality design, reliable data, the appropriate use of methods, rigorous and careful analysis, and transparent reporting and interpretation of the results.

Relevance:

- The research conducted should be of scientific relevance and be beneficial for the society.

2.3 Transparency:

- Research conducted should have transparency in developing, undertaking, reviewing, reporting, and communicating research in unbiased manner to ensure honesty.

2.4 Respect:

- Research should follow the guidelines and at the same time maintain respect for research participants and the environment.

2.5 Impartiality:

- Research should always be unbiased, without any conflict of interest to maintain the integrity and relevance of the study.

2.6 Independence:

- Researcher should have independence in design, conduct, analysis and interpretation of research without the influence of funders or other non researchers.

2.7 Accountability:

- Researcher should abide by the guidelines of the institution and have proper documentation of the entire research protocol . Timely review of the progress of the study should also be given to the institutional committee.

3. Responsibility Of Researcher

The researcher is the individual who would be carrying out this research. **Researchers** are responsible for collecting, organizing, and analysing opinions and data to solve problems, explore issues, and predict trend. Hence it is of utmost priority that they are aware of their moral responsibilities and abide by it.

The following are the responsibilities of the researcher while conducting the research

3.1 Training:

- Be trained to perform the procedures in the research

3.2 Research proposal:

- Preparation of a research proposal stating clearly the aims, objectives and the protocol that will be followed for the research

3.3 Approval:

- Submit all the necessary documents and obtain approval for the research

3.4 Guidelines :

- Abide by the institutional guidelines for research

3.5 Informed Consent:

- Gain informed consent from participants
- Protect the interest of vulnerable groups

3.6 Vulnerable Groups :

3.7 Anonymity and Confidentiality :

- Assure the anonymity of participants, where appropriate. Assure the confidentiality of information, where appropriate

3.8 Follow Up :

- Researcher should timely submit the status and progress of research

3.9 Misconduct:

- Researcher should strictly adhere to ethical research and refrain from any kind of malpractice

- Validation of research lies in its publication, hence it is the responsibility of the researcher to work towards the publication of the article

3.10 Publication:

4. Responsibility Of Institution

The institution has a pivotal role in research ethics. The research conducted in the institution has to be under the governance of institution. The responsibility of creating an environment for encouraging more and more research to be undertaken while ensuring ethical research lies with the institution

The institutional responsibilities include, but are not limited to:

4.1 **Research Review** - to review and approve the proposed research project

-to follow the progress of the study

4.2 **Training** –the institution should train both the researchers and the review and ethics committee

4.2.1 Training for committee member

- Relevant research ethics and regulatory guidelines
- Roles and Responsibilities of IEC-TODC members
- Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- Recent Developments in relevant health science specialities
- SOPs of the IEC-TODC

4.2.2 Training for researcher

- Selection of research topic
- Synopsis writing
- Biostatistics
- Dissertation writing
- Publication manuscript writing
- Ethics in research
- Guidelines of institution
- Research Misconduct

4.3 Collaboration /Linkages

The institution has collaboration with the sister institution and various other organizations required for research.

5. Institutional Committees

5.1 Institutional Review Board

The institutional review board (IRB) is a formally constituted group that is appointed to review, monitor and approve research involving human subjects. IRB should provide independent evaluation on the research that has been proposed in terms of its ethical acceptability, evaluation of any investigators' potential biases, and compliance with regulations and laws formed to protect human subjects. The board can disapprove any research that may not fulfil the above said criteria or can warrant any modifications as required in order to grant approval to the study.IRBs have an extremely crucial role in protecting human research participants from possible harm and exploitation

5.2 Composition

The review board comprises of members of faculty from the college

5.3 Institutional Ethical Committee

Research usually involves participation of human subjects. This participation however should be carefully evaluated so as to ensure that the participants of the study are not subjected to any type of harm or deprived of any standard care for the disease. The institution ethical committee is a formally appointed group that ensures that the research projects is aligned as per the principles of ethics in research. It approves the research proposal only after ensuring that the objectives of the study are for the benefit of the society and the study will not harm the ecosystem.

5.4 Composition

1) Chairperson (Non-affiliated to the institution).
2) Member Secretary (From the institution).
3) Three Clinicians (Two from the institution, one non-affiliated to the institution).
4) One Legal expert (Non-affiliated to the institution).
5) Basic medical scientist (Person with basic MBBS degree and post-graduation in Biochemistry/Pathology/Microbiology / Pharmacology)- (Not from the institution).
6) One Social Scientist/Representative from non-governmental organization/social worker (Non-affiliated to the institution).
7) One Lay person from the community (Non-affiliated to the institution).

6. Research Cycle

The research involves the following steps

6.1 choosing research topic

6.2 Research Design

6.3 formulation of synopsis

6.4 submissions of documents for approval

6.5 Review process

6.4 research process

6.5 follow up

6.6 conflict of interest

6.7 Dissertation writing

6.8 Publication

6.1 Choosing research topic

A research procedure should begin with the research question. The research question should be:

6.1.1 Clear: the research question should be clear so that it can be understood well.

6.1.2 Focused: the question should focus on the objective accurately to ensure that all the feasible resources can be used for it.

6.1.3 Concise: the research question should be comprehendible but should be yet to the point.

6.1.4 Refined : with a research design that matches the complexity of the problem being addressed.

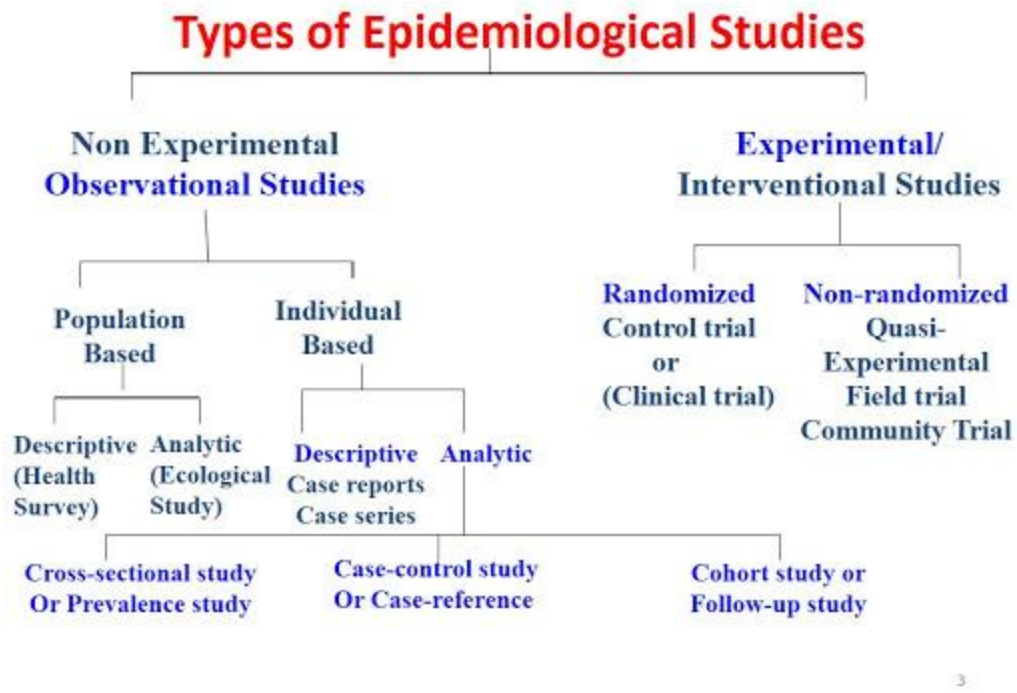
6.1.5 Logical: to ensure that the available evidence supports the research claims.

To concise at the point of research question the researcher is expected to

- Describe the research objectives and rationale
- Develop a project plan with milestones, roles, and responsibilities
- Ensure the viability of the study in view of resources expertise, facilities, funding
- Keep abreast with the relevant regulatory, ethical, organizational, and other guidelines
- Seek requisite licenses, approvals and permissions in advance

6.2 Research Design

The following flowchart concise all the types of study that can be undertaken to design a research. The researcher should undergo thorough training for understanding these research designs. The institute conducts workshops on research methodology so that the researcher is aware of all these designs and biostatistics in performing these studies. The researcher can then design their study accurately.



6.3 Formulation Of Synopsis

The next step in research protocol is formulating the research proposal for approval from the institutional review and ethics board. The synopsis should be prepared as per the proforma of the RGUHS.

6.4 Submissions Of Documents For Approval

The following documents shall be submitted to the secretary of the ethics committee.

6.4.1 Essential Documents :

4.2.1.1 Covering letter to the Member Secretary.

6.4.1.2 Project submission application form for initial review (see annexure).

6.4.1.3 The correct version of the research proposal: 2 sets of hard copies and one soft copy.

6.4.1.4 Informed consent form (see annexure) in English and in a regional language.

Proforma for clinical data collection

6.4.1.5 Budget Proposal

6.4.1.6Letter from the Department Head Concerned, here non routine or special tests are being done (applicable to academic studies)

6.4.2 the following additional documents are required for regulatory trials

6.4.2.1 Amendments to protocol (if any)

6.4.2.2 Informed Consent Document in Regional languages (if applicable)

6.4.2.3 Back translations of ICDs (if applicable)

6.4.2.4Translation and Back translation certificates (if applicable)

6.4.2.5 Amendments to the ICD (if any)

6.4.2.6 Case Record Form

6.4.2.7 Recruitment procedures: advertisement, notices, letters to doctors (if applicable)

6.4.2.8Patient instruction card, identity card, diary etc. (if applicable)

6.4.2.9Investigator Brochure (if applicable)

6**.5 Review Process**

6.5.1 Aspects Considered For Review

6.5.1 .1 Scientific design and conduct of the study: Use of valid scientific methods

6.5.1.2Social Values: The research must have anticipated social value, and outcome should be relevant to the health problems of the society.

6.5.1.3Benefit-Risk Assessment: The benefits must justify the risk inherent in the research. Risks may be physical, psychological, economic, or social; Withdrawal criteria, and rescue medication or procedures.

6.5.1.4Selection of the Study Population and Recruitment of Research Participants : To ensure voluntary recruitment, and fair selection of participants as per inclusion and exclusion criteria; participant is given option to opt out without the routine care being affected; No individuals or group of persons must bear the burdens of participation in research without any benefits except in studies where healthy volunteers are involved; Vulnerable group is not recruited unless proper justification is provided.

6.5.1.5Payment of participation and Compensation Procedures, without inducement but, reimbursing for incurred cost and convenience.

6.5.1.6Protection of research participant's privacy and confidentiality.

6.5.1.7Community considerations: due respect given to community and interests are protected; no stigma or discrimination ensues from the proposed research; plans for communication of results back to the community at the end of study; plan for dissemination of benefits of research to the community. \

6.5.1.8 Qualifications of investigators and assess adequacy of study sites.

6.5.1.9 Disclosure of potential conflicts of interest

6.5.1.10 Review of informed consent process: The review of proposals by members is documented in review forms, and in the minutes of meetings of the IEC-TODC.

6.5.2 DESCION MAKING FOR VULNERABLE POPULATION

6.5.2.1 Definition of Vulnerable Population: Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. They are the individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

- economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.);
- unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent
- children (up to 18 years);
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- tribals and marginalized communities;
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
- terminally ill or are in search of new interventions having exhausted all therapies;
- suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system
- (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

Among the above-mentioned vulnerable categories, children under the age of 18 make up a significant proportion of the subjects recruited in conduct of research at TODC. Checklists for recruitment of children in research are elaborated in annexures 9.5.1 and 9.5.2.

6.5.2.2 Reviewing protocols with vulnerable participants:

- The protocol should be reviewed as described already under the SOP "Review Procedures".
- Additionally, the protocol should be reviewed to assess if the following points are addressed:
    - Can the research be performed in any other non-vulnerable participants? --- Is there justification to use vulnerable population? ---- Do the benefits justify the risks ---- Are the participants selected equitably ---- Have the measures to protect Autonomy of the vulnerable population been described.
    - Appropriate Review forms are used.

6.5.2.3 Decision: The decision on allowing trials on vulnerable populations will be taken in a full board meeting of IEC. The decision will be communicated to the PI. Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented.

6.4 Research Process

The next step involves performing the research process the researcher should abide by all the values of research while performing the procedures. The clinical trails should be registered.

6.5 Review Of Progress Of The Study And Final Completion Reports

It is the responsibility of the Secretariat/ IEC Chairperson/ Member Secretary/ Member/s to review the study report and act on it.

6.5.1 Procedure :

6.5.1.1 Receipt of Review of Progress of the study and Final Completion Reports. The Secretariat will receive 1 copy each (soft and hard) of Review of Progress of the study and Final Completion Reports t for the regulatory trials Review of Progress of the study and Final Completion Reports is expected from the investigator within 1 month of completion of the study at the site. This is applicable only for regulatory trials.

6.5.1.2 It is the responsibility of the IEC Secretariat to review the report for completeness The Secretariat shall verify the submitted Review of Progress of the study and Final Completion Reports Form and forward it to the Member Secretary within 7 working days of receipt. The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting.

6.5.1.3 If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it as per the relevant SOP. The Secretariat shall include the Study Completion Report Form in the agenda for IEC members for discussion at the full board meeting.

4.5.1.4 During the Board meeting The Member Secretary will present the report and members can discuss as needed. Following the discussion, the Chairperson may take one of the following decision:

a) noted / approved b) request for additional information / clarification The Secretariat will note the decision in the meeting minutes

b) The Member Secretary will draft a letter to the PI conveying decision on the study completion report. The study shall be considered as closed if the decision by IEC is "Noted" or "Approved".

c) The Secretariat will accept and file the Report and get the Study Completion Report Form signed by the Chairperson. The final report will be placed in the master file and kept in the archival area.

d) The Secretariat will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

6.6 Conflict of interest

6.6.1. Types of COI:

6.6.1.1 Personal COI: If the investigator of a research proposal has close and immediate family relationship with the member of IEC-TODC (spouse, son/daughter, parents, sibling, dependent) ; If the IEC-TODC member is a collaborator, Principal investigator, co-investigator, financer, research staff, consultant for a research proposal which has come for review in IEC-TODC; If a research proposal is submitted by a departmental colleague with whom the member has conflict

of interest (dispute, bias, any benefits, etc.. ,) –if applicable and if the member feels there is a conflict of interest.

6.6.1.2. Professional COI: If the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

6.6.1.3. Financial COI: If 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).

6.6.2 Procedure for Declaring COI:

6.6.2.1. The IEC member should identify the COI whenever a research proposal is assigned to him/her for the review. The COI should be declared in the format provided in SOP of IEC-TODC, and submitted to the member secretary.

6.6.2.2. The 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.

6.6.2.3. 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 Secretariat and return the documents.

6.6.2.4. 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 secretariat so that the review is reassigned to other members.

6.6.2.5. 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

6.6.2.6. The 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.

6.6.2.7. 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.

6.6.2.8. At the beginning of each meeting, the IEC-TODC 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.

6.6.2.9. 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 Chairperson should be appointed for discussion on such a project.

6.6.2.10. When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by the IEC member with the help of the IEC Chairperson / Member Secretary or by IEC Chairperson / Member Secretary (as applicable)

6.6.2.11. 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

6.6.2.12. The declaration and management of COI should be recorded in the proceedings of the IEC-TODC meetings.

6.7 Dissertation writing

The format should be followed from the RGUHS website.

6.8 Publication

The purpose of research is to benefit the society and the field of dentistry in diagnosis and treatment planning. This purpose will only be accomplished if the research reaches other members of the fraternity. This is possible by displaying our work in various journals. Hence publication of the research is an vital aspect. While doing so the researcher should follow publication ethics as follows

- All the work reported in the manuscript must be original and free from any kind of plagiarism.
- The work should not have been published elsewhere or submitted to any other journal(s) at the same time.
- Any potential conflict of interest must be clearly acknowledged.
- Proper acknowledgements to other work reported (individual/company/institution) must be given. Permission must be obtained from any content used from other sources.
- Only those who have made any substantial contribution to the interpretation or composition of the submitted work, should be listed as 'Authors'. While other contributors should be mentioned as 'co-authors'.

