Chettinad
Dental College & Research Institute

STANDARD OPERATING PROCEDURE (SOP)

FOR

INSTITUTIONAL HUMAN ETHICS COMMITTEE CHETTINAD DENTAL COLLEGE AND RESEARCH INSTITUTE (IHEC-CDCRI)

VERSION No: SOP / IHEC-CDCRI / 2023 / 01

Chettinad
Dental College & Research Institute

Standard Operating Procedure (SOP)

For

Institutional Human Ethics Committee

Chettinad Dental College and Research Institute

(IHEC-CDCRI)

VERSION No: SOP / IHEC-CDCRI / 2023 / 01

Effective Date: 18-05-2023

Validity: 5 years

Next Review Date: 18-05-2028

Office Address

Chettinad Dental College and Research Institute,

E-Block, 3rd Floor, Room No.6, Rajiv Gandhi Salai,

Kelambakkam, Kanchipuram Dt, Tamil Nadu – 603103.

Telephone No.: 04447413350, Fax: 04447413343

CONTENTS

CONTENTS

REVIEW AND AUTHORIZATION

We, the undersigned have reviewed the working Standard Operating Procedure (SOP) of "Institutional Human Ethics Committee – Chettinad Dental College and Research Institute (IHEC-CDCRI)" and authorize that it complies with "New Drugs and Clinical Trials Rules, 2019", ICMR's "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017" and "Guideline for Good Clinical Practice ICH E6(R2)"

VERSION No: SOP / IHEC-CDCRI / 2023 / 01

Effective Date: 18-05-2023

Validity: 5 years

Next Review Date: 18-05-2028

Prepared and Reviewed By	Authorized By
Dr. Daya Srinivasan,	**Dr.Aruna T,**
Member Secretary,	**Chairperson,**
IHEC-CDCRI	**IHEC-CDCRI**
Date: 17.5.2023	**Date:** 17.5.2023

Professor & Head
Dept. of Pedodontics
Chettinad Dental College & Research Institute
Kelambakkam - 603 103.

PROFESSOR & H.O.D.,
DEPARTMENT OF PHARMACOLOGY,
GOVT. KILPAUK MEDICAL COLLEGE,
CHENNAI - 600 010.

LIST OF ANNEXURES

ABBREVIATIONS

AE	Adverse Event
CDCRI	Chettinad Dental College and Research Institute
CDSCO	Central Drugs Standard Control Organization
COI	Conflict of Interest
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
CTRI	Clinical Trial Registry of India
DCGI	Drug Controller General of India
EC	Ethics Committee
GCP	Good Clinical Practice
HMSC	Health Ministry's Screening Committee
ICD	Informed Consent Document
ICF	Informed Consent Form
ICH	International Council for Harmonisation
ICMJE	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IHEC	Institutional Human Ethics Committee
MoU	Memorandum of Understanding
MTP	Medical Termination of Pregnancy
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction.

1. Introduction

Chettinad Dental College and Research Institute (CDCRI) was established in the year 2007 by Raja Muthaiah Chettiar Charitable and Educational Trust. The institute is recognized by the Dental Council of India (DCI) for offering Bachelor of Dental Surgery (BDS) and Master of Dental Surgery (MDS) courses. CDCRI is affiliated to The Tamil Nadu Dr. MGR Medical University, Chennai and offers admission to 100 BDS seats and 23 MDS seats in 9 dental specialities per year. The college is headed by the Principal.

The Ethics Committee (EC) is constituted to review and approve the research proposals conducted by faculty, undergraduate and postgraduate students. The EC of CDCRI will be known as "Institutional Human Ethics Committee – Chettinad Dental College and Research Institute" abbreviated as IHEC-CDCRI. The Committee functions within the campus of Chettinad Dental College and Research Institute located at E-Block, 3rd Floor, Room No.6, Rajiv Gandhi Salai, Kelambakkam, Kancheepuram Dt, Tamil Nadu - 603103. The IHEC-CDCRI telephone number is 044-47413350 and the fax number is 044-47413343.

The committee will evaluate all the research proposals on biomedical and health research (whether clinical, basic science, policy implementation, epidemiological, behavioural, public health research, etc) involving human participants, their biological material, or their data.

The IHEC-CDCRI established in accordance with the "New Drugs and Clinical Trials Rules, 2019", "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017" and "Guideline for Good Clinical Practice ICH E6(R2)" and takes into consideration the cultural and ethical values of India.

2. Terms of Reference

2.1 Purpose:

The ethics committee is constituted to review the proposals for all biomedical, social, and behavioural science research involving human participants, their biological material, and data. The purpose of such research should be:

- Directed towards enhancing knowledge about the human condition while maintaining sensitivity to the Indian cultural, social, and natural environment;
- Conducted under conditions such that no person or persons become mere means for the betterment of others and that human beings who are participating in any biomedical and/or health research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency; and
- Subjected to a regime of evaluation at all stages of the research, such as design, conduct and reporting of the results thereof.

2.2 General Roles and Responsibilities of EC members:

Every EC member of IHEC-CDCRI should:

- Ensure protection of the dignity, rights, safety, and well-being of the research participants.
- Ensure ethical conduct of research by the investigator team.
- Be responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- Perform their function through competent initial and continuing review of all scientific, ethical, medical, and social aspects of research proposals received by them in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

- Ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- Assist in the development and education of the research community in the given institute (including researchers, clinicians, students, and others), responsive to local healthcare requirements.
- Adhere to specific responsibilities of as defined in the SOP.
- Ensure that privacy of the individual and confidentiality of data including the documents of EC meetings are protected.
- Review progress reports, final reports and AE/SAE and give needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
- Recommend appropriate compensation for research related injury, wherever required.
- Carry out monitoring visits at study sites as and when needed.
- Participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
- Ensure that replicative ("Me Too") is not encouraged and submission of same research to different funding agencies is not accepted.

2.3 Tenure of EC Member:

The term of a member in IHEC-CDCRI will be for 5 years. A defined percentage (35-50%) of EC members will be changed on a regular basis.

2.4 Conditions of Appointment:

Every EC member should adhere to the membership, training requirements and furnish all the necessary documents as defined in the SOP.

Terms of reference will be maintained in the office of EC. This includes membership requirements, conditions of appointment, policy for removal, replacement, resignation procedure, procedure for of meetings, etc., of the IHEC-CDCRI.

3. Scope of Review of Research Proposals

The IHEC-CDCRI will evaluate faculty and student proposals on biomedical and health research involving human participants, their biological material, or their data. All the studies should be initiated only after approval from the ethics committee. These studies may include but not be limited to:

- clinical trials
- epidemiological research
- social science research
- research on medical records or other personal information
- research on stored samples
- health systems research
- implementation research

The IHEC-CDCRI will evaluate only those clinical studies which do not require regulatory clearance from the CDSCO / DCGI. The committee will not evaluate any proposals for testing new drugs or devices, BA/BE studies, biobanking or animal studies. Research using dental, oral (mesenchymal) or other stem cells should be limited only to in-vitro tests or ex-vivo tests. Research proposals using stem cells for therapeutic purposes on humans (in-vivo) will not be evaluated.

The IHEC-CDCRI may offer review services to other institutes, colleges, CROs and other hospitals that do not have an institutional human ethics committee. Proposals from individuals who are not affiliated to any institute or organization will not be accepted for review.

If other centres would like to obtain the review services of IHEC-CDCRI, they should abide by the terms and conditions defined in this SOP under various executive aspects.

4. Authority to Constitute IHEC-CDCRI

The Head of the Institute of Chettinad Dental College and Research Institute, will be the authority to constitute the IHEC-CDCRI. The head of institute is the Principal. The Principal will choose the Chairperson, Member Secretary, and all other members based on their qualifications, competence, and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals as per their bio-data (Annexure 1). An invitation letter will be sent to all the eligible members (Annexure 2) and the members must provide a letter of acceptance (Annexure 3) in return. Upon receipt of the letter of acceptance the final appointment of the member will be made (Annexure 4) by the Principal. The list of members (Annexure 5) will be maintained at the office of IHEC-CDCRI.