Authorship

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

7. Guidelines:

The studies on animals should follow the following guidelines:

1. Respect for animals' dignity

Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Researchers must be respectful when choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

2. Responsibility for considering options (*Replace*)

Researchers are responsible for studying whether there are alternatives to experiments on animals. Alternative options must be prioritised if the same knowledge can be acquired without using laboratory animals. If no good options are available, researchers should consider whether the research can be postponed until alternative methods have been developed. When justifying experiments on animals, researchers therefore must be able to account for the absence of options and the need to acquire knowledge immediately.

3. The principle of proportionality: responsibility for considering and balancing suffering and benefit

Researchers must consider the risk that laboratory animals experience pain and other suffering (see guideline 5) and assess them in relation to the value of the research for animals, people or the environment. Researchers are responsible for considering whether the experiment may result in improvements for animals, people or the environment. The possible benefits of the study must be considered, substantiated and specified in both the short and the long term. The responsibility also entails an obligation to consider the scientific quality of the experiments and whether the experiments will have relevant scientific benefits.

Suffering can only be caused to animals if this is counterbalanced by a substantial and probable benefit for animals, people or the environment.

There are many different methods for analysing harm and benefit. Research institutions should provide training on suitable models, and researchers are responsible for using such methods of analysis when planning experiments on animals.

4. Responsibility for considering reducing the number of animals (*Reduce*)

Researchers are responsible for considering whether it is possible to reduce the number of animals the experiment plans to use and must only include the number necessary to maintain the scientific quality of the

experiments and the relevance of the results. This means, among other things, that researchers must conduct literature studies, consider alternative experiment designs and perform design calculations before beginning experiments.

5. Responsibility for minimising the risk of suffering and improving animal welfare (*Refine*)

Researchers are responsible for assessing the expected effect on laboratory animals. Researchers must minimise the risk of suffering and provide good animal welfare. Suffering includes pain, hunger, thirst, malnutrition, abnormal cold or heat, fear, stress, injury, illness and restrictions on the ability to behave normally/naturally.

A researcher's assessment of what is considered acceptable suffering should be based on the animals that suffer the most. If there are any doubts regarding perceived suffering, consideration of the animals must be the deciding factor.

Researchers must not only consider the direct suffering that may be endured during the experiment itself, but also the risk of suffering before and after the experiment, including trapping, labelling, anaesthetizing, breeding, transportation, stabling and euthanising. This means that researchers must also take account of the need for periods of adaptation before and after the experiment.

6. Responsibility for maintaining biological diversity

Researchers are responsible for ensuring that the use of laboratory animals does not endanger biological diversity. This means that researchers must consider the consequences to the stock and to the ecosystem as a whole. The use of endangered and vulnerable species must be reduced to an absolute minimum. When there is credible, but uncertain, knowledge that the inclusion of animals in research or the use of certain methods may have ethically unacceptable consequences for the stock and the ecosystem as a whole, researchers must observe the precautionary principle.

7. Responsibility when intervening in a habitat

Researchers are responsible for reducing disruption and any impact on the natural behaviour of individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and their living conditions, for example as a result of installing radar masts, antennas or other measurement instruments. In such cases, researchers must seek to observe the principle of proportionality (see guideline 3) and minimise the possible negative impact.

8. Responsibility for openness and sharing of data and material

Researchers are responsible for ensuring that there is transparency about research findings and facilitating the sharing of data and material from experiments on animals. Such transparency and sharing are important in order to avoid unnecessary repetition of experiments.

In general, the negative results of experiments on animals should be public knowledge. Disclosing negative results may give other researchers information about which experiments are not worth pursuing, shine a light on unfortunate research design, and help reduce the use of animals in research.

9. Requirement of expertise on animals

Researchers and other parties who handle live animals must have adequately updated and documented expertise on animals. This includes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

10. Requirement of due care

There are national laws and rules and international conventions and agreements regarding the use of laboratory animals, and both researchers and research managers must comply with these. Any person who plans to use animals in experiments must familiarise themselves with the current rules.

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STANDARD OPERATING PROCEDURES

INSTITUIONAL ETHIC COMMITTEE
THE OXFORD DENTAL COLLEGE
10th MILESTONE,
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II. IEC-TODC: SOP

I. Prepared by: SOP team IEC 2020

II. Verified by Member Secretary IEC TODC

III. Approved and issued by Dr Mohamed Faizuddin,

Chairperson, IEC-TODC

IV. Contact Details of IEC TODC

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Email id: todciec@gmail.com, deandirectortodc@gmail.com

III. DISTRIBUTION LIST

Following are the authorized holders of controlled PDF, Soft copy of IEC TODC SOP

Name	Designation
Dr Mohammed Faizuddin	Chairperson IEC-TODC
Dr.Srirekha .A	Member Secretary IEC-TODC
Dr Geetha Anantharamiah	Basic Medical Scientist IEC-TODC
Dr.Raveendra KR	Member- Clinician IEC-TODC
Dr.Priya Subramaniam	Member- Clinician IEC-TODC
Dr.Bharathi A Patil	Member- Clinician IEC-TODC
Dr.Girish Kumar	Member- Legal Expert IEC-TODC
Dr Kameshwari Devi	Member- Social Scientist IEC-TODC
Rukmaya Gowda N	Member- Lay Person IEC-TODC

IV. TABLE OF CONTENTS

V. LIST OF ABBREVIATIONS

AE	Adverse Event
CDSCO	Central Drugs Standard Control Organization
CTRI	Clinical Trial Registry of India
DCGI	Drug Controller General of India
DSMB	Data and Safety Monitoring Board
IEC- TODC	Institutional Ethics Committee- The Oxford Dental College
GCP	Good Clinical Practice
ICD	Informed Consent Documents
ICMR	Indian Council of Medical Research
IP	Investigational Product
PI	Principal Investigator
NABH	National Accreditation Board for Hospitals and Health Care Providers
SAE	Serious Adverse events
SUSARS	Serious Unexpected Serious Adverse Reactions
SOP	Standard Operating Procedures
TOR	Terms of Reference

VI. STANDARD OPERATING PROCEDURES

SOP-1: Constitution of IEC: Selection, Roles and Responsibilities of Members of IEC-TODC

1.1. Purpose: The purpose of this SOP is to define and describe the terms of reference, which provide the framework for constitution, selection, roles and responsibilities of members of the Institutional Ethics Committee -The Oxford Dental College (IEC-TODC), and the procedure for maintaining confidentiality of all activities and documents.

1.2. Scope: This SOP is applicable to appointment of members of IEC-TODC; defining their roles and responsibilities.

1.3. Responsibility: The appointment of the members of IEC-TODCwill be done by the Head of the Institution. Every member is expected to follow this SOP.

1.4. Procedure:

1.4.1. The IEC-TODCis primarily for The Oxford Dental College (IEC-TODC). So, the appointing authority for the IEC-TODCis Dean and Director of TODC.

1.4.2. The Dean sends an official request letter to the members who will confirm their acceptance to the Dean by providing all required information such as curriculum vitae, and certificates of training on research ethics and good clinical practice. The consent letter includes consent from the member, declaration of maintaining confidentiality of research project-related data/documents/discussions, and willingness to get updated on research ethics, good clinical practice and regulations on human research. On receiving this consent, the Dean will issue the final appointment order.

1.4.3. Composition of IEC-TODC:

1.4.3.1. The IEC-TODC is multi-disciplinary and multi-sectorial in composition. It is independent and shall have 7 to 15 members. The Chairperson shall be from outside the institution. The member Secretary will belong to the institution. There will be adequate representation of age and gender, and mix of scientific and non-scientific members. The basic composition of IEC-TODC is as per the guidelines of Central Drug Standard Control Organization (CDSCO).

1.4.3.2. The Composition shall be as follows: (as per CDSCO guidelines)

1) Chairperson (Non-affiliated to the institution).
2) Member Secretary (From the institution).
3) Three Clinicians (Two from the institution, one non-affiliated to the institution).
4) One Legal expert (Non-affiliated to the institution).

5) Basic medical scientist (Person with basic MBBS degree and post-graduation in Biochemistry/Pathology/Microbiology / Pharmacology)- (Not from the institution).
6) One Social Scientist/Representative from non-governmental organization/social worker(Non-affiliated to the institution).
7) One Lay person from the community (Non-affiliated to the institution).

1.4.3.3. The Chairperson and Member Secretary will not have the dual roles in the ethics committee. They can't fulfil the role of a member (clinician/basic medical scientist/social scientist/legal expert, etc..) as it interferes with their own responsibilities.

1.4.4.4. All members including Chairperson, Member Secretary and joint Secretary will review the research proposals. The Member Secretary does not have voting rights. Chairperson will exercise voting if it is required to make a decision on ethical approval to a research proposal.

1.4.5. Criteria for Selection of IEC-TODC members:

1.4.5.1. Chairperson:

- Should be from outside the institution.
- Should have a minimum of three years' experience as a member of an IEC.
- Should have undergone training in "Good Clinical Practice" (GCP) and "guidelines for conducting biomedical research on human beings."
- Should not have any known record of professional misconduct.

1.4.5.2. Member Secretary:

- A senior faculty from the institution with a postgraduate degree, and with a minimum experience of five years in the institution.
- Should have undergone training in "Good Clinical Practice" (GCP) and "guidelines for conducting biomedical research on human beings."
- Should have a minimum of two years' experience as a member of an Institutional Ethics Committee.
- Should have worked as a convener/member of any committees/core teams of the Institution.
- Should have good communication skills.
- Should not have any known record of professional misconduct.

1.4.5.3. 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.
- The basic medical scientists and clinicians should have post graduate qualifications.
- The Lay Person should not have any graduate or post graduate qualification in any science discipline. He/she is a literate person from the public or community. He/she is aware of the local language, cultural and moral values of the community.
- The legal expert should have a basic degree in law from a recognized university with a minimum experience of three years in the legal field.
- The social scientist is someone expert in the study of human society and its personal relationship like anthropologist, scientist and penologist. He/she also may be a representative of a non-governmental organization.
- A newly appointed member who has not undergone any training in ethics/good clinical practice /ethical guidelines of biomedical research on human beings does not have the voting rights. He/she has to undergo training within six months of the appointment. The member gets the voting rights once he/she undergoes training.

1.4.6. Requirements from Members when they give consent to be the members of IEC-TODC**:** The secretariat should collect a copy of recent curriculum vitae from all the members. The copies of degree certificates and medical council registration certificates should be collected from medical members of committee. In addition, certificates of training if any, in research methodology/ethics in clinical research/good clinical practice/Guidelines for biomedical research on human beings should be collected and filed in the IEC office.

1.4.7. Consent Letter and Confidentiality agreement from Members: (refer annexure 3.5.7)

- When the members agree to be part of IEC-TODC, they need to sign a consent letter in which they declare their commitment for all activities of the committee, and maintaining confidentiality of activities and documents of IEC-TODC.
- The staff of secretariat of IEC-TODC has to sign an agreement of maintaining confidentiality.
- Chairperson of IEC-TODC will sign on all the confidentiality forms of members and secretariat staff.

1.4.8. Tenure of Membership: The tenure of membership will be for a continuous period of 3 years from the date of appointment.

1.4.9. Appointment of New Members: New members will be appointed under following circumstances: (refer annexures 3.5.1-3.5.6)

- When a regular member completes his/her tenure.
- If a regular member resigns before the completion of the term.
- If a regular member ceases to be a member due to any reason such as death or disqualification.
- To fulfil the membership requirements as per SOP/guidelines/regulations.

The new member will be identified by the Chairperson based on the membership requirements after discussion by the IEC. The name of new member to be appointed may be suggested by members of IEC. Chairperson sends the proposal to head of the institution. The final decision on appointment is taken by head of the institution.

1.4.10. Continuation of Membership after the Tenure:

The tenure of the members in the IEC-TODC is three years. The decision on continuation of a member will be taken by the Dean of TODC. The Dean may take suggestions from the Chairperson and the Member Secretary. However, the final decision is taken by the Dean. The Dean will communicate to those who are replaced, acknowledging their service and contribution to the ethics committee. For the Chairperson and the Member Secretary replacements, same procedure will be followed. The Chairperson and Member secretary could get a second term after completion of the tenure. The Chairperson and Member Secretary can have maximum two consecutive terms. The Dean will send an appointment proposal letter to the members who will

replace existing members and also to the existing members who are going to continue. After obtaining consent, final appointment letter will be issued.

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

- Members must submit a recent, signed CV.
- Members must submit training certificates in ethics and GCP (if available during induction)
- Members should be ready to undergo training in ethical guidelines and GCP and submit the training certificates to the Member Secretary, IEC-TODC.
- Members must be willing to publicize his/her full name and affiliation.
- Members should sign the confidentiality agreement, and maintain confidentiality regarding documents, discussions, and related matters of IEC-TODC.

1.4.12. Termination of Membership: This refers to termination from membership even before the member completes his/her tenure. Reasons for termination may be resignation of the member from the IEC-TODC, resignation of the member from the institution, death of the member or disqualification of the member.

1.4.13. Voluntary termination: It is due to resignation of the member. The resignation has to be submitted in writing to Chairperson, IEC-TODC. One-month prior notice is necessary for the resignation. It will be effective from the date of acceptance by the Chairperson.

For affiliated members: If a member resigns from the institution, even if he/she does not submit resignation to IEC-TODC, the membership to IEC-TODC stands automatically cancelled. This termination is effective once the member is relieved from the institution.

1.4.14.Disqualification:

A member is disqualified from membership under following circumstances:

A) Misconduct:

- If the Chairperson or the Member Secretary receives a communication in writing from public /investigators/ another member of IEC regarding misconduct of the member
- If the Chairperson observes/gets information on any type of professional /ethical misconduct (not maintaining confidentiality /not declaring of conflict of interest/any type of bias towards research studies/investigators, reviewed by IEC-TODC)

- Action to be taken: The Chairperson satisfies himself/herself that prima facie a case exists before initiating any action. If in the opinion of the Chairperson, the matter of significance and integrity of the IEC could be questioned, he/she will first keep the member under suspension till the final decision is taken. During the period of suspension, the member will not have any voting rights, privileges and will not perform any duties of a member of IEC-TODC.

The Chairperson will call for a meeting of IEC-TODC, following the usual rules of quorum. The suspended member will be given sufficient opportunity to defend himself/herself in the meeting. The decision will be taken by consensus.

B) Disqualification due to continuous absence: a member will be disqualified if he/she does not attend more than three consecutive meetings of IEC. If the member has given a prior intimation to Chairperson/member Secretary about the absence, the member will be given an opportunity to continue with the membership. This member will be issued a warning from Chairperson. However, the membership will cease if this habit repeats once again.

In case of absence without intimation for more than three consecutive meetings of IEC-TODC, the member is liable for disqualification. The member will be issued a one-month notice by the Chairperson seeking explanation for the absence. If the member gives satisfactory explanation for the continued absence and assures attendance for future meetings, the Chairperson may decide on continuation of the membership. In the absence of any reply from the member, the Chairperson will discuss the matter of disqualification of membership in the meeting of IEC-TODC. Final decision on disqualification is taken by the Chairperson. In all the above cases of disqualification, the Chairperson communicates to the Dean, TODC in writing. The decision of disqualification is communicated to the member by the Dean.