5. Composition of IHEC-CDCRI

The members of IHEC-CDCRI should be multi-disciplinary and multi-sectorial. There should be adequate representation of age and gender. A minimum of 7 members and a maximum of 15 members can be appointed in the EC. At least 50% of the members should be non-affiliated and must be from other institutions. The EC should have a balance between medical and non-medical members. The list of EC members with their affiliations and qualifications are given below:

1. Chairperson / Vice Chairperson (Non-Affiliated):

- A well-respected person from any background with prior experience of having served in an EC.
- Appointment of a Vice Chairperson is optional.

2. **Member Secretary/ Alternate Member Secretary (Affiliated):**
    - Should be a staff member of CDCRI. Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. Should be able to devote adequate time to this activity which should be protected by the institution.
    - Appointment of an Alternate Member Secretary is optional.

3. **Basic Medical Scientist/s (Affiliated / Non-Affiliated):**
    - Non-medical or medical person with qualifications in basic medical sciences.
    - In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.

4. **Clinician (Affiliated / Non-Affiliated):**
    - Should be individual/s with recognized medical qualification, expertise, and training.

5. **Legal Expert/s (Affiliated / Non-Affiliated):**
    - Should have a basic degree in Law from a recognized university, with experience.
    - Desirable: Training in medical law.

6. **Social Scientist / Philosopher / Ethicist / Theologian (Affiliated / Non-Affiliated):**
    - Should be an individual with social/ behavioural science/ philosophy/religious qualification and training and/or expertise and be sensitive to local cultural and moral values.
    - Can be from an NGO involved in health-related activities.

7. Lay Person (Non-Affiliated):

- Literate person from the public or community and not pursued a medical science/ health related career in the last 5 years.
- May be a representative of the community from which the participants are to be drawn.
- Is aware of the local language, cultural and moral values of the community.
- Desirable: involved in social and community welfare activities.

8. Subject Experts / Consultants (Affiliated / Non-Affiliated):

- The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc.
- They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.
- The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision-making power.
- These consultants must sign the confidentiality agreement regarding meeting, deliberations, and related matters.
- These consultants or subject experts cannot vote for a decision. A formal invitation letter will be sent to the consultant.
- Confidentiality agreement should be signed before submitting the study documents.
- Updated CV of the independent consultant will be collected and filed.

6. Member Specific Roles and Responsibilities

The specific roles and responsibilities of every member of IHEC-CDCRI are given below:

1. Chairperson / Vice Chairperson (Non-Affiliated):

- Conduct EC meetings and be accountable for independent and efficient functioning of the committee.
- Ensure active participation of all members in all discussions and deliberations.
- Ratify minutes of the previous meetings.
- In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

2. Member Secretary / Alternate Member Secretary (Affiliated):

- Organize an effective and efficient procedure for receiving, preparing, circulating, and maintaining each proposal for review.
- Schedule EC meetings, prepare the agenda and minutes.
- Organize EC documentation, communication, and archiving.
- Ensure training of EC secretariat and EC members.
- Ensure SOPs are updated as and when required.
- Ensure adherence of EC functioning to the SOPs.

- Prepare for and respond to audits and inspections.
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient, or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

3. Basic Medical Scientist/s (Affiliated / Non-Affiliated):

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress, and completion report.
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4. Clinician (Affiliated / Non-Affiliated):

- 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 (SAE, protocol deviation or violation, progress, and completion report).
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management, and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

5. **Legal Expert/s (Affiliated / Non-Affiliated):**

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any.

6. **Social Scientist / Philosopher / Ethicist / Theologian (Affiliated / Non-Affiliated):**

- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any.
- Ethical review of the proposal, ICD along with the translations.
- Serve as a patient/ participant / societal / community representative and bring in ethical and societal concerns.

7. **Lay Person (Non-Affiliated):**

- Ethical review of the proposal, ICD along with translation(s).
- 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. Assess on societal aspects if any.

Dual Roles:

- The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role.

Vice Chairperson and Alternate Member Secretary:

- The appointment of Vice Chairperson and Alternate Member Secretary are optional.
- They have same TORs as regular members and can attend meetings in the absence of regular members to meet the quorum requirements.

Roles of Subject Experts / Consultants:

- Subject experts / consultants will have the same TORs as the other members.
- Their role will be to evaluate the scientific and ethical issues with respect to their specialization.

7. Requirements for EC Members

Every member appointed on the IHEC-CDCRI should be willing to fulfill the requirements given below:

- Provide a letter of acceptance (Annexure-3) for accepting their position and duties in the EC.
- Provide a recent and updated Bio-Data in the specified format (Annexure 1) at the time of appointment.
- Must sign the Confidentiality Disclosure Agreement (Annexure 6) on their appointment and maintain the confidentiality and privacy of the EC meetings
- Must provide the Conflict of Interest Declaration Form (Annexure 7) at the time of EC meetings and must declare any financial or non-financial conflict of interest to the Chairperson.
- Submit training certificate on human research protection and/or GCP at the time of appointment or within 6 months of appointment.

- Be willing to undergo training or update their skills/knowledge during their tenure as an EC member and be aware of relevant guidelines and regulations.
- Read, understand, accept, and follow the COI policy of the EC and declare it, if applicable, at the appropriate time.
- Be willing to place her/his full name, profession, and affiliation to the EC in the public domain.
- Be committed and understanding to the need for research and for imparting protection to research participants in research.
- All the EC members must be aware of the terms and conditions, roles and responsibilities as specified in the SOP and
- They must be updated on the national and international regulatory requirements from time to time.

8. Conditions of Appointment of EC Members

All the EC members will be appointed only if they accept to the terms and conditions mentioned below:

- Appointment will be based only on their qualifications, experience, commitment, interest, and willingness to allot time and effort for the purpose of the committee.
- The tenure of the membership in the EC will be for 5 years after which new members will be nominated by the Head of the Institute.
- A defined percentage (35-50%) of EC members will be changed on a regular basis.
- After the completion of the term, the members may be reappointed into to EC for the same or different roles as decided by the Head of the Institution.

- There is no limit to the number of times the membership can be extended.
- Members who are appointed for a particular role cannot substitute for the role of any other member who is absent for a meeting.
- Every member must ensure that they complete their work / responsibilities well within the time frame as fixed during the EC meetings.
- Any delay in their duties should be communicated to the Chairperson and Member Secretary well in advance and should not in any manner hinder with the smooth functioning of the EC.
- The role of Chairperson / Member Secretary is an additional activity to their primary responsibility based on their qualifications.
- Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

9. Training of EC Members

All EC members should be trained in human research protection or GCP guidelines (if applicable) and relevant national and international regulatory guidelines at the time of appointment.

- The training can be provided by the EC / Institution or external members or agencies so that they become aware of their role and responsibilities.
- Members who have not completed any training at the time of appointment should complete the training within 6 months of appointment.
- All members should submit their training certificates to the EC and all trainings should be documented.

- Completion of the online certification course - NIeCer 102: Ethics Review of Health Research, through the Swayam portal will be encouraged.
- Members should be well trained in the functioning of the EC and the SOP of IHEC-CDCRI.
- Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members.
- EC members should be aware of local, social, and cultural norms and emerging ethical issues.

9.1 Organizing Training Programs by the EC:

- The EC should organize at least one training program per year on ethical guidelines, GCP or drug and clinical trial rules by inviting external experts.
- Attendees may be EC members, faculty, and students of CDCRI.
- All the training programs organized by the EC should be documented and certificate should be provided to all the attendees.