1.4.15. Roles and Responsibilities of Chairperson of IEC-TODC:

- To conduct meetings and to be accountable for efficient functioning of the committee
- To ensure active participation of all members in all discussions and deliberations
- Seek conflict of interest from members and ensure quorum and fair decision making

- Handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data
- To ratify the minutes of previous meetings
- To review serious adverse events with causality assessment
- Is the final authority of IEC-TODC to take any decision on disqualification of members and recommend to the head of the institution for termination of the member.
- Is the approval authority for SOPs of IEC-TODC
- Is responsible for making any communications on behalf of the IEC-TODC to Head of the institution, CDSCO/DCGI and any other regulatory bodies

1.4.16. Roles and Responsibilities of Member Secretary of IEC-TODC:

- To organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- To schedule IEC meetings, prepare the agenda and minutes
- To organize IEC documentation, communication and archival
- To arrange for training of IEC secretariat and members
- To ensure that SOPs are updated as and when required
- To ensure adherence of IEC functioning as per SOPs
- To prepare for and respond to audits and inspections
- To ensure completeness of documentation at the time of receipt of protocols, and timely inclusion in the agenda for IEC review
- To assess the need for exemption from review, expedited review or full review. (refer 8.5, SOP-5).

1.4.17. Roles and Responsibilities of Members of IEC-TODC (In General for all Members):

- All members are expected to review the research proposals and attend the ethics committee meetings, and participate in the discussions and deliberations
- To review the revised submissions, additional submissions, progress reports and final reports
- To review the reports of serious adverse events, and recommend appropriate actions
- To carry out monitoring visits at study sites as and when needed

- To maintain confidentiality of the documents and deliberations of ethics committee meetings
- To declare conflict of interest if any, to the Chairperson
- To participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

1.4.18. Roles and Responsibilities of Basic Medical Scientist: Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology statistics, continuing review process, serious adverse events, progress report and final report.

1.4.19. Roles and Responsibilities of Clinician:

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol, serious adverse events, progress report and final report.
- Thorough review of protocol, investigator's brochure and other protocol related documents

1.4.20. Roles and Responsibilities of Lay Person:

- Ethical review of the proposal, informed consent documents along with translations
- Evaluate benefits and risks from the participant's perspective, and opine whether benefits justify the risks
- Serve as a patient /participant/community representative and bring in ethical and societal concerns

1.4.21. Roles and Responsibilities of Legal Expert:

- Ethical review of the proposals, informed consent documents along with translations, MOU, compensation proposals, other site approvals, investigator's undertaking, and protocol-specific other permissions.
- Interpret and inform members about new regulations if any.

1.4.22. Roles and Responsibilities of Social Scientist:

- Ethical review of the proposals, informed consent documents along with translations
- Assess impact on community involvement, socio-cultural context
- Serve as representative of community/society and bring in ethical and societal concerns

1.4.23. Secretariat of IEC-TODC**:** Secretariat is composed of the clerical staff and attenders of TODC. Secretariat will assist the Member Secretary and joint Secretary in all their functions. The clerical staff are involved in receiving the proposals, preparing the communication letters, approval letters, and any other typing work assigned by Member Secretary and Chairperson. They are also involved in typing agenda for the meeting, typing the proceedings of meetings, and preparation for the meetings. Attenders are involved in distribution of research proposals to members for review and physical arrangements for the meetings.

1.4.24. Payment of Remuneration to IEC-TODC **Members**: The IEC-TODC members are paid honorarium for attending meeting of IEC. The remuneration is decided by the head of the institution while appointing the members. In addition, the institution may sponsor the members to attend trainings on ethical guidelines and GCP.

1.5. Annexure for SOP-1

Annexure -1.5.1.

Appointment Proposal Letter

To: Dr./Mr/Ms. ----------

Address: ----------

Sub: Reconstitution of IEC-TODC

Dear Sir /Madam,

The IEC-TODC has completed tenure of two years. I acknowledge your services and contribution as a member of IEC-TODC for the last two years. As a part of the reconstitution of IEC-TODC, I request you to the member/Member Secretary/Chairperson of IEC-TODC for the next three years, effective from ----------. A detailed appointment letter will be issued once I receive acceptance letter from you. I request you to submit your recently updated, signed CV along with certificates of training on GCP, Bioethics and guidelines on biomedical and health science research.

With Regards,

Dean,

The Oxford Dental College, Bangalore.

Annexure 1.5.2. INSTITUTIONAL ETHICS COMMITTEE THE OXFORD DENTAL COLLEGE (IEC-TODC) ACCEPTANCE OF APPOINTMENT AS A MEMBER OF IEC-TODC

To :

The Dean,

The Oxford Dental College, Bangalore.

Dear Sir,

Sub : Acceptance of Appointment as a Member of IEC-TODC

Ref : Your Proposal Letter No. ----------, Dated. ---------- I am thankful to you for appointing me as a member of IEC-TODC with effect from_____. I herewith accept my appointment. I am ready to undergo regular training on good clinical practice, ethical guidelines on biomedical and health science research and bioethics as required. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain the entire research project related information confidential. I shall sign the confidentiality agreement, and shall declare conflict of interest if any as and when applicable I am submitting my recently updated, signed CV and certificates of training as requested by you.

Thanking You,

Yours Sincerely,

Signature :

Name :

Designation and Department/Affiliations:

Date :

Place

Annexure 1.5.3. Appointment Letter for Member of IEC TODC

To : ----------

Sub : Appointment as member of Father Muller Institutional Ethics Committee. Category : Basic Medical Scientist/Clinician/Theologian/Social Scientist/Lay Person/ Legal Expert

Dear Sir/ Madam,

I am pleased to select you as a member of Institutional ethics Committee-The Oxford dental College (IEC-TODC) with effect from ----------. As a member of the committee, you will have tenure of two years. You will be receiving an honorarium of Rs. ---------- per sitting for the services rendered by you. I request you to kindly extend your co operation to the Chairperson and Member Secretary of IEC-TODC, in effective and efficient functioning of IEC-TODC. Please find the enclosed terms and conditions of your appointment, roles and responsibilities. You will be issued a copy of the policies and standard operating procedures of IEC-TODC once you sign the consent letter and confidentiality agreement . You will have the voting rights in the IEC only after you receive the initial training on policies and standard operating procedures.

Congratulations and all the best.

With Regards,

Dean,

The Oxford Dental College, Bangalore.

Annexure 1.5.4

Terms and Conditions of appointment, and Roles and Responsibilities of Member, IEC-TODC

1) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IEC-TODC

2) You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain

3) Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings

4) To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and initial review and final review of research proposals .

5) As a member of IEC-TODC you need to do initial review, final review of research proposals and evaluate progress reports and final reports . You need to participate in onsite monitoring visits and review of serious adverse events as and when required. You are required to attend regular as well as emergency meetings of IEC-TODC. You are expected to participate actively in all discussions and deliberations of IEC-TODC.

6) You shall not keep any literature or study related documents with you after the discussion and final review

7) Willing to undergo training or update programmes on relevant guidelines and regulations, research ethics ,and good clinical practice during the tenure as ethics committee member

8) As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.

9) One month notice on either side will be necessary prior to resignation/termination of appointment.

The Details of the roles and responsibilities of a member of IEC-TODC are mentioned in the policies and standard operating procedures of IEC-TODC.

Annexure 1.5.5.

Institutional Ethics Committee-The Oxford Dental College (IEC-TODC)

Appointment Letter : Chairperson

To : ----------

Sub : Appointment as Chairperson of IEC-TODC Dear Sir/Madam, I am pleased to appoint you as the Chairperson of IEC-TODC with effect from ----------. You will have a tenure of two years from the date of appointment. As head of the institution, I assure you that IEC-TODC will be provided with all required infrastructure and facilities required for its effective functioning. The ethics committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution. You will be receiving an honorarium of Rs. ----------per sitting for the services rendered by you. Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of IEC-TODC. Congratulations and all the best.

With Regards,
Dean,
The Oxford Dental College, Bangalore.

Annexure 1.5.6
Institutional Ethics Committee-The Oxford Dental College (IEC-TODC)
Appointment Letter : Member Secretary

To : ----------

Sub : Appointment as Member Secretary of IEC-TODC
Dear Sir/Madam,
I am pleased to appoint you as the Member Secretary of IEC-TODC with effect from ----------
You will have a tenure of two years from the date of appointment. As head of the institution, I assure you that IEC-TODC will be provided with all required infrastructure and facilities required for its effective functioning. The ethics committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution. You will be receiving an honorarium of Rs. ----------per sitting for the services rendered by you. Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of IEC-TODC.
Congratulations and all the best.
With Regards,
Dean,
The Oxford Dental College, Bangalore.

Annexure 1.5.7
Institutional Ethics Committee-The Oxford Dental College (IEC-TODC)
Consent Letter from Appointed Members

To :

Dean,
The Oxford Dental College, Bangalore.

Sub : Consent to be the Chairperson /Member Secretary/Member of IEC-TODC.

Ref : Your letter No.----------; Dated ---------- Dear Sir/Madam, In response to your letter, I give my consent to be the Chairperson/Vice Chairperson/Member Secretary/Member of Institutional Ethics Committee- The Oxford Dental College. I shall execute my roles and responsibilities as per the policies and standard operating procedures of **IEC-TODC**, and as mentioned in my appointment order. I shall maintain high ethical standards, and will not be unduly influenced in discharging my assigned work. I will sign the confidentiality agreement during my induction. I am aware of the conflict of interest policy of **IEC-TODC**, and I will declare conflict of interest (if any) during my induction as a member, review of research proposals and decision making in **IEC-TODC**.

Thanking You,

Yours Sincerely, Signature :

Name :

Designation and Department/Affiliations:

Date :

Place :

Annexure- 1.5.8: Confidentiality Agreement to be Signed By Member of IEC-TODC in recognition of the fact, that I, _____ *(Member's name, his/her position on* **IEC-TODC** *and affiliation)* herein referred to as the "undersigned", have been appointed as a member of the IEC-TODC 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 neither 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-TODC**. All Confidential information (and any copies and notes thereof) shall remain the sole property of the**IEC-TODC**. 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-TODC**. *A copy will be given to the Undersigned.]* I acknowledge that I have received a copy of this Agreement signed by the **IEC-TODC** Chairperson and me.

Signature and Date

SOP-2: THE TERMS OF REFERENCE OF THE COMMITTEE.

2.1 SOP-1: Constitution of IEC: Selection, Roles and Responsibilities of Members of IEC-TODC for details of member recruitment and termination (Refer 1.4.1.-1.4.24)

2.1.1 SOP-1.1-Criteria for Selection of IEC-TODC members (Refer 3.1-3.7)

2.1.2 SOP-1.2- Procedure for removal, resignation or replacement of members of IEC-TODC (Refer 4.1-4.3)

2.2. SOP-2: Standard Operating Procedures ofIEC-TODC (Refer 3.1-8.1.4.12).

2.3. SOP-3: Handling conflict of interest among Ethics Committee members

{Refer SOP-3: Handling conflict of interest (COI) among Ethics Committee members (8.1-8.5)}

2.4.SOP-4: Submission of Documents to IEC-TODC and Management of Submitted Documents

2.4.1. Purpose: This SOP describes the guidelines for submission of protocols to IEC-TODC and how the secretariat manages the submitted protocols

2.4.2. Scope:

The Scope this SOP includes:

1. Submission of Research Project and related documents for Initial Review of the Protocol.
2. Resubmission of Protocols or Research Projects with corrections.
3. Submissions of written communications related to the protocol.

2.4.3. Responsibility: It is the responsibility of the Principal Investigators to submit the protocols as per the guidelines of IEC-TODC. It is the responsibility of IEC Secretariat to receive and record the received protocols. and any other documents for review. The Member Secretary is responsible for scrutinizing the received documents.

2.4.4. Procedure:

2.4.5.1. Documents to be Submitted by the Principal Investigator:

2.4.5.1.1. Time Line: The Principal Investigator should submit the research proposals to the Secretariat of IEC-TODC as per the following time line:

1) New Proposals for Initial Review/ Re-submission of Protocols with Corrections/Amended Protocols and related documents: should be submitted at least 10 days prior to the scheduled meeting of IEC-TODC.

2) Submission of Serious Adverse Events (SAE): As per the timelines stated in the SOP for initial and detailed reporting of SAE.

3) All other documents for consideration at the full board meeting.

2.4.5.1.2 The following documents shall be submitted to the secretary of the ethics committee.

Essential Documents:

1) Covering letter to the Member Secretary

2) Project submission application form for initial review.

3) The correct version of the research proposal: 2 sets of hard copies and one soft copy.

4) Patient information leaflet in English and Kannada

5) Informed consent form or waiver of consent form.

2.4.5.2. Management of Protocols:

2.4.5.2.1. Initial Verification and Assigning Protocol Number:

1. The proposals are verified for the completeness If there are any deficiencies the proposals will be returned to the investigator for resubmission

2. Once a protocol is deemed to be complete in all respects the IEC-TODC secretariat will issue a protocol number. The No. will be in this format: IEC-TODC/CATEGORY/PROTOCOL NO./YEAR.

3. All PG dissertations, PhD theses, staff projects and other academic projects will be included for protocol evaluation.

4. The IEC-TODC secretary will screen the proposals and depending on the risk involved categorizes them into types namely, exemption from review, expedited review and full committee review (refer 8.5, SOP-5).

5. The investigator is informed by email and a notice will be displayed in the college circular notice board about the presentation date and time.

2.4.5.2.2. Transmission and Storage of Documents:

1. The clerk will make a photocopy of the completed document receipt form and return the original copy to the applicants for their records.

2. The hard copies of proposals categorized for full committee review will be sent to all members of IEC-TODC at least 1 week prior to the meeting. The soft copies of all protocols {full and expedited review [refer 8.5, SOP-5] will be sent by email to those members who have opted for the electronic version.

3. The proposals categorised as exempt review will be cleared by the Member Secretary at the earliest and the decision will be communicated to the investigators.

4. A progression and completion report of the research work have to be collected from the students will be collected annually.

5. All the protocols and the submission file will be categorised as regulatory trials/academic projects/other projects and archived in a designated storage area.

2.4.5.3. Resubmission of Protocols with corrections and Amendments of protocol/ related documents:

1. For resubmitted protocol, the PI will submit one soft copy and one hard copy of the amended Protocol and related documents.

2. The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment.

3. The protocol related documents which do not require to be changed and are already submitted for the IEC office during initial review are not required to be submitted again.

4. The Member Secretary (MS) will decide a. if it is a resubmitted protocol it will follow all steps of: categorization as full review/expedited review and initial review (refer 8.5, SOP-5). All the steps followed for a new submission will be followed for the resubmitted protocol. b. if it is a resubmitted protocol based on query response, the Member Secretary will handle it as decided in the meeting (e.g. Carry out review by one or more members selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol or keep on full board agenda).

2.5. Review procedures

2.5.1. Purpose : The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review into full board / expedited review or exemption from review process.

2.5.2. Scope : This SOP covers the process of categorization of new research study protocols submitted to Institutional Ethics Committee (IEC) for initial review.

2.5.3. Responsibility: The Member Secretary is responsible for categorizing the protocols for review as full review, expedited review and exempted from review. The suggestions/guidance of the Chairperson is taken whenever necessary. It is the responsibility of the members of IEC-TODC to do the review as per the guidelines.

2.5.4. Procedure :

2.5.4.1. Exemption from Review: Proposals that are exempted from review include those with less than minimal risk where there are no linked identifiers. This could be seen in following situations –

i) Research conducted on data that is in the public domain for systematic reviews or meta-analysis.

ii) In-vitro studies that involve little or no use of tissues (such as teeth) obtained from patient.

iii) In-vitro studies that involve dental materials with no patient involvement with/without the use of simulation software such as finite element analyses.

iv) Case reports: IEC-TODC issues ethical clearance to case reports for presentation /publication on receiving and verifying informed consent from the patient, abstract of the case report and findings. Wherever possible patient identity must be masked in the photographs used in case reports. The Member Secretary may ask for a copy of the informed consent form signed by the patient whenever the identity of the patient is not masked. Member Secretary will go through (screening for documents to be submitted to IEC) the proposals which are exempted from review, and get the decision ratified in the full committee meeting.

Exceptions: when research on educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm; when interviews involve direct approach or access to private papers.

2.5.4.2. Expedited Review: The proposals that pose "no more than minimal risk" are considered for expedited review. Expedited review will be conducted by chairperson, member secretary and 1-2 designated members. The approval granted through expedited review will be ratified at the next full committee meeting. In following situations, expedited review will be done:

- Minor deviations from originally approved protocols (originally approved through full review by the IEC).

- Revised proposal previously approved through full review or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples.
- Research involving clinical documentation materials which are non-identifiable (data, documents, records).
- Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigators.
- Revised proposal previously approved through expedited review, full review or continuing review of approved proposals.
- Minor deviations from originally approved research causing no risk or minimal risk.
- Progress/annual reports where there is no additional risk e.g. activity limited to data analysis.
- When in emergency situations like serious outbreaks or disasters a full review is not possible, prior written permission may be taken before use of test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention. Same participants should not be included in the clinical trial that may be initiated based on the findings of the pilot study.

2.5.4.3. Full Review: All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review

- All studies involving interventions (clinical trials) involving trials on new drugs, materials or combinations of drugs, materials.
- Studies involving vulnerable population even if the risk is minimal.
- Collection of blood samples by finger prick, heel prick, ear prick or venipuncture.
- Collection of biological specimens by research purposes by non-invasive means – skin appendages, dental procedures, external secretions, stimulated or unstimulated saliva collection, buccal scrapings, skin swab or mouth washings, sputum.

- Use of medical devices for study population such as implants and physical sensors.

2.5.5. Aspects Considered During Review of Research Proposal:

1) **Scientific design and conduct of the study**: Use of valid scientific methods
2) **Social Values**: The research must have anticipated social value, and outcome should be relevant to the health problems of the society.
3) **Benefit-Risk Assessment**: The benefits must justify the risk inherent in the research. Risks may be physical, psychological, economic, or social; Withdrawal criteria, and rescue medication or procedures.
4) **Selection of the Study Population and Recruitment of Research Participants** : To ensure voluntary recruitment, and fair selection of participants as per inclusion and exclusion criteria; participant is given option to opt out without the routine care being affected; No individuals or group of persons must bear the burdens of participation in research without any benefits except in studies where healthy volunteers are involved; Vulnerable group is not recruited unless proper justification is provided.
5) **Payment of participation** and Compensation Procedures, without inducement but, reimbursing for incurred cost and convenience.
6) **Protection of research participant**'s privacy and confidentiality.
7) **Community considerations**: due respect given to community and interests are protected; no stigma or discrimination ensues from the proposed research; plans for communication of results back to the community at the end of study; plan for dissemination of benefits of research to the community.
8) **Qualifications of investigators** and assess adequacy of study sites.
9) **Disclosure of potential conflicts of interest**
10) **Review of informed consent process**

The review of proposals by members is documented in review forms, and in the minutes of meetings of the IEC-TODC.

2.6. Agenda preparation, conduct of meeting and minutes of meetings

2.6.1. Purpose: The purpose of this SOP is to describe the preparation of agenda, distribution of agenda, preparation for meeting, conducting the meeting and preparing minutes of meetings of IEC-TODC.

2.6.2. Scope: This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all IEC meetings.

2.6.3. Responsibility: The Member secretary is responsible for preparation of the agenda, recording the minutes of meeting and circulation of the minutes to all members of IEC-TODC. The Chairman conducts the meetings of IEC-TODC, and approves the minutes of meeting.

2.6.4. Procedure:

2.6.4.1. The meeting schedule: The IEC-TODC meeting is held twice a year on a pre-assigned date agreed upon by all members. Frequency of the meeting is increased depending on the number of research proposals for full review.

2.6.4.2. Preparation of Agenda:

2.6.4.2.1. The research proposals received by the IEC-TODC are categorized for review as: exempted from review, expedited review and full review (refer 8.5, SOP-5). This is done by the Member Secretary who will do the initial scrutiny of the research proposals. The review is done only for the proposals categorized for expedited and full review. The expedited review will be done by the Chairperson, the Member Secretary and one member of IEC-TODC. The full review will be done by all members of IEC-TODC.

2.6.4.2.2. The research proposals categorized for full review will be included in the agenda for presentation during the meeting of IEC-TODC. The expedited reviews and exempted from review are included for ratification by all members in the meeting.

2.6.4.2.3. The agenda includes: quorum of previous meeting (list of members present and absent), ratification of the minutes of previous meeting, presentation of the research proposals (full review) by the principal investigators, ratification of the expedited reviews, presentation of the proposals categorized under "exempted from review" by the Member Secretary, and any other issues as recommended by the members and approved by the Chairperson. Other issues could be report of onsite monitoring, training needs, accreditation of ethics committee, serious adverse events, review of protocol deviations/amendments, continuing review of research studies, completion reports of research studies, revision of SOPs, changes in the committee composition, report of subcommittees appointed by the Chairperson (if any) and emergency concerns.

2.6.4.2.4. If any member is unable to attend the meeting, he/she should inform the Chairperson (through the Member Secretary) well in advance. (Preferably one week before the scheduled date of meeting). The leave should be requested in a written leave letter in emergency

situations if the member is not able to inform in advance, e mail communication could be done. If the Chairperson is unable to attend the meeting, he/she will inform the Member Secretary, and ask him to conduct the meeting with the Vice Chairperson as the acting Chairperson for the meeting.

2.6.4.2.5. All regular members of IEC-TODC, independent consultants and principal investigators of research proposals categorized for full review are required to attend the meeting. If any member is unable to attend the meeting, they need to inform the Chairperson or Member Secretary by any means of communication. Independent consultants chosen for full review are intimated to attend the meeting during the presentation of those research proposals which they have reviewed.

2.6.4.2.6. The principal investigator should attend the meeting and present the proposal. Co investigators are allowed to attend the meeting.

2.6.4.3. Conduct of Meeting:

2.6.4.3.1. The IEC-TODC full board meeting will be held as per the schedule provided there is quorum as per requirement

2.6.4.3.2. There should be the presence of at least 6 members out of the total 10 members of the committee to constitute quorum.

2.6.4.3.3. Besides the Chairperson and the Member Secretary the quorum will consist of One basic medical scientist One social worker (or a social scientist, theologian, ethicist, philosopher, member or representative of a non-governmental voluntary agency or a similar person), A clinician, A lay person from the community and A legal expert

2.6.4.3.4. The signature of all members who attended the meeting will be taken on the attendance sheet

2.6.4.3.5. Guests or observers may be allowed in the meeting provided they have taken prior permission, and signed confidentiality agreement

2.6.4.3.6. The Chairperson initiates the meeting after ensuring quorum. The Chairperson ensures the quorum for every clinical trial presentation in the meeting.

2.6.4.3.7. The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict. The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict prior to the start of the meeting.

2.6.4.3.8. If a conflict of interest has been declared by a member, the Chairperson will ask the member concerned to leave the meeting room when the concerned issue is being discussed.

2.6.4.3.9. The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.

2.6.4.3.10. The Member Secretary will present the agenda of the day's meeting for discussion.

2.6.4.3.11. The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.

2.6.4.3.12. The Principal Investigators are asked to present the research proposals as per the order of proposals mentioned in the agenda. When one investigator is presenting the proposal, investigators of other research proposals should not be present in the meeting room. However, co investigators of the same research proposal (or guides in case of postgraduate dissertations) are allowed to be in the meeting room. In case of informed absence of principal investigator, co-investigator may be allowed to make the presentation. However, if the members feel that co-investigator is not familiar with the protocol details, the principal investigator may be asked to attend the next meeting of IEC for the presentation.

2.6.4.3.13. The members of IEC-TODC should not discuss on the decisions about the research proposals when the investigators are inside the meeting room. The members should discuss only after the investigator leaves the meeting room.

2.6.4.3.14. For other matters in the agenda (other than full review), the member secretary will present the review findings (expedited review), list of proposals under exempted from review, protocol deviations/amendments, etc.

2.6.4.3.15. Reports of any subcommittees will be presented in the meeting by the heads of respective committees, as per the agenda

2.6.4.3.16. The proceedings of the meeting will be recorded by the Member Secretary. If the Member Secretary has conflict of interest in any research proposal, the joint secretary will do this job.

2.6.4.4. Decision Making:

2.6.4.4.1. The final decision on approval of a research proposal is by consensus... In the review forms, the members need to tick one of the following:

1) Approved 2) Approved with suggestions

3) Resubmit with revisions 4) Rejected

In the "Suggestions" of section of the form, member can write down his/her suggestions of any and points to be considered for revision of the research proposal. Reasons for rejecting the proposal also should be mentioned in this section of review form. Final decision is taken by consensus. The Chairperson ensures participation of all members in the deliberations. The decisions are based on risk assessment, scientific validity, and adherence to ethical principles for the initial and periodic approvals.

2.6.4.4.2. The independent consultants called to the meeting will be present only for the presentation of the concerned research proposal. He/she will give the opinion during the meeting and will leave the meeting room. They don't have any voting rights.

2.6.4.5. Minutes of the Meeting:

2.6.4.5.1. The minutes of the meeting are prepared by the member secretary on summarizing the discussions held in the meeting and decision taken by consensus.

2.6.4.5.2. Following are the contents of the minutes of meeting:

1) Date, time and venue of the meeting.

2) List of members who attended and who were absent for the meeting.

3) List of guests/observers (if any) who attended the meeting.

4) Name of the individual who served as chairman for the meeting.

5) Ensuring of quorum by the chairman.

6) Ratification of minutes of the previous meeting: to be mentioned.

7) Research proposals for full review: summary of discussions and approval status.

8) Research proposals for expedited review: summary of discussions and approval status.

9) Research proposals exempted from review: list of the proposals.

10) Discussion of protocol deviations/amendments, with actions taken.

11) Discussion of onsite monitoring visits if any, with actions taken.

12) Discussion of progress reports and final reports if any, with actions taken.

2.6.4.5.3. The minutes are prepared within 3 working days of the meeting day.

2.6.4.5.4. The minutes are sent to all members of the committee by e mail and their inputs are taken. The Chairperson gives the final approval for the minutes.

2.6.4.5.5. The minutes are presented in the next meeting for ratification.

2.6.4.6. Communication of the Decision to Investigators:

2.6.4.6.1. The decision of the IEC is communicated to the principal investigators. All communications are done by the member secretary (or joint secretary in his absence).

2.6.4.6.2. The communication of the decision will include:

1) Name and address of IEC.

2) The date and place of the decision.

3) The name and designation of the investigators.

4) Protocol no. given by the IEC.

5) Title of the research proposal reviewed.

6) Version No., date, amendment no. of the protocol (for clinical trials).

7) List of documents reviewed (for clinical trials)-clear description of these documents along with version No., and date.

8) List of IEC members who attended the meeting-clear description of their role and affiliation.

9) A clear statement of the decision reached.

10) Any advice by the IEC to the applicant including the schedule /plan of ongoing review by the IEC-TODC.

11) In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

12) In case of rejection, reasons for rejection will be clearly stated.

13) Signature of the member secretary with date.

2.6.4.6.3. The investigator is asked to register the study in Clinical Trial Registry of India (CTRI). Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies as well as trials being conducted in the purview of the department of AYUSH are expected to register the trial in the CTRI before enrolment of the first participant.

2.6.4.7. Validity of Approval: Though the approval is granted for the entire duration of the study, the validity of the approval letter is only up to one year. Depending on the risk involved, the progress of the project will be monitored annually. The approval will be continued if progress is satisfactory. The decision of IEC may be reversed if IEC receives information that may adversely affect the benefit/risk assessment.

2.6.4.8. Calling an Emergency Meeting of IEC-TODC:

2.6.4.8.1. The Member Secretary in consultation with the Chairperson may call for an emergency meeting on following occasions: 1) Urgent issues which if not discussed and decided may have adverse impact on patient safety 2) Serious adverse events 3) Other issues deemed appropriate by the Chairperson or the Member Secretary.

2.6.4.8.2. The Secretariat will endeavour to contact each and every IEC member and inform him/her about the date, time and venue of the meeting as well as the reason for calling for the meeting.

2.6.4.8.3. The documents for discussion in emergency will be sent by e mail. The notice of this meeting may be sent at least one day in an advance.

2.6.4.8.4. The rules of quorum will be applicable. If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (at least one scientific and one non-scientific member) are present, given the urgency of the matter under consideration. The IEC members will act according to the relevant IEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

2.6.4.8.5. Calling additional meetings of IEC-TODC: The Member Secretary in consultation with the Chairperson can call for additional meetings depending on the requirement. These are the meetings other than emergency meetings. Additional meetings are called if the number of research proposals for full review are more than 15, and if the IEC-TODC is not able to include discussion of issues such as progress reports, onsite monitoring, study completion reports, etc.. in the half-yearly meeting due to constraint of time. The procedure for agenda, conduct and minutes is the same as that followed for the usual meetings.

Annexure-2.7: Format for Minutes of meeting:

Date and Time of meeting:

- Members present and absent: list with designations
- Guests or observers present: list with designations
- Name of the individual who served as Chairperson:
- Ensuring of quorum by the Chairperson:
- Ratification of the minutes of the previous meeting:
- Research proposals for full review:

Protocol No.	Title of the Study	Name of the Principal Investigator	Remarks by the members (opinion/suggestion/other remarks)	Approval status

VII. Research Proposals for expedited review:

Protocol No.	Title of the Study	Name of the Principal Investigator	Names of the members who did the expedited review, with remarks	Approval status

VIII. Research Proposals exempted from review:

Protocol No.	Title of the Study	Name of the Principal Investigator	New/Revised Submission	Approval status

IX. Discussion of Progress Reports and Study Completion Reports:

Protocol No.	Title of the Study	Name of the Principal Investigator	Remarks on the report submitted	Action taken as per the requirement

2.8. Selection of Independent Consultants

2.8.1Purpose: The purpose of this SOP is to define and describe the terms of reference, which provide the framework for constitution, selection, roles and responsibilities of independent consultants, and the procedure for maintaining confidentiality of all activities and documents.

2.8.2. Scope: This SOP is applicable to appointment of independent consultants of IEC-TODC; defining their roles and responsibilities

2.8.3. Responsibility: The appointment of the members of subject expert panel (panel of independent consultants) for IEC-TODC will be done by the Head of the Institution. The independent consultants need to maintain confidentiality of the reviews, meetings and documents.

2.8.4. Procedure:

2.8.4.1. Appointment:

2.8.4.1.1. The Chairperson and the Member Secretary place a proposal to the Dean, TODC for appointing independent consultants. Independent consultants are experts from various subjects for which experts are not available among regular members of TODC. The consultants could be affiliated or non-affiliated to TODC. The Dean of TODC appoints independent consultants.

2.8.4.1.2. The Dean communicates to the consultants a proposal of appointment. The consultant will confirm their acceptance to the Dean/Principal by providing all required information such as curriculum vitae, and certificates of training on research ethics and good clinical practice. The consent letter includes consent from the member, declaration of maintaining confidentiality of research project- related data/documents/discussions, and willingness to get updated on research ethics, good clinical practice and regulations on human research. On receiving this consent, Dean will issue the final appointment order. The list of independent consultants is maintained in the office of IEC-TODC.

2.8.4.2. Tenure: The tenure of appointment of an independent consultant is 3 years.

2.8.4.3. Consulting an Independent Consultant for Review:

The Member Secretary in consultation with the Chairperson decides on sending a research proposal for review depending on the requirement. The requirements are as follows:

1) If the research is from a specialty for which experts are not available in the IEC-TODC, and there is need for expert opinion. The subject experts could be affiliated or non-affiliated. Preferably, subject non-affiliated experts are invited to review to avoid any bias or conflict of interest. The suggestion for requirement of expert may also come from the Chairperson or any member of IEC-TODC who feels the necessity during review process.

2) The Member Secretary requests the independent consultant to review the research proposal (expedited/full review as required). The review form and proposal copy along with all enclosed documents (budget form, questionnaire, proforma, informed consent documents, etc..). For the expedited review, the consultant is requested to do the review and submit the filled review form to the ethics committee secretariat within one week. This review will be placed before the full committee meeting for ratification.

3) For full review, the consultant is requested to attend the meeting of IEC-TODC. He/she should be present only during the presentation of that particular proposal which was reviewed by him/her. The opinion of the consultant is taken. However, the consultant does not have voting rights.