10. Procedure for Resignation / Replacement of EC Members

- Member can resign from the committee after giving written notification with reasons to do so, to the Chairperson, Member Secretary and Head of the Institution with a notice period of at least 1 month.
- The member will continue to serve in the respective role during the notice period or until a new member is appointed for that role.
- The authority to remove/replace a member lies with the Head of the Institution.
- A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.

- A new member with suitable qualification may be appointed to replace an outgoing member by the Head of the Institution.
- Membership will be updated and notified to the Regulatory Authority periodically.

11. Honorarium to EC Members and Fee for Review

- No fee will be collected from the investigators for review of any internal or collaborative research proposals submitted to IHEC-CDCRI.
- Honorarium for the members and transport arrangement / allowance will be fixed based on the Institute's recommendations from time to time.

12. Administration and Management

Supporting staff such as EC Secretary / EC Co-ordinator of the IHEC-CDCRI may be appointed by the Principal. The supporting staff must report to the Member Secretary. The functions of the supporting staff are the following but not limited to:

- Organizing EC meetings regularly, maintaining attendance, and meeting records.
- Preparation of agenda, minutes of the meetings, and approval letter.
- Communicating with EC members and institution/site/investigator.
- Arrangement of training for personnel and EC members.
- Answering queries of the investigators.
- Filing study related documents, maintenance of study files and archiving.
- Performing site audit visit.

- Organizing an effective and efficient tracking procedure for each proposal received.
- Participate in the development and subsequent implementation of SOPs.

13. Procedure for Writing, Reviewing, Distributing and Amending SOP for Ethics Committee

- The SOP will be prepared according to the applicable national regulatory requirements and guidelines from time to time.
- The objective is to contribute to the effective functioning of the IHEC-CDCRI so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the committee as prescribed by the regulatory guidelines.
- It is the responsibility of the Chairperson to appoint a member or team to formulate the SOPs.
- The validity of the SOP will be five years from the date of its implementation and will be revised once in five years.
- If there is any requirement for revision of SOP before five years, due to changes in regulatory guidelines or to incorporate any relevant Gazette notification from the regulatory body, the committee may call for an EC meeting and discuss on revision procedures. The Chairperson will appoint SOP writing Team to revise the SOP.
- The draft SOP must be reviewed and approved by the Chairperson of the ethics committee.
- Approved SOPs will be implemented from the effective date.
- All members of Ethics Committee should review the SOPs.
- Training on new SOP will be conducted for all members.

- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement the SOP accordingly.

14. Procedure for Submission of Research Protocol

14.1 Format for Research Protocol:

All the protocols submitted should adhere to the uniform format (Annexure 12) and requirements as specified in the SOP.

14.2 Pre-Screening of Proposals by Scientific Committee:

All the research proposals from the faculty and students of CDCRI / or external institutes (signed an MoU with IHEC-CDCRI) must be submitted to the EC only after a scientific review and approval by the Scientific Committee of CDCRI (Annexure 16).

14.3 Types of Applications:

Principal Investigator can submit the documents for IHEC-CDCRI for review under any of the 5 categories mentioned below:

- Initial Review Application
- Resubmission of Study with Corrections
- Protocol Amendment or any other amendments
- Annual Status Reports /Continuing Review of the study
- Study Completion / Termination

14.3 Submission of Applications:

- All submissions may be made as hard and soft copies. A separate data base / portal may be created for this purpose.

- The application for review of proposed biomedical research should be submitted only by a qualified applicant responsible for the ethical and scientific conduct of the research
- All the research projects should be addressed to the Member Secretary/Chairperson for Submission.
- All the research projects should be submitted at least 2 weeks prior to the meeting.
- The research Protocol (Annexure 12), covering letter (Annexure 10) and Investigator Declaration (Annexure 13), duly signed by the Principal Investigator (PI) or Co-investigators needs to be submitted along with the research documents.
- A check list of all the other that need to be submitted to the EC are mentioned in Annexure 11. This also must be signed and submitted to the EC.
- Two (2) hard copies of all the research documents should be enclosed along with the submission letter. The EC members will receive only the softcopy of the submitted proposals to review.

14.5 Receipt of Submission Packages:

- The office of the EC will review the documents submitted comparing with the submission checklist and verify by ticking the EC receipt section in the check list.
- If any missing documents are there EC will inform the applicant to submit the required documents
- If the application is intact, the member secretary will give acknowledgement in the submission letter by signing and stamping for investigator use.
- Every valid application will receive a unique reference number for further correspondence.

- The Member Secretary/Administrative Staff will acknowledge the receipt of the submission/covering letter and a copy of the same will be handed over to the concerned person. The Administrative Staff will circulate the research documents to the members by e-mail.
- One hard copy will be labeled and stored at EC office and this copy will be archived at EC office. The other copy will be handed over to the Investigator with approval or disapproval stamp.

15. Types of Reviews

The proposals received by the EC may be categorized into three following three categories:

- Exempted from review
- Expedited Review
- Full Committee Review

The Chairperson and the Member Secretary can discuss with the other members and determine the type of review required for a proposal.

These categories may be explained as follows:

15.1 Exempted from Review:

Proposals with less than minimal risk where there are no linked identifiers, for example;

- In-Vitro Studies without involvement of any human samples
- Research conducted on data available in the public domain for systematic reviews or meta-analysis;
- Observation of public behavior when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
- Quality control and quality assurance audits in the institution;

- Comparison of instructional techniques, curricula, or classroom management methods;
- Consumer acceptance studies related to taste and food quality; and
- Public health programs by Govt agencies such as program evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring (where there are no individual identifiers).

15.2 Expedited Review:

Proposals that pose no more than minimal risk may undergo expedited review, for example;

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
- Research involving clinical documentation materials that are non-identifiable (data, documents, records);
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
- Revised proposals 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, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
- Multicenter research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters.

15.3 Full Committee 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, some examples are;

- Research involving vulnerable populations, even if the risk is minimal;
- Research with minor increase over minimal risk
- Studies involving deception of participants
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
- Major deviations and violations in the protocol;
- Any new information that emerges during the research for deciding whether to terminate the study in view of the altered benefit–risk assessment;
- Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

16. Risk Assessment and Categories of Risk

The EC should assess the inherent benefits and risks, ensure a favorable balance of benefits and risks, evaluate plans for minimizing the risk and discomfort and decide on the merit of the research before approving it.

The type of EC review based on risk involved in the research, is categorized as given below:

16.1 Less than Minimal Risk:

Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.

16.2 Minimal Risk:

Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include: Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva, or urine samples, etc.

16.3 Minor Increase Over Minimal Risk or Low Risk:

Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as:

- Routine research on children and adolescents; research on persons incapable of giving consent;
- Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials;

- Use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises, or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women.
- Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

16.4 More than Minimal Risk or High Risk:

Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device, or invasive procedure etc.,

17. Procedure for Conducting IHEC-CDCRI Meeting

17.1 Frequency of Meeting:

- IHEC-CDCRI meetings usually will be held once in 3-4 months.
- Emergency or special meetings may be scheduled if required.

17.2 Call for Meeting:

- The Member Secretary or Administrative Staff is responsible for the conduct of meetings, maintaining the records and communicating with all the members of the committee.
- Meeting dates will be informed by the Administrative Staff/Member Secretary in 1 week advance to all the members and/or investigators.
- After confirmation from all the members or majority members, meeting date will be decided.

17.3 Meeting Agenda:

- Agenda will be prepared by the Administrative Staff and signed by the Member Secretary.
- Agenda will have the following - date, time, purpose of the meeting and protocol that are going to be reviewed in the meeting. (Refer Annexure 8 for meeting agenda)
- Agenda will be prepared by EC office and distributed to all EC members and investigators at least 3 days prior to the meeting.