2.8.4.4. Requirements from Independent Consultants: The secretariat should collect a copy of recent, signed curriculum vitae from the independent consultants. In addition, certificates of training if any, in research methodology/ethics in clinical research/good clinical practice/Guidelines for biomedical research on human beings should be collected and filed in the IEC office. The consultants should also sign a confidentiality agreement.

2.8.4.5. Conditions to be fulfilled by a consultant after appointment:

1) Must submit a recent, signed CV

2) Must submit training certificates in ethics and Good clinical practice (GCP) (if available during induction).

3) Members must be willing to publicize his/her full name and affiliation

4)Should sign the confidentiality agreement, and maintain confidentiality regarding documents, discussions, and related matters of IEC-TODC.

5) Should declare "conflict of interest" whenever it exists Termination of Membership:

The consultant is a member only for the review of specific research proposals. Any independent consultant found of professional conduct will be terminated from the membership.

2.9.Annexures :

Annexure-2.9.1:
Appointment Letter of Independent Consultant
To :
Dr. ----------
Dear Sir/Madam,

Sub: Proposal of Appointment as "Subject Expert" for Institutional Ethics Committee I am pleased to appoint you as a member in "The Panel of Subject Experts" of IEC-TODC.

Following are the terms and conditions of appointment:

1) You will not be a regular member of Ethics Committee

2) As a subject expert, you are required to review of research proposals pertaining to your subject/specialty area, whenever you are requested by the Member Secretary of Ethics Committee. Whenever requested, you are required to complete the review in the stipulated time of one week. Review form which is provided along with the proposal needs to be filled.

3) For the research proposals categorized under "Full Review", you have to attend the meeting of Ethics Committee along with the filled review forms. You have to be present in the meeting only for the presentation of that proposal reviewed by you. You can clarify any queries with the researcher/investigator during the meeting, and will share your opinion with the regular members of ethics committee.

4) For the research proposals categorized under "expedited review", you will not be attending the meeting. Only the filled review form has to be sent to Member Secretary of Ethics Committee.

5) You will not have any voting rights in the Ethics Committee meeting

6) You need to sign a letter of conflict of interest, and declare to maintain confidentiality of the discussions and reviews

7) You will be paid a remuneration of Rupees ---------- /proposal for the review work done

With Regards,

Dean& Director,

The Oxford Dental College & Hospital

Anenxure-2.9.2

The Oxford Dental college Institutional Ethics Committee –

Consent Letter from Appointed Member of "Subject Expert Panel"

To :

The Dean, The Oxford Dental College ,Bangalore.

Sub : Consent to be the member of Subject expert panel of The Oxford Dental college.

Ref : Appointment letter No.----------; Dated ----------

Dear Sir,

In response the appointment letter, I give my consent to be the member of The Oxford Dental college Institutional Ethics Committee "subject expert panel". As a subject expert, I shall do review of research proposals pertaining to my subject/specialty area, whenever I am requested by the Member Secretary of Ethics Committee. I shall participate in the ethics committee meetings whenever asked to do so. I shall maintain the entire research project related information confidential. I am ready to declare conflict of interest whenever I have the conflict of interest with regard to any research proposal. The research proposal-related materials given to me for review will be returned to ethics committee once I complete the review process.

Thanking You, Date :

Place :

Yours Sincerely,

Signature :

Name :

Designation and Department/Affiliations :

Anenxure-2.9.1

Confidentiality Agreement to be Signed by Independent consultant of IEC-TODC

In recognition of the fact, that I, _____

(Consultant"s *name, his/her position on IEC and affiliation)* herein referred to as the "undersigned", have been appointed as a member of the subject expert panel of IEC-TODC 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 consultant of the IEC-TODC 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 subject expert panel of IEC-TODC. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC-TODC. 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 consultant) 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-TODC. *A copy will be given to the Undersigned.]* I acknowledge that I have received a copy of this Agreement signed by the IEC-TODC Chairperson and me.

Signature

Date

2.10 Submission of Documents to IEC-TODC and Management of Submitted Documents

2.10.1. Purpose: This SOP describes the guidelines for submission of protocols to IEC-TODC and how the secretariat manages the submitted protocols

2.10.2. Scope: The Scope this SOP includes:

1. Submission of Research Project and related documents for Initial Review of the Protocol
2. Resubmission of Protocols or Research Projects with corrections
3. Submissions of written communications related to the protocol
4. Continuing Review of Approved Protocols :

a. Protocol completion/Termination

b. Protocol deviations/violation

c. SAE initial/ follow up/ final reports

d. Submission of Protocol deviations, Protocol violations

2.10.3. Responsibility: It is the responsibility of the Principal Investigators to submit the protocols as per the guidelines of IEC-TODC. It is the responsibility of IEC Secretariat to receive and record the received protocols. and any other documents for review. The Member Secretary is responsible for scrutinizing the received documents.

2.11.Procedure :

2.11.1. Documents to be Submitted by the Principal Investigator :

2.11.2.Time Line: The Principal Investigator should submit the research proposals to the Secretariat of IEC-TODC as per the following time line:

1) New Proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols and related documents: should be submitted at least 10 days prior to the scheduled meeting of IEC-TODC (second Saturday of every month).

2) Submission of SAE (On-Site): As per the timelines stated in the SOP for initial and detailed reporting of SAE.
3) All other documents for consideration at the full board meeting (except those related to participant safety, which may be submitted any time (must be submitted at least 72 hours in advance)

2.11.3. The following documents shall be submitted to the secretary of the ethics committee.

A) Essential Documents :

1) Covering letter to the Member Secretary.
2) Project submission application form for initial review (see annexure).
3) The correct version of the research proposal: 2 sets of hard copies and one soft copy.
4) Informed consent form (see annexure) in English and in a regional language.
5) Proforma for clinical data collection
6) Budget Proposal
7) Letter from the Department Head Concerned, here non routine or special tests are being done (applicable to academic studies)

B) the following additional documents are required for regulatory trials

1. Amendments to protocol (if any)
2. Informed Consent Document in Regional languages (if applicable)
3. Back translations of ICDs (if applicable)
4. Translation and Back translation certificates (if applicable)
5. Amendments to the ICD (if any)
6. Case Record Form
7. Recruitment procedures: advertisement, notices, letters to doctors (if applicable)
8. Patient instruction card, identity card, diary etc. (if applicable)
9. Investigator Brochure (if applicable)

For any queries kindly contact the Member Secretary.

Contact Address: The Oxford Dental College, 10th Milestone

Hosur Road

Bommanahalli

Bangalore 560068

Email: todciec@gmail.com

2.12. Annexure-Guidelines for Conducting Clinical Research in TODC :

2.12.1.All clinical studies should be reviewed and approved by the IEC BEFORE initiation of the study

2.12.2. No retrospective approvals will be granted

2.12.3. Studies may be considered for full board or expedited review or may be granted exemption from review depending on the risk involved.

2.12.4. It is mandatory to register regulatory clinical trials in the Clinical Trials Registry of India (ctri.nic.in).

2.12.5. he investigator team should be trained in GCP or ethics in clinical research.

2.12.6. If a clinical study is planned on an "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani etc.), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be appropriately qualified and registered with the relevant Council and he/she should not have a conflict of interest with the study, investigator or sponsor. This is in accordance with the ICMR 2017 guidelines.

2.12.7. The research study protocol should be scientific and complete with respect to the following sections:

A. Introduction with relevant literature,

B. Objectives,

C. Justification for a clinical study (demonstrate clinical equipoise) and its implications for future,

D. Detailed methodology describing

- settings of the study,
- duration of entire study and duration for participation for each individual,
- eligibility criteria (inclusion and exclusion criteria),
- sample size (number of participants that may need screening, number that is required to be completed for analysis)
- Sampling method

- Ethical aspect : A statement saying that the study will be conducted in adherence to relevant national/international laws; Placebo justification if applicable; Risk benefit assessment; Compensation for participation if applicable; Compensation for research related injury; Informed consent process, including Audiovisual recording of consent (AV consent) if applicable; Ancillary care; Choice of participants; Method of recruitment (if advertisement etc.); If vulnerable population what protections are in place; Policy regarding autonomy (voluntariness, right to withdraw); Confidentiality - Statement of Participant confidentiality; including ownership of data and coding procedures; Policy regarding dissemination of data, presentation of data, publication. vii. Description of variables, inpatient/outpatient, number of outpatient visits
- Statistics: Sample size determination, Power estimates / level of significance, Tests for comparison/ any other descriptive statistical analysis.

2.12.8. While submitting your research proposal to the IEC, ensure that you have included an informed consent document that is prepared as per guidelines in Schedule Y (2005), ICMR 2017 guidelines and ICH – GCP (1996).

2.12.9. Informed consent documents should be made in English and Kannada and other relevant regional languages

Contact Address: The Oxford Dental College, 10th Milestone
Hosur Road
Bommanahalli
Bangalore 560068
Email: todciec@gmail.com

SOP-3 CONDITIONS OF APPOINTMENT AND QUORUM REQUIRED

3.1 Criteria for Selection of IEC-TODC members:

3.1 **Criteria for selection of 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.
- The basic medical scientists and clinicians should have post graduate qualifications.
- The Lay Person should not have any graduate or post graduate qualification in any science discipline. He/she is a literate person from the public or community. He/she is aware of the local language, cultural and moral values of the community.
- The legal expert should have a basic degree in law from a recognized university with a minimum experience of three years in the legal field.
- The social scientist is someone expert in the study of human society and its personal relationship like anthropologist, scientist and penologist. He/she also may be a representative of a non-governmental organization.
- A newly appointed member who has not undergone any training in ethics/good clinical practice /ethical guidelines of biomedical research on human beings does not have the voting rights. He/she has to undergo training within six months of the appointment. The member gets the voting rights once he/she undergoes training.

3.1.1. Chairperson:

- Should be from outside the institution

b. Should have a minimum of three years experience as a member of an IEC

- Should have undergone training in "Good Clinical Practice" and "guidelines for conducting biomedical research on human beings"
- Should not have any known record of professional misconduct

3.1.2. Member Secretary:

- A senior faculty from the institution with a postgraduate degree, and with a minimum experience of five years in the institution.
- Should have undergone training in "Good Clinical Practice" and "guidelines for conducting biomedical research on human beings"
- Should have a minimum of three years' experience as a member of an institutional ethics Committee
- Should have worked as a convener/member of any committees/core teams of the Institution
- Should have good communication skills

a. Should not have any known record of professional misconduct

3.1.3. 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.
- The basic medical scientists and clinicians should have post graduate qualifications.
- The Lay Person should not have any graduate or post graduate qualification in any science discipline. He/she is a literate person from the public or community. He/she is aware of the local language, cultural and moral values of the community
- The legal expert should have a basic degree in law from a recognized university with a minimum experience of three years in the legal field.
- The social scientist is someone expert in the study of human society and its personal relationship like anthropologist, scientist and penologist. He/she also may be a representative of a non-governmental organization.
- A newly appointed member who has not undergone any training in ethics/good clinical practice /ethical guidelines of biomedical research on human beings does not have the voting rights. He/she has to undergo training within six months of

the appointment. The member gets the voting rights once he/she undergoes training.

3.2. Requirements from Members when they give consent to be the members of IEC-TODC**:** The secretariat should collect a copy of recent curriculum vitae from all the members. The copies of degree certificates and medical council registration certificates should be collected from medical members of committee. In addition, certificates of training if any, in research methodology/ethics in clinical research/good clinical practice/Guidelines for biomedical research on human beings should be collected and filed in the IEC office.

3.3. Consent Letter and Confidentiality agreement from Members:

- When the members agree to be part of IEC-TODC, they need to sign a consent letter in which they declare their commitment for all activities of the committee, and maintaining confidentiality of activities and documents of IEC-TODC
- The staff of secretariat of IEC-TODC has to sign an agreement of maintaining confidentiality
- Chairperson of IEC-TODC will sign on all the confidentiality forms of members and secretariat staff

3.4. Tenure of Membership: The tenure of membership will be for a continuous period of 2 years from the date of appointment.

3.5. Appointment of New Members: New members will be appointed under following circumstances:

- When a regular member completes his/her tenure
- If a regular member resigns before the completion of the term
- If a regular member ceases to be a member due to any reason such as death or disqualification
- To fulfil the membership requirements as per SOP/guidelines/regulations

The new member will be identified by the Chairperson based on the membership requirements after discussion by the IEC. The name of new member to be appointed may be suggested by members of IEC. Chairperson sends the proposal to head of the institution. The final decision on appointment is taken by head of the institution.

3.6. Continuation of Membership after the Tenure:

The tenure of the members in the IEC-TODC is two. After the completion of two years, at least 1/3rd of the members will be replaced by new members. The replacement of a member will be done with new member of the same category (clinician/lay person/social scientist/philosopher, etc...). The decision on continuation of a member will be taken by the Dean of TODC. The Dean may take suggestions from the Chairperson and the Member Secretary. However, the final decision is taken by the Dean. A member can have maximum two continuous terms in IEC-TODC. He/she may become a member again in IEC-TODC after a gap of at least two years. The Dean will communicate to those who are replaced, acknowledging their service and contribution to the ethics committee. For the Chairperson and the Member Secretary replacements, same procedure will be followed. The Chairperson and Member secretary could get a second term after completion of the tenure. The Chairperson and Member Secretary can have maximum two consecutive terms. The Dean will send an appointment proposal letter to the members who will replace existing members and also to the existing members who are going to continue. After obtaining consent, final appointment letter will be issued.

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

- Members must submit a recent, signed CV.
- Members must submit training certificates in ethics and GCP (if available during induction)
- Members should be ready to undergo training in ethical guidelines and GCP and submit the training certificates to the Member Secretary, IEC-TODC.
- Members must be willing to publicize his/her full name and affiliation.
- Should sign the confidentiality agreement, and maintain confidentiality regarding documents, discussions, and related matters of IEC-TODC.

{Also refer to SOP-1: Constitution of IEC: Selection, Roles and Responsibilities of Members of IEC-TODC for details of member recruitment and termination (1.1-1.4.24)}

SOP-4. PROCEDURE FOR REMOVAL, RESIGNATION OR REPLACEMENT OF MEMBERS

Procedure for removal, resignation or replacement of members of IEC-TODC

4.1 Tenure of Membership: The tenure of membership will be for a continuous period of 2 years from the date of appointment. If a member of the IEC-TODC desires to quit the IEC either through resignation or retirement from the IEC. institution or both, they will be considered for termination from the IEC.

Termination of Membership: This refers to termination from membership even before the member completes his/her tenure. Reasons for termination may be resignation of the member from the IEC-TODC, resignation of the member from the institution, death of the member or disqualification of the member.

4.2. Voluntary termination: It is due to resignation of the member. The resignation has to be submitted in writing to Chairperson, IEC-TODC. One-month prior notice is necessary for the resignation. It will be effective from the date of acceptance by the Chairperson. If a member resigns from the institution, even if he/she does not submit resignation to IEC-TODC, the membership to IEC-TODC stands automatically cancelled. This termination is effective once the member is relieved from the institution.

4.3. Disqualification:

A member is disqualified from membership under following circumstances:

A) Misconduct:

- If the Chairperson or the Member Secretary receives a communication in writing from public /investigators/ another member of IEC regarding misconduct of the member
- If the Chairperson observes/gets information on any type of professional /ethical misconduct (not maintaining confidentiality /not declaring of conflict of interest/any type of bias towards research studies/investigators, reviewed by IEC-TODC)
- Action to be taken: The Chairperson satisfies himself/herself that prima facie a case exists before initiating any action. If in the opinion of the Chairperson, the matter of significance and integrity of the IEC could be questioned, he/she will first keep the

member under suspension till the final decision is taken. During the period of suspension, the member will not have any voting rights, privileges and will not perform any duties of a member of IEC-TODC.

The Chairperson will call for a meeting of IEC-TODC, following the usual rules of quorum. The suspended member will be given sufficient opportunity to defend himself/herself in the meeting. The decision will be taken by consensus.

B) Disqualification due to continuous absence: a member will be disqualified if he/she does not attend more than three consecutive meetings of IEC. If the member has given a prior intimation to Chairperson/member Secretary about the absence, the member will be given an opportunity to continue with the membership. This member will be issued a warning from Chairperson. However, the membership will cease if this habit repeats once again.

In case of absence without intimation for more than three consecutive meetings of IEC-TODC, the member is liable for disqualification. The member will be issued a one-month notice by the Chairperson seeking explanation for the absence. If the member gives satisfactory explanation for the continued absence and assures attendance for future meetings, the Chairperson may decide on continuation of the membership. In the absence of any reply from the member, the Chairperson will discuss the matter of disqualification of membership in the meeting of IEC-TODC. Final decision on disqualification is taken by the Chairperson. In all the above cases of disqualification, the Chairperson communicates to the Dean, TODC in writing. The decision of disqualification is communicated to the member by the Dean.

SOP-5. STANDARD OPERATING PROCEDURES TO BE FOLLOWED BY THE COMMITTEE IN GENERAL

All research proposals on biomedical, social and behavioural science research for health involving human participants, their biological material and data are reviewed and approved by The Oxford Dental College-Institutional Ethics Committee (IEC-TODC) to safeguard the dignity, rights, safety and well-being of all research participants. ECs are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research. The EC is competent and independent in its functioning.

5.1 The institution (The Oxford Dental College, Bangalore) is responsible for establishing IEC-TODC to ensure an appropriate and sustainable system for quality ethical review and monitoring.

5.2 The institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the Member Secretary to run the IEC-TODC functions.

5.3 The IEC-TODC is responsible for scientific and ethical review of research proposals. The IEC-TODC determines that the research methods are scientifically sound, and additionally examine the ethical implications of the chosen research design or strategy.

5.4 All types of biomedical and health research (whether clinical, basic science, policy, implementation, epidemiological, behavioural, public health research, etc) are reviewed by the IEC-TODC before it is conducted.

5.5. PREPARATION OF STANDARD OPERATING PROCEDURES OF IEC-TODC

5.5.1. Purpose: To define the process for writing, reviewing, distributing and amending SOPs of IEC-TODC. These SOPs ensure that the activities of IEC-TOD Care conducted in accordance with Indian regulations and relevant, national and international ethical guidelines

5.5.2. Scope: Writing, verifying, reviewing, revising/amending and issuing the SOPs of IEC-TODC.

5.5.3. Responsibilities: The SOPs are reviewed and revised once a year. In the interregnum, amendments if required are done and notified. The Chairperson of IEC-TODC appoints the teams for preparation/ revision of SOPs. The prepared SOPs are reviewed by all members of IEC-TODC in

a meeting. The Chairperson verifies and approves the SOPs. The Chairperson authorizes the Member Secretary to issue the SOPs as per the distribution list. The secretariat staff of IEC-TODC assist in clerical work and distribution.

5.5.4. Procedure:

5.5.4.1. The Chairperson of IEC-TODC appoints teams for preparation/revision of SOPs. Number of teams will depend on the amount of work involved.

5.5.4.2. Each team will have a leader and two or three members. The team leader should be the one who has thorough understanding of the ethical review process, evident by his/her experience and the training he/she has undergone. The leader will discuss with the team members and design the SOPs.

5.5.4.3. Each SOP will have following headings:

1) Purpose

2) Scope

3) Responsibilities

4) Procedure in detail

5.5.4.4. The draft of the SOP will be presented in the meeting of full committee. Suggestions or corrections from the members will be incorporated.

5.5.4.5. The SOPs are reviewed by the Chairperson, the Member Secretary and a senior member of IEC-TODC. The Chairperson will be the final approving authority for SOPs

5.5.4.6. The Member secretary, IEC-TODC is authorized by chairman, and will be responsible for printing the SOP

5.5.4.7. The members are trained on the SOPs, and then they are issued a hard copy of the SOP

5.5.4.8. The new SOP is effective from the date of issue

5.5.4.9. The SOP will be reviewed once a year. The procedure for preparation will be followed for revision of SOP as well.

5.5.4.10. When the revised SOP is made, it becomes the current version, and the previous version will be considered "obsolete". The Member secretary will take back the "obsolete" version and then issue "current" version to the members. The members will not keep the "obsolete" versions with them.

5.5.4.11. Secretariat will mark the "obsolete versions" and will keep only one copy of the "obsolete" version for reference. Other copies will be disposed of by shredding.

5.5.4.12. If any changes are required in the SOP in between (other than regular revision) due to any suggestions from members of IEC-TODC, implementation of revised guidelines, etc., amendments will be made. The chairperson will assess the need for amendment and authorize the Member Secretary to do the needed amendments. Only the soft copy in PDF will be issued to all members within seven days of amendment approval.

5.6. Submission of Documents to IEC-TODCand Management of Submitted Documents

5.6.1. Purpose: This SOP describes the guidelines for submission of protocols to IEC-TODC and how the secretariat manages the submitted protocols

5.6.2. Scope:

The Scope this SOP includes:

1. Submission of Research Project and related documents for Initial Review of the Protocol.
2. Resubmission of Protocols or Research Projects with corrections.
3. Submissions of written communications related to the protocol.

5.6.3. Responsibility: It is the responsibility of the Principal Investigators to submit the protocols as per the guidelines of IEC-TODC. It is the responsibility of IEC Secretariat to receive and record the received protocols. and any other documents for review. The Member Secretary is responsible for scrutinizing the received documents.

5.6.4. Procedure:

5.6.4.1. Documents to be Submitted by the Principal Investigator:

5.6.4.1.1. Time Line: The Principal Investigator should submit the research proposals to the Secretariat of IEC-TODC as per the following time line:

1) New Proposals for Initial Review/ Re-submission of Protocols with Corrections/Amended Protocols and related documents: should be submitted at least 10 days prior to the scheduled meeting of IEC-TODC.

2) Submission of Serious Adverse Events (SAE): As per the timelines stated in the SOP for initial and detailed reporting of SAE.

3) All other documents for consideration at the full board meeting.

5.6.4.1.2. The following documents shall be submitted to the secretary of the ethics committee.

Essential Documents:

1) Covering letter to the Member Secretary.
2) Project submission application form for initial review (see annexure).
3) The correct version of the research proposal: 2 sets of hard copies and one soft copy.
4) Informed consent form (see annexure) in English and in a regional language.
5) Proforma for clinical data collection
6) Budget Proposal
7) Letter from the Department Head Concerned, here non routine or special tests are being done (applicable to academic studies)

5.6.4.2. Management of Protocols:

5.6.4.2.1. Initial Verification and Assigning Protocol Number:

1. The proposals are verified for the completeness If there are any deficiencies the proposals will be returned to the investigator for resubmission

2. Once a protocol is deemed to be complete in all respects the IEC-TODC secretariat will issue a protocol number. The No. will be in this format: IEC-TODC/CATEGORY/PROTOCOL NO./YEAR.

3. All PG dissertations, PhD theses, staff projects and other academic projects will be included for protocol evaluation.

4. The IEC-TODC secretary will screen the proposals and depending on the risk involved categorizes them into types namely, exemption from review, expedited review and full committee review (refer 8.5, SOP-5).

5. The investigator is informed by email and SMS about the presentation date and time

5.6.4.2.2. Transmission and Storage of Documents:

1. The clerk will make a photocopy of the completed document receipt form and return the original copy to the applicants for their records.

2. The hard copies of proposals categorized for full committee review will be sent to all members of IEC-TODC at least 1 week prior to the meeting. The soft copies of all protocols {full and expedited review [refer 8.5, SOP-5]} will be sent by email to those members who have opted for the electronic version.

3. The proposals categorised as exempt review will be cleared by the Member Secretary at the earliest and the decision will be communicated to the investigators.

4. All the protocols will be stored in submission file which again will be categorised as regulatory trials/academic projects/other projects.

5.6.4.3. Resubmission of Protocols with corrections and Amendments of protocol/ related documents:

1. For resubmitted protocol, the PI will submit one soft copy and one hard copy of the amended Protocol and related documents.

2. The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment.

3. The protocol related documents which do not require to be changed and are already submitted for the IEC office during initial review are not required to be submitted again.

4. The Member Secretary (MS) will decide a. if it is a resubmitted protocol it will follow all steps of: categorization as full review/expedited review and initial review (refer 8.5, SOP-5). All the steps followed for a new submission will be followed for the resubmitted protocol. b. if it is a resubmitted protocol based on query response, the Member Secretary will handle it as decided in the meeting (e.g. Carry out review by one or more members selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol or keep on full board agenda).

5.7. Review Procedures

5.7.1. Purpose :The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review into full board / expedited review or exemption from review process.

5.7.2. Scope : This SOP covers the process of categorization of new research study protocols submitted to Institutional Ethics Committee (IEC) for initial review.

5.7.3. Responsibility: The Member Secretary is responsible for categorizing the protocols for review as full review, expedited review and exempted from review. The suggestions/guidance of the Chairperson is taken whenever necessary. It is the responsibility of the members of IEC-TODC to do the review as per the guidelines.

5.7.4. Procedure :

5.7.4.1. Exemption from Review: Proposals that are exempted from review include those with less than minimal risk where there are no linked identifiers. This could be seen in following situations –

- Research conducted on data that is in the public domain for systematic reviews or meta-analysis.
- In-vitro studies that involve little or no use of tissues (such as teeth) obtained from patient.
- In-vitro studies that involve dental materials with no patient involvement with/without the use of simulation software such as finite element analyses.
- Case reports: IEC-TODC issues ethical clearance to case reports for presentation /publication on receiving and verifying informed consent from the patient, abstract of the case report and findings. Wherever possible patient identity must be masked in the photographs used in case reports. The Member Secretary may ask for a copy of the informed consent form signed by the patient whenever the identity of the patient is not masked. Member Secretary will go through (screening for documents to be submitted to IEC) the proposals which are exempted from review, and get the decision ratified in the full committee meeting.

Exceptions: when research on educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm; when interviews involve direct approach or access to private papers.

5.7.4.2. Expedited Review: The proposals that pose "no more than minimal risk" are considered for expedited review. Expedited review will be conducted by chairperson, member secretary and 1-2 designated members. The approval granted through expedited review will be ratified at the next full committee meeting. In following situations, expedited review will be done:

- Minor deviations from originally approved protocols (originally approved through full review by the IEC).

- Revised proposal previously approved through full review or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples.
- Research involving clinical documentation materials which are non-identifiable (data, documents, records).
- Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigators.
- Revised proposal previously approved through expedited review, full review or continuing review of approved proposals.
- Minor deviations from originally approved research causing no risk or minimal risk.
- Progress/annual reports where there is no additional risk e.g. activity limited to data analysis.

i) When in emergency situations like serious outbreaks or disasters a full review is not possible, prior written permission may be taken before use of test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention. Same participants should not be included in the clinical trial that may be initiated based on the findings of the pilot study.

5.7.4.3. Full Review: All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review

- All studies involving interventions (clinical trials) involving trials on new drugs, materials or combinations of drugs, materials.
- Studies involving vulnerable population even if the risk is minimal.
- Collection of blood samples by finger prick, heel prick, ear prick or venipuncture.
- Collection of biological specimens by research purposes by non-invasive means – skin appendages, dental procedures, external secretions, stimulated or unstimulated saliva collection, buccal scrapings, skin swab or mouth washings, sputum.
- Use of medical devices for study population such as implants and physical sensors.

5.7.5. Aspects Considered During Review of Research Proposal:

- **Scientific design and conduct of the study**: Use of valid scientific methods
- **Social Values**: The research must have anticipated social value, and outcome should be relevant to the health problems of the society.
- **Benefit-Risk Assessment**: The benefits must justify the risk inherent in the research. Risks may be physical, psychological, economic, or social; Withdrawal criteria, and rescue medication or procedures.
- **Selection of the Study Population and Recruitment of Research Participants** : To ensure voluntary recruitment, and fair selection of participants as per inclusion and exclusion criteria; participant is given option to opt out without the routine care being affected; No individuals or group of persons must bear the burdens of participation in research without any benefits except in studies where healthy volunteers are involved; Vulnerable group is not recruited unless proper justification is provided.
- **Payment of participation** and Compensation Procedures, without inducement but, reimbursing for incurred cost and convenience.
- **Protection of research participant**'s privacy and confidentiality.
- **Community considerations**: due respect given to community and interests are protected; no stigma or discrimination ensues from the proposed research; plans for communication of results back to the community at the end of study; plan for dissemination of benefits of research to the community.
- **Qualifications of investigators** and assess adequacy of study sites.
- **Disclosure of potential conflicts of interest**
- **Review of informed consent process**

The review of proposals by members is documented in review forms, and in the minutes of meetings of the IEC-TODC.

5.8 Agenda preparation, conduct of meeting and minutes of meetings

5.8.1. Purpose: The purpose of this SOP is to describe the preparation of agenda, distribution of agenda, preparation for meeting, conducting the meeting and preparing minutes of meetings of IEC-TODC.

5.8.2. Scope: This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all IEC meetings.

5.8.3. Responsibility: The Member secretary is responsible for preparation of the agenda, recording the minutes of meeting and circulation of the minutes to all members of IEC-TODC. The Chairman conducts the meetings of IEC-TODC, and approves the minutes of meeting.

5.8.4. Procedure:

5.8.4.1. The meeting schedule: The IEC-TODC meeting is held twice a year on a pre-assigned date agreed upon by all members. Frequency of the meeting is increased depending on the number of research proposals for full review.

5.8.4.2. Preparation of Agenda:

5.8.4.2.1. The research proposals received by the IEC-TODC are categorized for review as: exempted from review, expedited review and full review (refer 8.5, SOP-5). This is done by the Member Secretary who will do the initial scrutiny of the research proposals. The review is done only for the proposals categorized for expedited and full review. The expedited review will be done by the Chairperson, the Member Secretary and one member of IEC-TODC. The full review will be done by all members of IEC-TODC.

5.8.4.2.2. The research proposals categorized for full review will be included in the agenda for presentation during the meeting of IEC-TODC. The expedited reviews and exempted from review are included for ratification by all members in the meeting.

5.8.4.2.3. The agenda includes: quorum of previous meeting (list of members present and absent), ratification of the minutes of previous meeting, presentation of the research proposals (full review) by the principal investigators, ratification of the expedited reviews, presentation of the proposals categorized under "exempted from review" by the Member Secretary, and any other issues as recommended by the members and approved by the Chairperson. Other issues could be report of onsite monitoring, training needs, accreditation of ethics committee, serious adverse events, review of protocol deviations/amendments, continuing review of research

studies, completion reports of research studies, revision of SOPs, changes in the committee composition, report of subcommittees appointed by the Chairperson (if any) and emergency concerns.

5.8.4.2.4. If any member is unable to attend the meeting, he/she should inform the Chairperson (through the Member Secretary) well in advance. (Preferably one week before the scheduled date of meeting). The leave should be requested in a written leave letter in emergency situations if the member is not able to inform in advance, e mail communication could be done. If the Chairperson is unable to attend the meeting, he/she will inform the Member Secretary, and ask him to conduct the meeting with the Vice Chairperson as the acting Chairperson for the meeting.

5.8.4.2.5. All regular members of IEC-TODC, independent consultants and principal investigators of research proposals categorized for full review are required to attend the meeting. If any member is unable to attend the meeting, they need to inform the Chairperson or Member Secretary by any means of communication. Independent consultants chosen for full review are intimated to attend the meeting during the presentation of those research proposals which they have reviewed.

5.8.4.2.6. The principal investigator should attend the meeting and present the proposal. Co investigators are allowed to attend the meeting.

5.8.4.3. Conduct of Meeting:

5.8.4.3.1. The IEC-TODC full board meeting will be held as per the schedule provided there is quorum as per requirement

5.8.4.3.2. There should be the presence of at least 6 members out of the total 9 members of the committee to constitute quorum.