17.4 Meeting Procedure:

- The Chairperson will preside over the meetings.
- Investigator/ Co-Investigator may be invited to present the proposal or elaborate on specific issue.
- In case of the academic projects, the postgraduate or undergraduate student or faculty shall be informed that they can do the presentation along with the guide's presence.
- Attendance will be maintained.
- The Principal Investigator will present the protocol. When the PI is not available any of the Co-Investigators can present the protocol and clarify the points raised by the members.

17.5 Recording Minutes of the Meeting:

- The minutes of the meeting must be documented and maintained by the administrative staff in the prescribed format (Annexure 9).
- Minutes should record any COI declaration by members.

18. Quorum Requirements for EC Meeting

1. A minimum of five members should be present in the meeting room.
2. The quorum should include both medical, non-medical or technical or/and non-technical members.
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
6. No decision is valid without fulfilment of the quorum.

19. Ethical Review Procedures

- Review of all proposals will be done only through formal meetings and will not resort to decision through circulation of proposal.
- All EC members (as per quorum requirements) should review all proposals.

The submitted proposal shall be reviewed both for scientific content and ethical principles. Following aspects will be considered during review of research proposal: (Refer Annexure 19 for Check List for Review)

- Scientific design and conduct of the study.
- Prior approval from scientific review committee.
- Patient information sheet and informed consent form in English and regional language.
- Procedure for selection of participants including inclusion/exclusion, withdrawal criteria and other issues like advertisement details.
- Potential benefits to the study subjects.
- Predictable risks to the study subjects.

- Compensation to subjects for participating in the study.
- Justification for use of placebo, if any.
- Management of research related injuries, Such as adverse events/Serious Adverse events.
- Monitoring of serious adverse events.
- Compensation for study related injury.
- Protection of privacy and confidentiality.
- Involvement of the community, wherever necessary.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure of study sites.

19.1 Categorization of Research Proposals:

The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.

- A researcher cannot decide that her/his proposal falls in the exempted, expedited, or full review category.
- All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis.
- Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested (Refer Annexures 17, 18).
- The final decision on the type of review required for the protocol lies with the EC.

19.2 Procedure for Expedited Review:

- Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.
- Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.
- EC members should be given enough time (at least 1 week) to review the proposal, except in the case of expedited review.

19.3 Procedure for Full Committee Review:

- All proposals that are determined to undergo full committee review must be deliberated and the decision about the proposal taken at a full committee meeting.
- Full committee meetings will be held based on pre-decided schedule.
- A meeting will be considered valid only if the quorum is fulfilled.
- A list of absentee members as well as members leaving or entering in-between the meeting should be recorded.
- Proposals should be taken up item-wise, as given in the agenda.
- No of proposals reviewed in a meeting should justify that there is ample time devoted for review of each proposal.
- If there are many proposals for consideration per meeting either meetings may be more frequent.
- Time allotted for the meeting should be reasonable to allow ample discussion on each agenda item.
- The researcher may be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review.
- The EC may utilize electronic methods such as video/conference calls for connecting with other subject experts/independent consultants during the meeting.
- The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review should be ratified.

20. Policy to Monitor / Prevent Conflict of Interest

Any kind of financial or non-financial Conflicts of Interest of both the EC members and the Investigators should be declared.

20.1 COI Declaration by EC Members:

- EC must ensure that the members do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.
- Members shall declare to the Committee any interests they may have in relation to an application for ethical review or any other matter for consideration at that meeting.
- If a member has declared a COI for a proposal, then this should be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes. (Refer Annexure 9).
- The member who has declared COI should withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon.
- The member will also not take part in the voting process.
- This should be recorded in the minutes of the meeting and the quorum must be rechecked.
- If any EC member was found to be guilty of not declaring their COI inn advance, the respective proposals will be rejected and the study will be terminated and appropriate action will be taken on the EC member.

20.2 COI Declaration by Investigators:

- All investigators must declare their conflicts of interest as a part of their research proposal (Annexure 12) and investigator declaration (Annexure 13).

- If any investigator was found to be guilty of not declaring their COI inn advance, their proposals will be rejected and the study will be terminated.

21. Review of Clinical Trials

- Clinical trials will be evaluated by a full committee review.
- If required independent consultants/experts will be invited to offer their opinion on specific research proposals.
- Experts will give their specialized views but will not take part in the decision making or voting.
- The IHEC-CDCRI will assess the appropriateness of the Investigator for the conduct of respective clinical trial. The suitability of the Investigator to conduct the trial will be assessed based on the educational qualification, clinical experience, clinical trials experience and training in clinical research.
- At the time of review of clinical trial protocols, the EC will assess the appropriateness of the trial site for the conduct of respective clinical trial. The suitability of the trial site to conduct the trial will be assessed based on infrastructure, equipment, doctors available, number of in-patients and out- patients and the experience of the investigators in conducting the trials.
- The Ethics Committee shall undertake through review of the informed consent forms and patient information sheets in English and vernacular language whenever the clinical trial protocols are reviewed.
- The EC will ensure that all study related injuries (AE/SAE) are treated free of the cost by the investigator. There shall be no cost imposed on the patient for investigations, medical or surgical treatment or hospital expenses.

- In case of SAEs, the EC will review the protocol for appropriate section defining the compensation for SAEs. The EC will ensure that the compensation for SAEs is as per the guidelines provided in "New Drugs and Clinical Trials Rules, 2019".

21.1 Reporting AE / SAE:

- All AEs should be recorded and reported to the EC according to a pre-planned timetable, depending on the level of risk and as recommended by the EC.
- Reporting of SAE may be done through email or fax communication (including on non-working days).
- A report on how the SAE was related to the research must also be submitted within 14 days.
- The EC is responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum and type of assistance to be provided to the participants.

21.2 Insurance / Compensation for Trial Related Injury:

- The investigators / Institution must ensure that all the trial participants have an insurance cover for trial related injury or harm.
- Insurance policy document must be submitted along with the protocol for review. The document should have details of conditions for coverage, date of commencement and expiry of the policy.
- Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.
- For other sponsored research, it is the responsibility of the sponsor to include insurance coverage or provision for possible compensation for research related injury or harm.

21.3 Registration of Trial in Clinical Trial Registry of India:

- All clinical trials must be prospectively registered in the CTRI. The trial registration document must be submitted during the review.
- If trial registration is not completed at the time of submission to the EC, it must be completed before the commencement of the trial.
- No trial can be started without completion of CTRI registration.

22. Review of External Projects

- External institutions which do not have their own EC or those who like to collaborate with CDCRI for multicentric research can apply for review for proposals by IHEC-CDCRI.
- All procedures for review will be similar as that of internal research project and external Institution must follow the SOP of IHEC-CDCRI.
- External Institution which requires facility of IHEC-CDCRI should submit the request letter from the Head of the Institute and Investigator addressing to the Member Secretary/Chairperson of IHEC-CDCRI for reviewing the research proposal. Member secretary/Administrative Staff will acknowledge the receipt and forward the request letter to Head of the Institution.
- The Institutional profile and brief Curriculum vitae of the Investigator will be collected and forwarded to the Chairperson and upon acceptance the request would be undertaken for review by IHEC-CDCRI.
- If required Member secretary/Administrative Staff will conduct the site visit to verify the suitability of the facility to conduct the research activities. Other members may also participate in this feasibility assessment.
- External Institution may sign a Memorandum of Understanding (MoU) may with CDCRI for collaborative projects (Refer Annexure 27).

- MoU must be signed by the Chairperson, Institutional Head of CDCRI, and the Head of the External Institution.
- Periodic review of the external institution will be performed. IHEC-CDCRI will conduct audits at the External site as and when required.
- IHEC-CDCRI has authority to terminate or withheld the conduct of the research project at the external institution if there is any misconduct pertaining to the trial.