5.8.4.3.3. Besides the Chairperson and the Member Secretary the quorum will consist of One basic medical scientist One social worker (or a social scientist, theologian, ethicist, philosopher, member or representative of a non-governmental voluntary agency or a similar person), A clinician, A lay person from the community and A legal expert.

5.8.4.3.4. The signature of all members who attended the meeting will be taken on the attendance sheet

5.8.4.3.5. Guests or observers may be allowed in the meeting provided they have taken prior permission, and signed confidentiality agreement

5.8.4.3.6. The Chairperson initiates the meeting after ensuring quorum. The Chairperson ensures the quorum for every clinical trial presentation in the meeting.

5.8.4.3.7. The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict. The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict prior to the start of the meeting.

5.8.4.3.8. If a conflict of interest has been declared by a member, the Chairperson will ask the member concerned to leave the meeting room when the concerned issue is being discussed.

5.8.4.3.9. The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.

5.8.4.3.10. The Member Secretary will present the agenda of the day's meeting for discussion.

5.8.4.3.11. The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.

5.8.4.3.12. The Principal Investigators are asked to present the research proposals as per the order of proposals mentioned in the agenda. When one investigator is presenting the proposal, investigators of other research proposals should not be present in the meeting room. However, co investigators of the same research proposal (or guides in case of postgraduate dissertations) are allowed to be in the meeting room. In case of informed absence of principal investigator, co-investigator may be allowed to make the presentation. However, if the members feel that co-investigator is not familiar with the protocol details, the principal investigator may be asked to attend the next meeting of IEC for the presentation.

5.8.4.3.13. The members of IEC-TODC should not discuss on the decisions about the research proposals when the investigators are inside the meeting room. The members should discuss only after the investigator leaves the meeting room.

5.8.4.3.14. For other matters in the agenda (other than full review), the member secretary will present the review findings (expedited review), list of proposals under exempted from review, protocol deviations/amendments, etc.

5.8.4.3.15. Reports of any subcommittees will be presented in the meeting by the heads of respective committees, as per the agenda

5.8.4.3.16. The proceedings of the meeting will be recorded by the Member Secretary. If the Member Secretary has conflict of interest in any research proposal, the joint secretary will do this job.

5.8.4.4. Decision Making:

5.8.4.4.1. The final decision on approval of a research proposal is by consensus... In the review forms, the members need to tick one of the following:

1) Approved
2) Approved with suggestions
3) Resubmit with revisions
4) Rejected

In the "Suggestions" of section of the form, member can write down his/her suggestions of any and points to be considered for revision of the research proposal. Reasons for rejecting the proposal also should be mentioned in this section of review form. Final decision is taken by consensus. The Chairperson ensures participation of all members in the deliberations. The decisions are based on risk assessment, scientific validity, and adherence to ethical principles for the initial and periodic approvals.

5.8.4.4.2. The independent consultants called to the meeting will be present only for the presentation of the concerned research proposal. He/she will give the opinion during the meeting and will leave the meeting room. They don't have any voting rights.

5.8.4.5. Minutes of the Meeting:

5.8.4.5.1. The minutes of the meeting are prepared by the member secretary on summarizing the discussions held in the meeting and decision taken by consensus.

5.8.4.5.2. Following are the contents of the minutes of meeting:

1) Date, time and venue of the meeting.
2) List of members who attended and who were absent for the meeting.
3) List of guests/observers (if any) who attended the meeting.
4) Name of the individual who served as chairman for the meeting.
5) Ensuring of quorum by the chairman.
6) Ratification of minutes of the previous meeting: to be mentioned.
7) Research proposals for full review: summary of discussions and approval status.
8) Research proposals for expedited review: summary of discussions and approval status.
9) Research proposals exempted from review: list of the proposals.
10) Discussion of protocol deviations/amendments, with actions taken.
11) Discussion of onsite monitoring visits if any, with actions taken.

12) Discussion of progress reports and final reports if any, with actions taken.

5.8.4.5.3. The minutes are prepared within 3 working days of the meeting day.

5.8.4.5.4. The minutes are sent to all members of the committee by e mail and their inputs are taken. The Chairperson gives the final approval for the minutes.

5.8.4.5.5. The minutes are presented in the next meeting for ratification.

5.8.4.6. Communication of the Decision to Investigators:

5.8.4.6.1. The decision of the IEC is communicated to the principal investigators. All communications are done by the member secretary (or joint secretary in his absence).

5.8.4.6.2. The communication of the decision will include:

1) Name and address of IEC.

2) The date and place of the decision.

3) The name and designation of the investigators.

4) Protocol no. given by the IEC.

5) Title of the research proposal reviewed.

6) Version No., date, amendment no. of the protocol (for clinical trials).

7) List of documents reviewed (for clinical trials)-clear description of these documents along with version No., and date.

8) List of IEC members who attended the meeting-clear description of their role and affiliation.

9) A clear statement of the decision reached.

10) Any advice by the IEC to the applicant including the schedule /plan of ongoing review by the IEC-TODC.

11) In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

12) In case of rejection, reasons for rejection will be clearly stated.

13) Signature of the member secretary with date.

5.8.4.6.3. The investigator is asked to register the study in Clinical Trial Registry of India (CTRI). Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies as well as trials being conducted in the purview of the department of AYUSH are expected to register the trial in the CTRI before enrolment of the first participant.

5.8.4.7. Validity of Approval: Though the approval is granted for the entire duration of the study, the validity of the approval letter is only up to one year. Depending on the risk involved, the progress of the project will be monitored annually. The approval will be continued if progress is satisfactory. The decision of IEC may be reversed if IEC receives information that may adversely affect the benefit/risk assessment.

5.8.4.8. Calling an Emergency Meeting of IEC-TODC:

5.8.4.8.1. The Member Secretary in consultation with the Chairperson may call for an emergency meeting on following occasions: 1) Urgent issues which if not discussed and decided may have adverse impact on patient safety 2) Serious adverse events 3) Other issues deemed appropriate by the Chairperson or the Member Secretary.

5.8.4.8.2. The Secretariat will endeavour to contact each and every IEC member and inform him/her about the date, time and venue of the meeting as well as the reason for calling for the meeting.

5.8.4.8.3. The documents for discussion in emergency will be sent by e mail. The notice of this meeting may be sent at least one day in advance.

5.8.4.8.4. The rules of quorum will be applicable. If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (at least one scientific and one non-scientific member) are present, given the urgency of the matter under consideration. The IEC members will act according to the relevant IEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

5.8.4.8.5. Calling additional meetings of IEC-TODC: The Member Secretary in consultation with the Chairperson can call for additional meetings depending on the requirement. These are the meetings other than emergency meetings. Additional meetings are called if the number of research proposals for full review are more than 15, and if the IEC-TODC is not able to include discussion of issues such as progress reports, onsite monitoring, study completion reports, etc.. in the half-yearly meeting due to constraint of time. The procedure for agenda, conduct and minutes is the same as that followed for the usual meetings.

Annexure-5.8.5: Format for Minutes of meeting:

Date and Time of meeting:

- Members present and absent: list with designations
- Guests or observers present: list with designations
- Name of the individual who served as Chairperson:
- Ensuring of quorum by the Chairperson:
- Ratification of the minutes of the previous meeting:
- Research proposals for full review:

Protocol No.	Title of the Study	Name of the Principal Investigator	Remarks by the members (opinion/suggestion/other remarks)	Approval status

VII. Research Proposals for expedited review:

Protocol No.	Title of the Study	Name of the Principal Investigator	Names of the members who did the expedited review, with remarks	Approval status

VIII. Research Proposals exempted from review:

Protocol No.	Title of the Study	Name of the Principal Investigator	New/Revised Submission	Approval status

IX. Discussion of Progress Reports and Study Completion Reports:

Protocol No.	Title of the Study	Name of the Principal Investigator	Remarks on the report submitted	Action taken as per the requirement

SOP-6. STANDARD OPERATING PROCEDURES TO BE FOLLOWED BY THE COMMITTEE FOR VULNERABLE POPULATION

6.1. Purpose: This SOP describes the requirements and process of review of research that involves vulnerable participants.

6.2. Scope: This SOP covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the IEC.

6.3. Responsibility: It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines. IEC Chairperson / Member Secretary are responsible for ensuring that IEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes. The Member Secretary/ Chairperson is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research and for securing consulting expertise as and when required for selected reviews. IEC member is responsible for conducting review of research planned for vulnerable populations, including an assessment of potential for coercion.

6.4. Procedures:

6.4.1. Definition of Vulnerable Population: Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. They are the individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

- economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.);
- unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent
- children (up to 18 years);
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);

- tribals and marginalized communities;
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
- terminally ill or are in search of new interventions having exhausted all therapies;
- suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system
- (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

Among the above-mentioned vulnerable categories, children under the age of 18 make up a significant proportion of the subjects recruited in conduct of research at TODC. Checklists for recruitment of children in research are elaborated in annexures 9.5.1 and 9.5.2.

6.4.2. Reviewing protocols with vulnerable participants:

- The protocol should be reviewed as described already under the SOP "Review Procedures".
- Additionally, the protocol should be reviewed to assess if the following points are addressed:

    - Can the research be performed in any other non-vulnerable participants? --- Is there justification to use vulnerable population? ---- Do the benefits justify the risks ---- Are the participants selected equitably ---- Have the measures to protect Autonomy of the vulnerable population been described.
    - Appropriate Review forms are used.

6.4.3. Decision: The decision on allowing trials on vulnerable populations will be taken in a full board meeting of IEC. The decision will be communicated to the PI. Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented.

6.5. Annexures.

Annexure-6.5.1. :Checklist for Research Involving Children (To be filled by PI and submitted to IEC ; To be cross verified by Reviewer During Review) (Part-1)

Name of Principal Investigator :			
Title of the Protocol :			
To be done by Principal Investigator		**To be done by Reviewer**	
Risk –Benefit Assessment : (Tick the appropriate answer)		**Risk –Benefit Assessment : (Tick the appropriate answer)**	
Less Than Minimal Risk ; Direct Benefit		Less Than Minimal Risk; Direct Benefit	
Less Than Minimal Risk; Indirect Benefit		Less Than Minimal Risk; Indirect Benefit	
Greater Than Minimal Risk; Potential benefit to child		Greater Than Minimal Risk ; Potential benefit to child	
Greater Than Minimal Risk; No direct benefit, offer knowledge about child"s condition/disorder		Greater Than Minimal Risk ; No direct benefit, offer knowledge about child"s condition/disorder	

Signature of the Principal Investigator with Date

Comments of the Reviewer :

Recommendations of the Reviewer:

Name and Signature of the Reviewer with Date :

Annexure-6.5.2 Checklist for Research Involving Children (To be filled by PI and submitted to IEC ; To be cross verified by Reviewer During Review) (Part-2)

Does the research pose greater than minimal risk to children?	Yes	No	Not Applicable
If yes: Are convincing scientific and ethical justifications given?			
Does the study involve healthy children?			
a) If yes: Is the inclusion of healthy children justified?			
Are the studies conducted on animals and adults appropriate and justified?			
a) If No: Is the lack of studies conducted on animals and adults justified?			
Is permission of both parents necessary?			
a) If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
b) If Yes: Are the conditions acceptable?			
Will efforts be made to ensure that parents" permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honouring their dissent?			
Are provisions made to protect participants privacy and the confidentiality of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Are parents required to be present during the conduct of the research? (Are proposed participants 'very young?')			

Signature of the Principal Investigator with Date

Comments of the Reviewer:

Recommendations of the Reviewer:

Name and Signature of the Reviewer with Date:

SOP-7. POLICY REGARDING TRAINING FOR NEW AND EXISTING COMMITTEE MEMBERS ALONG WITH STANDARD OPERATING PROCEDURES

Procedure for Training and Assessment of Members:

7.1. Purpose :The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the IEC-TODC members and the Secretariat.

7.2. Scope : This SOP applies to all the IEC-TODC members.

7.3. Responsibilities It is the responsibility of the IEC-TODC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC-TODC members and the secretariat. The Chairperson is responsible for assessment of all IEC-TODC members and complete a self-assessment exercise at prescribed intervals.

7.4. Procedure

7.4.1. Topics for training

IEC-TODC members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and Responsibilities of IEC-TODC members
- Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- Recent Developments in relevant health science specialities
- SOPs of the IEC-TODC

7.4.2. Induction Training of new IEC-TODC Members

1) Every time a new committee is constituted, the members must undergo initial training within one month on ethics in clinical research and good clinical research and SOPs. An individual selected as a new member of the IEC-TODC will be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC-TODC. The Member Secretary will provide an introductory training to the new member. The member during the observer period will not have voting rights, but will have to sign letter of confidentiality. Appointment of observer as member would be on discretion of chairperson in consultation with members, following which the appointment letter would be issued to the member.

2) The newly inducted member will be encouraged to undergo training on good clinical practice, bioethics and guidelines on clinical research. The authorities of TODC may sponsor the member for such trainings.

3) The new member will receive trainings from any member of IEC-TODC or Chairperson or Member Secretary on the above topics. An expert from clinical research, bioethics or GCP will be invited to IEC-TODC to give training

4) The in-house training sessions of IEC-TODC will have pre-test and post-test to assess the effectiveness of trainings.

5) The Member Secretary and the Chairperson will orient all the members on the SOP of the IEC-TODC.

7.4.3. Ongoing (On Job and Developmental) Trainings at IEC-TODC:

1) Member Secretary, member, chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year. The authorities of TODC may sponsor the members for such trainings.

2) The Member Secretary of IEC-TODC in consultation with the Chairperson prepares an annual training schedule, and will conduct trainings or workshops on good clinical practice, bioethics, relevant guidelines on clinical research and other relevant topics. The resource persons for such trainings could be a member of IEC-TODC, or external GCP trained personnel or a bioethics expert. The trainings are imparted not only to the IEC-TODC members but, also to the institutional faculty who are investigators of ongoing research studies or potential investigators.

7.4.4. Assessment of IEC members

1. The IEC-TODC members' performance should be evaluated once a year using an assessment form by the Chairperson.
2. The Chairperson should do self-assessment once a year.

7.4.5. Maintenance of training records of the IEC-TODC Members and the Administrative Staff

The secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual IEC-TODC members. The copies will be filed in the individual members" files. The records regarding training copies of the secretariat will also be maintained in their respective files.

7.5. Annexures

7.5.1: Assessment Form for Ethics Committee Members

1. Current tenure

2. Terms served

3. Training received (Training record to be attached)

4. Type of training received

5. No of meetings attended

6. No of projects reviewed per meeting as primary reviewer

7. Participation in SAE report review process- yes/no

8. Participation in site monitoring visits - yes/no

9. Number and type of continuing training workshops organised for IEC-TODC members (applicable to Member Secretary)

10. Any other significant contribution to the field of research ethics

Annexure 7.5.2. Training Records of the Member (Trainings in house+attended outside):

Name of the Member: **Designation in** IEC-TODC:				
Date	**In House/Outside**	**Name/Names of Trainer/s**	**Topic**	**Organizer**

SOP-8. POLICY TO MONITOR OR PREVENT THE CONFLICT OF INTEREST ALONG WITH STANDARD OPERATING PROCEDURES

Handling conflict of interest (COI) among Ethics Committee members

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

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

8.3. Responsibility: All IEC-TODC members are responsible for self-identifying and disclosing the conflict of interest. The Chairperson of IEC-TODC is finally responsible for ensuring that all members of IEC-TODC self-declare conflict of interest during review of research proposals

8.4. Procedure:

8.4.1. Information to members on conflict of interest (COI):

1) During the appointment of members, one of the conditions is "To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any at appropriate time".

2) The member will be signing the consent letter after going through the terms and conditions in the appointment letter.