23. Review of Multicentric Research

In order to save time, effort and duplicate reviews, the evaluation of multicentric research can be done by either of these procedures:

23.1 Separate Review by ECs of All Participating Site/s:

- The ECs/Secretariats of all participating sites should establish communication with one another.
- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications as per local needs.
- Separate review may be requested for studies with a higher degree of risk, clinical trials, or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.

23.2 Common Review for All Participating Site/s:

- The EC's of all the participating institution/s can decide to have one designated main EC, the decisions of which may be acceptable to other ECs. This EC should be in India and registered with the relevant authority.

- The meeting of the designated main EC can be attended by nominated members of ECs of the participating centers.
- The protocol may be modified to suit local requirements which must be approved by the main EC.

Note: The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, etc., the local participating sites would be required to obtain local ethical approval.

24. Review of Proposals During Emergencies

A humanitarian emergency or disaster is an event or series of events that represents a critical threat to the health, safety, security or well-being of a community or other large group of people, usually covering a wide land area.

- Research during humanitarian emergencies and disasters can be reviewed through an expedited review/scheduled/unscheduled full committee meeting and this may be decided by the Member Secretary on a case-to-case basis depending on the urgency and need.
- If an expedited review is done, full ethical review should follow as soon as possible.
- Meticulous documentation and archiving are required to enable future application in similar situations.
- The EC should closely monitor the conduct and outcome of research.
- Re-review should be done if the emergency situation changes.

Suggestions to expedite the review process are given below:

- Virtual or tele-conferences should be attempted when face-to face meetings are not possible.

- In exceptional situations, preliminary research procedures including but not restricted to data/sample collection that are likely to rapidly deteriorate or perish may be allowed while the review process is underway.
- Available protocol templates could be reviewed to expedite the process.
- In situations where members of local ECs are unavailable due to the emergency, the ethics review may be conducted by any other recognized EC within India for initiating the study, until the local EC is able to convene its meeting.

25. Procedure for Decision Making and Communicating the Decision

- Decisions will be made only in meetings when quorum is achieved.
- Only members can make the decision.
- The expert consultants will only offer their opinions.
- Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
- Any opinion of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.
- Member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.
- Investigators will not participate in the deliberations.

25.1 Types of Decisions:

- **Approved** – with or without suggestions or comments;
- **Revision with minor modifications / amendments –** approval is given after examination by the Member Secretary or expedited review, as the case may be;
- **Revision with major modifications for resubmission** – this will be placed before the full committee for reconsideration for approval; or
- **Not approved** (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving

.

25.2 Minutes of the Meeting:

- Administrative Staff is responsible to prepare the minutes as per the format prescribed in this SOP (Refer Annexure 9)
- The draft document will be sent to the Member secretary, Chairperson and other members for approval.
- Final approval should be done by the Chairperson and the Member Secretary

Note: Minutes of Meeting are the internal documentation and will not be circulated to the outside parties.

25.3 Procedure for Approval:

- The Chairperson should ensure that one of the decisions (as mentioned under 25.1) is made for every application considered at IHEC-CDCRI meeting.
- Where the IHEC-CDCRI decides that further information or clarification is required, the Chairperson/member secretary ensures that the further information or clarification required reaches the committee.
- The Administrative Staff will prepare the draft approval letter as per the approval template given in Annexure 20.
- Approval draft will be sent to Chairperson for any correction.

- The Approval letter will then be signed by the Member Secretary / Chairperson.
- Copy of the Approval Letter is maintained in the specific study file at CARE- IHEC for Faculty Research.
- The positive decision can be changed after receiving any information that affects the benefit/ risk ratio.

25.4. Communicating the Decision:

- Decision of the meeting on the proposals will be communicated by the Member Secretary/ Administrative Staff.
- The Principal Investigator/ Team should clarify the queries-if any raised during the meeting within a stipulated time as communicated.
- The clarification from the Principal Investigator will be circulated to the members by the Administrative Staff.
- If the proposal is approved then the approval letter will be sent to the respective Principal Investigator.
- If the proposal is rejected, then a letter with reason for its decision will be sent.
- If the approval of the project is kept pending for any clarifications, it will be intimated in writing to the Principal Investigator.
- In case IHEC-CDCRI revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

26. Procedure for Monitoring the Approved Research

Once the study is approved, IHEC-CDCRI starts monitoring the Research. The approved research must be conducted as per protocol, adhere to the national ethical guidelines / GCP guidelines.

26.1 Research Protocol Amendments:

- Any change to be made in an approved protocol shall be considered as a protocol amendment.
- Any change of investigators or sites should be informed to the EC.
- All modifications / amendments should be notified to the EC in the prescribed format (Annexure 21)
- The Investigator should submit one copy of the amended protocol or any other study related documents along with the covering letter duly signed by the Investigator to the Administrative Staff. Soft copy of the same should be sent to IHEC-CDCRI. The modifications should be highlighted.
- The amendments shall be classified as Major or Minor.
- Major: amendment that alters the potential risk of the safety of the trial subjects, change in the protocol design etc. Minor: any amendment that does not alter the risk category of the protocol.
- The Member Secretary in consultation with Chairperson will decide whether to carry out a full board meeting or not.

26.2 Continuing Review / Annual Report:

- Ongoing research should be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk)
- Annual reports of all the research activities should be evaluated.
- The investigators should submit the annual reports to the EC in the prescribed format (Annexure 22).

26.3 Protocol Deviation / Violation:

- The EC should continually evaluate for any protocol deviations/violations and non-compliance, of all research activities.
- All protocol deviations (if necessary) should be reported the EC by the investigators in the prescribed format (Annexure 23).

- For protocol deviations/violations the EC should examine the corrective actions. If the violations are serious the EC may halt the study. The EC may report to the institutional head/government authorities.

26.4 Monitoring SAE:

- The Principal Investigator/Co-Investigator should submit the safety updates of the research projects in the prescribed format (Annexure 24).
- All SAEs and interventions undertaken at Investigator's site must have to be notified within 24 hours.
- All other sites' SAEs must be notified as per the timelines given in the guidelines or within 7 days of receipt.
- Safety Reports will be acknowledged by the Member Secretary and copy will be retained in the IHEC-CDCRI study file/binder.
- All the safety reports or updates will be circulated to the members by the member secretary during the meeting. If any clarification required related to the SAE, it will be raised to the Investigator and Investigator should clarify within required time frame.
- The SAE will be reviewed in the routine meeting or a special meeting can be arranged for reviewing the submitted SAE, if considered necessary based on the safety issues of the study participants.
- The EC will do due analysis of causality assessment of the SAEs and will classify the event as related or unrelated based on established scientific practices and published literature and drug labels.
- The EC will calculate the compensation for SAEs as prescribed in New Drugs and Clinical Trials Rules 2019 and will recommend to the CDSCO for the agency to consider the view of the EC while it is analyzing the SAE reports.
- The views and the decision made by the IHEC-CDCRI on the submitted SAE including the causality assessment and compensation will be

communicated to the regulatory authorities within 30 days of occurrence of the SAEs.

- Ethics Committee has an authority to suspend or terminate approval of research project that has been associated with unexpected serious harm to subjects.

26.5 Premature Termination / Suspension / Discontinuation:

- Premature termination, discontinuation or suspension of study or study participants should be notified to the EC in the prescribed format (Annexure 25).
- Reason for termination / suspension / discontinuation, action taken after termination, and plans for post study follow up of patients should be mentioned.

26.6 Study Completion / Final Report Submission:

- Final report should be submitted at the end of study in the prescribed format (Annexure 26).
- The Administrative Staff will verify the completeness of all the reports sent to IHEC-CDCRI. The reports will be circulated in the meeting.

27. Procedure for Documentation and Record Retention

- Records can be maintained either as hard copies or soft copies. A separate data base / portal may be created for this purpose.
- All the documents will be filed in the respective binders/ folders.
- Administrative Staff is responsible for secured maintenance of documentation.
- Member Secretary/Administrative Staff will have an access to the documents and are responsible for archival of records.

- Upon receiving request in writing from the relevant authorities, documents will be made available for the inspection/audit.

27.1 Duration of Record Retention:

- All records must be archived for a period of at least 3 years after the completion/termination of the study.
- Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study.
- Records may be archived for a longer period, if required by the sponsors/regulatory bodies.

27.2 Documents to be Maintained by the EC:

The list of documents to be maintained / archived by the EC are tabulated below:

Proposal Related Documents	Administrative Documents
• One hard copy and a soft copy of the initial research proposal and all related documents • Decision letters • Any amendments submitted for review and approval • Regulatory approvals • SAE, AE reports • Protocol deviations/violations • Progress reports, continuing review activities, site monitoring reports • Record of premature termination /suspension • Final report of the study • Publications, if any	• Constitution and composition of the EC • Appointment letters • Curriculum vitae of all EC members (Self-Attested) • Signed confidentiality agreements • COI declarations of members • Training records of EC members • Financial records of EC • Registration/accreditation documents • A copies of national and international guidelines • Regulatory notifications • Meeting-related documents • Agenda and minutes • All communications received or made by the EC • SOPs (All versions)

28. Monitoring Own Conduct of IHEC-CDCRI

- The EC is open for any external audit / inspection by the sponsor or regulatory agency.
- Periodic internal audit is scheduled once in 6 months.
- During internal audits, the functioning of the EC will be assessed for compliance to the EC SOP and regulatory requirements. The scope of the audit will also include the timely disposal of cases for which the adherence of timelines specified in the SOP and regulatory requirements will be scrutinized.
- The Chairperson in consultation with the member secretary will appoint any one of the members IHEC-CDCRI or any technically competent person from the Institute "Chettinad Dental College and Research Institute" or outside of the Institute to audit and submit the report.
- The records and registers will be scrutinized and if needed appropriate corrective and preventive actions will be initiated.
- The audit report will be placed in a full board EC meeting and discussed.
- The EC shall decide suitably if any corrective action is required.

29. Responsibilities of the Investigator(s)

- Investigator should not start the study unless and until the final approval is obtained from IHEC-CDCRI.
- All the documents required for the proposal should be submitted to the EC for review.
- Investigator should adhere to the study protocol which is approved by the IHEC-CDCRI throughout the conduct of the study.

29.10 Benefit-Risk Assessment:

- All research should be directed towards enhancing knowledge about the human condition while maintaining sensitivity to the Indian cultural, social, and natural environment.
- The research should be conducted under conditions such that no person or persons become mere means for the betterment of others and that human beings who are participating in any biomedical and/ or health research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency.
- The researcher / sponsor should attempt to maximize benefits and minimize risks to participants so that risks are balanced to lead to potential benefits at individual, societal and/or community levels.

29.11 Maintaining Privacy and Confidentiality:

- The researcher should safeguard the confidentiality of research related data of participants and the community.
- Potential limitations to ensure strict confidentiality must be explained to the participant.
- Researchers must inform prospective participants that although every effort will be made to protect privacy and ensure confidentiality, it may not be possible to do so under certain circumstances.
- Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published.
- A specific re-consent would be required for publication, if this was not previously obtained.
- Data of individual participants/community may be disclosed in certain circumstances with the permission of the EC such as specific orders of a court of law, public health risk etc.

29.12 Proving Information to Participants:

- Investigators have a responsibility to keep the research participants informed of the progress of research by appropriate means, at suitable time-frames in simple and non-technical language.
- Investigators must provide all the details as mentioned in the participant information sheet (Annexure 14).
- Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his / her attendant.

29.13 Obtaining Informed Consent:

- Informed consent should be obtained from all the participants before their participation in the study (Annexure 15).
- Site Specific Informed Consent Form is Mandatory.
- Consent along with translation in regional languages is mandatory.

29.14 Investigator Declaration:

- Researchers/ sponsors must ensure that they declare all financial and non-financial (personal, academic or political) conflicts of interests the EC during protocol submission (Annexure 12).
- A separate investigator declaration must be submitted (Annexure 13).
- EC has the right to suspend any study if any conflicts of interests are identified during the progress of the study.

29.15 Compensation for Research Related Harm:

- The Principal Investigator/Co-Investigator should submit the safety updates of the research projects in the prescribed format (Annexure 24).
- All SAEs and interventions undertaken at Investigator's site must have to be notified within 24 hours.

- All other sites' SAEs must be notified as per the timelines given in the guidelines or within 7 days of receipt.
- The investigators / Institution must ensure that all the trial participants have an insurance cover for trial related injury or harm.
- Insurance policy document must be submitted along with the protocol for review. The document should have details of conditions for coverage, date of commencement and expiry of the policy.
- Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.
- For other sponsored research, it is the responsibility of the sponsor to include insurance coverage or provision for possible compensation for research related injury or harm.

29.16 Providing Ancillary Care to Participants:

- Participants should be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the EC.

29.17 Registration of Clinical Trials:

- The investigators must ensure that all clinical trials are prospectively registered in the CTRI.
- The trial registration document must be submitted during the review.
- If trial registration is not completed at the time of submission to the EC, it must be completed before the commencement of the trial.
- No trial can be started without completion of CTRI registration.

29.18 Timely Submission of Reports to the EC:

All the investigators must submit the following reports to the EC in a timely manner as applicable:

- Notification of any protocol amendments (Annexure 21)
- Continuing Review / annual Report (Annexure 22)
- Any deviations/ violations in protocol (Annexure 23)
- AE/SAE (Annexure 24)
- Discontinuation / suspension of research (Annexure 25)
- Study completion/ final report (Annexure 26)

29.19 Post-Research Benefit Sharing:

- The research team should make plans wherever applicable for post-research access and sharing of academic or intervention benefits with the participants, including those in the control group.
- The benefits accruing from research should be made accessible to individuals, communities, and populations whenever relevant.

29.20 Responsible Authorship and Publication:

- The authorship of research should be considered at the time of its initiation.
- Authorship should never be gifted and 'ghost' authors are not acceptable.
- The primary author should be the person who has done most of the research work related to the manuscript being submitted for publication.
- Research performed as part of a mandatory requirement of a course/fellowship/training program including student research should have the candidate as the primary author.

The researchers should follow the guidelines of International Committee of Medical Journal Editors (ICMJE) on authorship as follows:

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

30. Guidelines for Compensation of Research Participants

IHEC-CDCRI strongly claims that issuing suitable compensation to the research participants whenever applicable is the primary obligation of the sponsor be it a pharmaceutical company, a government agency, or an institution.

30.1 Compensation in Case of Injury or Death During Clinical Trial

- In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.
- In case the injury occurring to the trial subject is a SAE and related to the clinical trial, such subject shall also be entitled for financial compensation as per New Drugs and Clinical Trials Rules 2019, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.
- In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation, as per the order of the licensing authority defined in New Drugs and Clinical Trials

Rules 2019, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

- The expenses on medical management and the financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.
- Any injury or death of the subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee(s), as the case may be, are entitled for financial compensation for such injury (SAE) or death:
    - Adverse effect of investigational product(s);
    - Violation of the approved protocol,
    - Failure of investigational product to provide intended therapeutic effect;
    - Use of placebo in a placebo-controlled trial;
    - Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
    - For injury to a child in-utero because of the participation of parent in clinical trial;
    - Any clinical trial procedures involved in the study.
- The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation, if the injury or death has occurred because of any of the above reasons.
- The Sponsor, whether a pharmaceutical company or an institution shall give an undertaking along with the application for clinical trial permission to the licensing authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.
- In case the sponsor fails to provide medical management for the injury to the subject and / or financial compensation to the trial subject for

clinical trial related injury or financial compensation to the subject's nominee(s) in case of clinical trial related death of the subject, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons thereof, suspend or cancel the clinical trial and / or restrict sponsor including his representative(s) to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

30.2 Responsibilities of Sponsor:

- Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairperson of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing authority with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event of death.
- The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairperson of the Ethics Committee and the head of the Institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event.
- In case of injury or death occurring to the clinical trial subject, the sponsor (whether a Pharmaceutical Company or an institution) or his representative, whosoever had obtained permission from the Licensing authority for conduct of the clinical trial, shall make payment for medical management of the subject and provide financial compensation for the clinical trial related injury or death in the manner as prescribed in the New Drugs and Clinical Trials Rules 2019.
- The sponsor (whether a Pharmaceutical Company or an institution) or his representative, whosoever had obtained permission from the

Licensing authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

30.3 Responsibilities of the Investigator(s):

- During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events.
- Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority, Sponsor or his representative, whosoever had obtained Permission from the Licensing Authority for conduct of the clinical trial and the Ethics committee that accorded approval to the study protocol, within 24 hours of their occurrence.
- The report of the serious adverse event of death, after due analysis shall be forwarded by the Investigator to chairperson of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event of death.
- The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairperson of the Ethics Committee and the head of the Institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event.