3) The conflict of interest policy of the IEC-TODC will be explained to the members on induction. It will be a part of the trainings imparted to the members

8.4.2. Types of COI:

8.4.2.1. Personal COI: If the investigator of a research proposal has close and immediate family relationship with the member of IEC-TODC (spouse, son/daughter, parents, sibling, dependent) ; If the IEC-TODC member is a collaborator, Principal investigator, co-investigator, financer, research staff, consultant for a research proposal which has come for review in IEC-TODC; If a research proposal is submitted by a departmental colleague with whom the member has conflict of interest (dispute, bias, any benefits, etc.. ,) –if applicable and if the member feels there is a conflict of interest.

8.4.2.2. Professional COI: If the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

8.4.2.3. Financial COI: If 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).

8.4.3. Procedure for Declaring COI:

8.4.3.1. The IEC member should identify the COI whenever a research proposal is assigned to him/her for the review. The COI should be declared in the format provided in SOP of IEC-TODC, and submitted to the member secretary.

8.4.3.2. The 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.

8.4.3.3. 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 Secretariat and return the documents.

8.4.3.4. 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 secretariat so that the review is reassigned to other members.

8.4.3.5. 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

8.4.3.6. The 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.

8.4.3.7. 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.

8.4.3.8. At the beginning of each meeting, the IEC-TODC 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.

8.4.3.9. 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 Chairperson should be appointed for discussion on such a project.

8.4.3.10. When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by the IEC member with the help of the IEC Chairperson / Member Secretary or by IEC Chairperson / Member Secretary (as applicable)

8.4.3.11. 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

8.4.3.12. The declaration and management of COI should be recorded in the proceedings of the IEC-TODC meetings.

8.5. Annexure:

Conflict of Interest Declaration Form
To:
Chairperson, IEC-TODC.
Dear Sir,
I am aware of the COI policy of IEC-TODC. I herewith declare my conflict of interest with regard to the following research proposal submitted to IEC-TODC for review.
Protocol No. Study
Title:
Name of Principal Investigator:
Type of COI (Personal/ Professional/Financial) and the Reason: Hence, I stay away from reviewing this research proposal, any deliberations/discussions on this study, and refrain from any decision making.
Name and Signature of Member
Date:
Name and Signature of Chairperson:
Date:

SOP-9. REVIEW OF PROGRESS OF THE STUDY AND FINAL COMPLETION REPORTS

9. 1. Purpose- The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Review of Progress of the study and Final Completion Reports submitted for studies approved by the Institutional Ethics Committee (IEC).
9.2. Scope- This SOP applies to the review of the Review of Progress of the study and Final Completion Reports which is a written report by the Principal Investigator (PI).

9.3. Responsibility- It is the responsibility of the Secretariat/ IEC Chairperson/ Member Secretary/

Member/s to review the study report and act on it.

9. 4. Procedure :

9.4.1. Receipt of Review of Progress of the study and Final Completion Reports

The Secretariat will receive 1 copy each (soft and hard) of Review of Progress of the study and Final Completion Reports t for the regulatory trials

9.4.2. Review of Progress of the study and Final Completion Reports is expected from the investigator within 1 month of completion of the study at the site. This is applicable only for regulatory trials.

9.4.3. It is the responsibility of the IEC Secretariat to review the report for completeness

The Secretariat shall verify the submitted Review of Progress of the study and Final Completion Reports Form and forward it to the Member Secretary within 7 working days of receipt. The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting.

9.4.4. If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it as per the relevant SOP. The Secretariat shall include the Study Completion Report Form in the agenda for IEC members for discussion at the full board meeting.

9.4.5. During the Board meeting The Member Secretary will present the report and members can discuss as needed. Following the discussion, the Chairperson may take one of the following decision:

a) noted / approved b) request for additional information / clarification The Secretariat will note the decision in the meeting minutes

b) The Member Secretary will draft a letter to the PI conveying decision on the study completion report. The study shall be considered as closed if the decision by IEC is "Noted" or "Approved".

c) The Secretariat will accept and file the Report and get the Study Completion Report Form signed by the Chairperson . The final report will be placed in the master file and kept in the archival area.

d) The Secretariat will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

9.5. Annexure: STUDY PROGRESSION REPORT

IEC-TODC Protocol No. :

CTRI NO:.....

Project Title: _____

_____

Principal Investigator

Department

SL No	ITEMS FOR OBSERVATION DURING THE RESEARCH	Comment by the Guide
1	Periodic consultation with guide/Co Guide	
2	Appropriate review	
3	Regular collection of study materials	
4	Depth of analysis/ Discussions	
5	Quality of research	

Guide Signature:.....

Action taken: Noted/ Requires more information/ action as follows:

_____

_____

IEC Meeting date (If reviewed in the meeting)_____ Final Decision:_____

_____

Signature of Member Secretary with date: _____

9.6. Annexure : STUDY COMPLETION REPORT FORM

IEC-TODC Protocol No. :

CTRI NO:.....

Project Title: _____

_____

Principal Investigator
Department

Results (summary) with Conclusion: (use extra blank paper, if more space is required).

_____

_____

Signature of Principal Investigator: Date

Guide Signature: .....

Action taken: Noted/ Requires more information/ action as follows:

_____

_____

IEC Meeting date (If reviewed in the meeting)_____ Final Decision:_____

_____

Signature of Member Secretary with date: _____

SOP-10. REVIEW OF SERIOUS ADVERSE EVENTS (SAE) IN CLINICAL TRIALS

10.1. Purpose : The purpose of this SOP is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) occurring in a clinical trial reported to the IEC for any study under the oversight of the IEC-TODC.

10.2. Scope: This SOP applies to the review of SAE reports (Adverse events/ SAE onsite as well as SAEs of the multicenter studies occurring at other sites/offsite) submitted to the IEC-TODC.

10.3. Responsibility: It is the responsibility of the principal investigator/investigator at site to submit an SAE report to IEC-TODC as well as to DCGI and sponsor . It is the responsibility of the IEC to review all SAEs reported to the IEC in a timely manner

10.4. Procedures:

1] Serious Adverse Event:

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect

2] Serious Adverse Event (AE) or Serious Adverse Drug Reaction (ADR)

An AE or ADR that is associated with death, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

3] Adverse Event

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

4] Suspected Unexpected Serious Adverse Reactions (SUSARS) : An unexpected adverse reaction (UAR) is an adverse reaction that is not consistent with the product information in summary of product characteristics. . A suspected unexpected serious adverse reaction (SUSAR) is any UAR that at any dose results in death; is life threatening (i.e. the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe); requires hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; is a congenital anomaly or birth defect.

10.5. Receipt of Report of SAE:

10.5.1. The IEC Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant:

i) Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence. ii). Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE
iii) Due analysis will also be submitted by the sponsor within 14 days
iv). The follow up reports of all on-site SAE till the event is resolved.

10.5.2. The IEC Secretariat will verify that the report is complete in all respects and that it has been received at the IEC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as a protocol violation and action should be taken as described in SOP for protocol deviations. The IEC Secretariat will sign and write the date on which the report is received. The Secretariat will forward these reports to the IEC Member Secretary within two working days.

10.6. Review and Decision on SAE Reports and Communication to PI and Regulatory Authority by IEC :

10.6.1. The Member Secretary will review the SAE report and present to the SAE subcommittee for review and opinion.
10.6.2. At the meeting of SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion. The SAE subcommittee hold the meeting and site visits as required.

10.6.3. If deemed necessary, the SAE subcommittee may refer the issue to the IEC full board. The report of SAE subcommittee will be presented in the IEC full board meeting. An emergency meeting of IEC may be held for this purpose. The emergency IEC meeting will be scheduled within 7 days for the same. The minutes of the SAE Subcommittee/ IEC meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE . The minutes will be circulated to the IEC members via email and approval/ objection will be sought from the members in a period of 5 working days. After approval from the Chairperson, the Member Secretary communicates the decision of IEC-TODC to the PI, within 7 working days after the meeting of SAE subcommittee.

10.6.4. The PI will be requested to reply to the query letter on the SAE report within 7 working days. The opinion regarding relatedness, medical management and compensation for research related injury will be communicated to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE in case of regulatory clinical trials. The SAEs

occurring at other sites will be reviewed by the Secretary of the IEC / SAE Subcommittee (as applicable) and informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites

10.7. Onsite Adverse events (AE):

10.7.1. The IEC Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by the IEC:

1. On site AE reports to be submitted by the PI annually in the continuing review report.

2. In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter

10.7.2. The IEC Secretariat will verify that the report is complete in all respects and signed and dated by the PI and that it has been received at the IEC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as deviation.

10.7.3. The reports are forwarded to the Member Secretary of IEC may put the AE reports for discussion at full board if deemed necessary Queries, if any on the report will be communicated to the PI by the Member Secretary of IEC following full board meeting.

10.8. Review during Full Board Meeting of IEC-TODC: A report of the SAEs is presented in the full board meeting of IEC-TODC during the monthly meeting. In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion. The decision is arrived at by consensus.

10.9. Decision of IEC-TODC on SAE :

The IEC-TODC arrives at one or more of the following decisions on review of SAE report.
4) Following detailed review of the SAE reports and related documents, the IEC/ SAE

Subcommittee can suggest one of the following actions:

- Note the information about the SAE in records for future reference.
- Request further follow up information and/ or additional details.
- Ask for periodic follow-up of the research participant till SAE is resolved

• Depending on complexities of issue, IEC/ SAE Subcommittee may decide to seek opinion of

outside expert consultant who is requested to respond within 14 working days.

• Provide recommendations regarding/ raise queries related to compensation for study related

10.10. If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators" brochure), re-consenting of research participants, the decision will be conveyed to the PI through telephone, fax or email within 24 hours. Such a communication will be

Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators" Brochure/ any other study related documents.

Suspend the study till additional information is available.

Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).

Suspend the study till amendments requested for by the IEC are carried out.

Suspend enrolment of new participants. Suspend certain activities under the protocol.

Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.

Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.

Terminate the study.

Any other appropriate action documented by the IEC Member-Secretary in the study file. A formal letter to the PI informing about the IEC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

Annexure-10.1.

SAE Reporting Form

1. Protocol Details :
1) Protocol Number :
2) Title of the Study :
3) Name of Principal Investigator, Designation, Department and Institution :

2. Participant Details :

1) Initials & Subject ID : 2) Gender :

3) Age at the time of the event :
4) Weight (Kg) :
5) Height (cm):
3. Report Type :Initial/ Follow up/Final.

If follow up report, state the date of Initial Report :
What was the assessment of relatedness to the trial in the initial report?
By PI By Sponsor By IEC

3. Describe the event and specify suspected SAE diagnosis : ----------

Related Unrelated	Related Unrelated	Related Unrelated

4. Date of Onset of the SAE : Date of Reporting : 5. Onset lag time after administration of intervention:

6. Location of SAE (Clinic/Ward/Home/Other) :
7. Details of suspected study drug/device/investigational procedure causing SAE:

a. Suspected Study Drug (Generic name) /Device/ Intervention :
b. Indication(s) for which suspect study drug was prescribed or tested:
c. Route(s) of administration, daily dose and regimen, dosage form and strength:
d. Therapy Start Date: Stop Date :

8. Was study intervention discontinued due to event? : Yes No
9 . Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? : Yes No

If Yes, provide details about the reduced dose....----------
10. Did the reaction reappear after reintroducing the study drug / procedure? : Yes No

If Yes, provide dose details .----------

11. Concomitant drugs history and lab investigations:
a. Concomitant Drug(s) and Date of Administration :

b. Relevant test/laboratory data with dates:

c. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

12. Have any similar SAE occurred previously in this study?

If yes, please provide details.

13. Seriousness of the SAE : (Tick the applicable)

Death

Hospitalization –initial or prolonged Disability

Yes No

Congenital anomaly

Permanent impairment or damage Others (Specify) :

Life-threatening	Required intervention to prevent complications/sequelae

14. Describe the medical management provided for adverse reaction (if any) to the research participant : ----------
15. Outcome of SAE :

- Fatal Continuing Unknown
- Recovered Recovering Others (Specify) :

16. Provide details about PI's final assessment of SAE relatedness to trial ----------

17. Was the Participant Continued on the Trial ? (Tick the applicable) : Yes/No /NA
18. Has this information been communicated to sponsor/CRO/regulatory agencies? : Yes/No/NA

Provide details if communicated (including date) :

19. Does this report require any alterations in protocol ? Yes/No

20. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

Signature of PI with Date

Annexure 10.2. : CONSTITUTION OF SAE SUBCOMMITTEE of IEC-TODC

Following members of IEC-TODC have been appointed as members of SAE subcommittee.

1.----------

2. ----------

3. ----------

Roles and Responsibilities:

- TheSAEsubcommitteeisresponsibleforreviewinganyseriousadverseevent(SAE) reported to IEC-TODC.
- The SAE subcommittee members will evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants
- At the meeting of SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion.

4. The SAE subcommittee hold meeting and site visits as required Please refer to the SOP of IEC-TODC for further details.

SOP- 11. DETAILS OF AUDIT CONDUCTED ON IEC-TODC:

11.1. Purpose : The purpose of this SOP is to describe the procedure for self-assessment of the functioning of IEC-TODC, periodically.

11.2. Scope : This SOP is applicable to self-assessment and internal audit of IEC-TODC.

11.3. Responsibility: It is the responsibility of the Member Secretary to prepare the periodic self-assessment /internal audit schedule. It is the responsibility of the Chairperson to ensure proper and unbiased conduct of internal audit. It is the responsibility of all members of IEC-TODC to participate in the internal audit as auditor/auditee.

11.4. Procedure :

11.4.1. Periodicity of Self-Assessment / Internal Audit : One internal audit is conducted in a year

11.4.2. Preparation of the Audit Schedule : The Member Secretary of IEC-TODC prepares the audit schedule with approval from the Chairperson. The audit checklist will be made available to the members for doing the audit.

11.4.3. Auditors and Auditee : Every member of IEC-TODC will be the auditor. However, one will not audit his/her own review. The Member Secretary and the Chairperson will be the auditee.

11.4.4. Audit Procedure: The audit involves verification of documents of IEC-TODC and interview with members of IEC-TODC, secretariat, Member Secretary, principal investigators of regulatory trials and participants of regulatory trials. The protocols of studies other than regulatory trials do not come under the preview of internal audit.

11.4.5. Report of Internal Audit: The report of internal audit is submitted to the Chairperson

11.4.6. Corrective Action: The Chairperson and the Member Secretary will take necessary corrective actions for the non-conformities /partial compliances raised in the internal audit. The members of IEC-TODC will go through the corrective actions taken.

11.5. Annexures.

Annexure-11.5.1. Format of the Self- Assessment / Internal Audit Schedule :

IEC-TODC /CCM/----/Year. Date: ----------

The periodic internal audit of the IEC-TODC will be held as per the schedule. Each team of Auditors will have 2 members

Dates	Area/Standards of Audit	Auditors	Auditee
	Constitution of IEC, Composition; Subject Experts; Training and Assessment of IEC Members; SOP revision.	Team 1 Member-1 : Member-2 :	
	Review Procedures : initial, continued, completion/final reports; Meetings of IEC; Decision Making.	Team 2 Member-1 : Member-2 :	
	Serious Adverse Events (SAE); Protocol Deviations and Violations; On site Monitoring	Team 3 Member-1 : Member-2 :	
	Administrative Support; Functioning of Secretariat; Handling Grievances and Complaints; Record Keeping and Archival; Communications	Team 4 Member-1 : Member-2 :	

The auditors are requested to conduct the audit as per the checklist, and complete the audit process as per the schedule.

There will be an opening meeting on : at :
The closing meeting will be held on: at :
The audit report should be submitted to the Chairperson during the closing meeting.
Member Secretary, IEC-TODC Chairperson, IEC-TODC

(Name, Signature and Date)

VIII. REFERENCES

1. ICMR. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Indian Council of Medical Research: New Delhi; 2017
2. New Drugs and Clinical Trials Rules, 2019. Department of Health and Family Welfare, New Delhi.
3. FERCI. Standard Operating Procedures. Forum for Ethics Review Committees in India. http://ferci.org/sops
4. Guide Book To Standards For Accreditation of Ethics Committees, IEC-TODC.