30.4 Responsibilities of the Ethics Committee:

- In case of serious adverse event of death occurring to the trial subject, the Ethics Committee shall forward it's report on the serious adverse event of death, after due analysis, along with its opinion on the financial

compensation, if any, to be paid by the Sponsor or his representative, whosoever had Obtained permission from the Licensing for conducting the clinical trial, to the Chairman of the Expert committee Constituted by the Licensing Authority with a copy of the report to the Licensing Authority within 30 calendar days of the occurrence of the Serious adverse event of death.

- In case of serious adverse event other than death occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the Licensing Authority within 30 calendar days of the occurrence of the serious adverse event.

30.5 Serious Adverse Event:

- A serious adverse event is an untoward medical occurrence during clinical trial that is associated with death, in patient hospitalization (in case the study was being conducted on out-patient), prolongation of hospitalization (in case the study was being conducted on in-patient), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life threatening.

31. Guidelines for Protection of Vulnerable Population

IHEC-CDCRI emphasize & exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy aca1demic institutions), patients with incurable diseases, um-employed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, fetuses/neonates, pregnant women, minors or others incapable of personally giving consent.

IHEC-CDCRI will take all possible efforts to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed such as,

- Research on genetics should not lead to racial inequalities;
- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
- Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected and hence IHEC-CDCRI will take all necessary safeguarding measures for the same. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented- IHEC-CDCRI may even ask the Investigator for the copy of the ICF signed by such participants along with the ICF administration process and may also oversee the ICF administration & consent process taking place at the site;
- Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel

etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

31.1 Research Involving Pregnant Women & Fetus

- Research involving pregnant women and fetuses should involve the least possible risk.
- IHEC-CDCRI will document specific findings to minimize the potential for risk or harm to the fetus, and additional attention must be given to the conditions for obtaining informed consent.
- IHEC-CDCRI vigilantly ensures that the Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries, the objective of obtaining new knowledge about the fetus, pregnancy and lactation, the design to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be the suitable participants.
- IHEC-CDCRI demands a proper justification for participation of Pregnant or nursing women that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing prenatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy etc.
- IHEC-CDCRI always makes sure that women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast- feeding to the nursing child should be properly assessed except in those studies where

breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

- IHEC-CDCRI ensures that pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.
- IHEC-CDCRI in the event of research related to pre-natal diagnostic techniques, will ensure that such research is limited to detect fetal abnormalities or genetic disorders and not for sex determination as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994

31.2 Research Involving Children:

- IHEC-CDCRI has strong concerns on undertaking the research on Children by the Investigator and also ensures the following,
- Children will not be involved in research that could be carried out equally well with adults;
- The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug, the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
- A parent or legal guardian of each child has given proxy consent;
- The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
- Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;

- Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
- The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
- The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

32. Bibliography

1. National Ethical Guidelines for Biomedical & Health Research Involving Human Participants, 2017.
2. Handbook on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2018.
3. New Drugs and Clinical Trial Rules, 2019.
4. National Ethical Guidelines for Biomedical Research Involving Children, 2017
5. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, 2020.
6. International Ethical Guidelines for Health-related Research Involving Humans (CIOMS and WHO), Geneva, 2016.
7. Standards and operational guidance for ethics review of health-related research with human participants (WHO), 2011.
8. Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), 2016.
9. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
10. The Belmont Report, 1979.
11. Nuremberg Code, 1947.

ANNEXURE 1

FORMAT FOR BIO-DATA

1. **Name:**

2. **Address (full work address):**

3. **Telephone number:** **E-mail-ID:**

4. **Present affiliation (Job title, department, and organization):**

5. **Affiliation with host institute: Yes/No**

6. **Qualification (starting from basic, add additional rows if needed):**

COURSE/SUBJECT	INSTITUTE/ORGANIZATION	YEAR

7. **Previous and other affiliations (add additional rows if needed):**

AFFILIATION	DESIGNATION	DURATION

8. **Role in proposed Ethics Committee (also add dual Role if any):**

9. **Suitability of the member in the assigned role, Elaborate (less than 100 words):**

10. **Previous EC experience: YES/NO, if yes add role/ duration with name of EC:**

NAME OF ETHICS COMMITTEE	DESIGNATION/ ROLE	DURATION	
		FROM	TO

11. **Relevant research training/experience in the area*:(add additional rows if needed):**

NAME OF ETHICS COURSE/ TRAINING	ORGANIZED BY	DATE	DURATION OF TIMIMG	ATTACH AGENDA/ TOPICS COVERED

12. **Relevant publications (any 5) and additional information (if any):**

Signature: **Date:**

* *Details must primarily include training in ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, GCP Guidelines (if applicable), New Drugs and Clinical Trials (NDCT) Rules, 2019, EC Functions & SOPs and relevant regulations of the country.*

ANNEXURE 2

INVITATION LETTER TO A MEMBER

Letter head

Letter Ref No: **Date:**

From

The Principal,

Chettinad Dental College and Research Institute,

Rajiv Gandhi Salai, Kelambakkam,

Kancheepuram Dt,

Tamil Nadu - 603103

To

Dear Sir/Madam

Greetings from Chettinad Dental College and Research Institute, Kelambakkam

Sub: Invitation to be a member for Institutional Human Ethics Committee of Chettinad Dental College and Research Institute (IHEC-CDCRI) – Reg.,

Based on your expertise in the field of medicine/dentistry and research, you are cordially invited to be a member of IHEC-CDCRI for a period of five years. I request you to kindly accept our invitation and confirm the same at the earliest. I'm attaching a copy of the Terms of Reference (TOR) along with this letter.

This is issued with approval of competent authority.

With Regards,

Principal

CDCRI

ANNEXURE 3

LETTER OF ACCEPTANCE FROM A MEMBER

From, Date:

To,

The Dean

The Principal,

Chettinad Dental College and Research Institute,

Rajiv Gandhi Salai, Kelambakkam,

Kancheepuram Dt,

Tamil Nadu – 603103

Dear Sir/Madam,

Sub: Consent to be a member of Institute Ethics Committee (IEC) - Reg.

Ref: Your Letter No: dated:

With reference to your letter stated above, I hereby extend my willingness to become a member of Institutional Human Ethics Committee of Chettinad Dental College and Research Institute (IHEC-CDCRI). I shall regularly attend EC meetings and shall abide by all the terms and conditions as required by the EC.

Thanking you,

Yours sincerely,

Signature with date

Name of the Member:

Address:

Telephone No: (Off) (Res):

E-mail:

ANNEXURE 4

Letter head

APPOINTMENT ORDER FOR EC MEMBER

Ref No: **Date:**

Dr/ Mr. / Mrs.:

I am pleased to appoint you as the _____ of the Institutional Human Ethics Committee - Chettinad Dental College and Research Institute (IHEC-CDRI) following the receipt of your acceptance letter. The appointment shall be effective from _____ for a period of _____ years / months or till further notice provided the following conditions are satisfied.

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

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

We sincerely hope your association with IHEC-CDCRI will be scientifically productive and beneficial to the Institute & the community at large.

Principal

CDCRI

ANNEXURE 5

LIST OF MEMBERS IN IHEC-CDCRI

S.No	Name	Qualification with Specialization	Current Organization	Telephone, Fax number, E-Mail and Address	Role of member in IHEC-CDCRI	Affiliation of member with CDCRI

Principal

CDCRI

ANNEXURE 6

CONFIDENTIALITY DISCLOSURE AGREEMENT

As member of IHEC- CDCRI, I hereby declare that,

- I will strictly follow the confidentiality regarding the committee and research projects.
- I will not disclose any information disclosed at EC meetings
- I will use confidential information only to fulfill the obligations of reviewing proposals.
- I will not reproduce information disclosed during IHEC-CDCRI deliberations.
- I will not disclose any confidential information to third party

This applies for a period of 5 years from my acceptance.

Signature:

Name:

Designation in Committee:

Date:

ANNEXURE 7

CONFLICT OF INTEREST DECLARATION FORM FOR EC MEMBER

In accordance with the policy of the IHEC-CDCRI, I would like to bring it to the notice of the committee that I have a conflict of interest, in this research project titled _____ and shall not participate in the review, comment, or approval of any activity related to the project.

Reason/s:

Signature:

Name:

Designation in the Committee:

Date:

ANNEXURE 8

Letter Head

IHEC-CDCRI MEETING AGENDA

Letter Ref No: Date:

Venue:

Meeting Date:

Time:

General Discussion: (Please mention list of topics for discussion)

Protocol for Discussion: (Please mention protocols for discussion including Investigator details)

The soft copy / hard copy of the study documents for above mentioned Protocol(s) were submitted for your review. The Principal Investigator/Designee will present the protocols during the meeting.

Member Secretary,
IHEC-CDCRI

ANNEXURE 9

Letter Head

MINUTES OF THE MEETING OF IHEC-CDCRI

1. **Date of Meeting:**
2. **Time of Meeting:**
3. **Venue / Mode of Meeting:**
4. **Meeting Agenda:**
5. **COI Declaration by Members:**
6. **Members Present:**
7. **Members Absent / Left During the Meeting:**
8. **Discussion Points:**
9. **Decision on Proposals:** list of approved, revision required, rejected.
10. **The outcome of voting, if any**.

Signature of Member Secretary	**Signature of Chairperson**
IHEC-CDCRI	**IHEC-CDCRI**
Date:	**Date:**

ANNEXURE 10

COVERING LETTER FOR SUBMISSION OF PROTOCOL

From, Date:

To

The Member Secretary,

IHEC-CDCRI,

<EC Address>

Dear Sir/Madam,

Subject: Submission of Research for Ethics Review by IHEC-CDCRI

Proposal Title:

We are submitting our research proposal titled "_____" for ethics review to IHEC-CDCRI. We are attaching all the documents as mentioned in the check list along with this letter. We request the ethics committee to consider our proposal for review and approval in the forthcoming meeting.

Thanking you,

Sincerely

Signature of the Principal Investigator

Name:

Affiliation and Designation:

Phone No.

E- Mail:

ANNEXURE 11

Check List of Documents Submitted for EC Review		
No.	Document	Tick if Applicable
1	Covering Letter	
2	Research Protocol	
3	Investigator Declaration	
4	Patient Information Sheet (English and Local Language)	
5	Informed Consent form (English and Local Language)	
6	Application for Exempt from Review	
7	Application for Expedited Review	
8	Case Record Form/ Questionnaire	
9	Recruitment Notices/ Advertisement	
10	Investigators Brochures	
11	Brief CV of all Investigators	
12	Ethics / GCP Training Certificates of Investigators	
13	MoU (Only for External Institutes)	
14	CTRI Registration (Prospective Registration)	
15	Insurance Policy for Participants	
16	Indemnity Policy of Investigators	

Signature of the Principal Investigator

Name:

Affiliation and Designation:

Phone No.

E- Mail:

ANNEXURE 12

Instructions:

- Page A4, Normal Margins, Double line spacing, Alignment - Justified
- Font Times New Roman, Size: Headings – 14, Text-12.

RESEARCH PROTOCOL FORMAT

1. **Title Page:**
   - Title - Should be concise, may include study design such as randomized controlled trial; an observational study; a case-control study etc.
   - Mention PI & Co-PI- names, qualification, affiliation & contact details.

2. **Abstract (up to 250 words):** structured abstract - Background, Objectives, Methods, and Expected Outcomes.

3. **Background (up to 500 words)**: State the research problem/question and how the present work answers the same.

4. **Study Objectives:** Clearly mention primary and secondary objectives.

5. **Methodology (up to 2000 words):** Include the following subheads

   i. Study Population: define the population, mention source of samples.
   ii. Inclusion/ Exclusion Criteria: mention the criteria used for screening the patients
   iii. Study Design: RCT, Cohort, Case-Control etc. If, RCT mention method of randomization, blinding, allocation concealment etc.
   iv. Sample Size: should have adequate power to the study to satisfactorily answer all the primary objectives,
   v. Intervention and Control: mention the new interventions and appropriate controls, if placebo is used – justify the same.
   vi. Methods: details of procedures, tools for testing, how the measurements will be made and recorded etc.,
   vii. Plan for Data Collection: mention the tools used for data collection, coding of data, storage of data.
   viii. Statistical analysis: mention type of testing, software/ tool to be used.

6. **Ethical Issues:** discuss all the ethical issues in the proposal –
    - Risk Assessment – mention the risk category
    - Privacy and Confidentiality: steps taken to maintain privacy
    - Informed consent form: English & local language (as attachment)
    - Patient information sheet: English & local language (as attachment)
    - Compensation for injury/ harm due to research
    - Ancillary care for participants
    - Insurance for trial participants (only for clinical trials)
    - Indemnity of investigators

    ,
7. **Expected Outcomes (up to 100 words):** mention how the proposal will add to / improve existing knowledge.

8. **Conflicts of Interest:** Declare financial and non-financial conflicts of interests of all the investigators.

9. **Sources of Funding/ Sponsors:** Mention the funds received for the project either from funding agencies or from sponsors. If self-funded -mention it.

10. **Duration of Study / Timeline:** Details of activities to be carried out along with timelines during preparatory phase, data collection, analysis & report writing to be provided.

11. **Institutional Support:** mention all the support which is given by the institute, including materials, equipment, work space etc.

12. **Plan for Publication:**
    - Post research benefit sharing
    - Authorship of investigators – according to ICMJE criteria (Refer SOP)
    - Informed consent from participants
    - Plan for privacy of patients during publication

ANNEXURE 13

INVESTIGATOR DECLARATION	
	Tick
I/We certify that the information provided in this application is complete and correct.	
I/We confirm that all investigators have approved the submitted version of proposal/related documents.	
I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines.	
I/We confirm that this study will be conducted in accordance with the New Drugs and Clinical Trial Rules, 2019 / GCP guidelines and other applicable regulations and guidelines.	
I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.	
I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.	
I/We declare that the expenditure in case of injury related to the study will be taken care of.	
I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.	
I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and participate in any audit of the study if needed.	
I/We confirm that we will maintain accurate and complete records of all aspects of the study.	
I/We will protect the privacy of participants and assure confidentiality of data and biological samples.	
I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.	
I/We have the following conflict of interest (PI/Co-PI): (mention "Nil" if not applicable) 1. ……. 2. …….	

Name	**Signature**	**Date**
1.PI……..		
2.Co-PI-1……		
3.CO-PI-2……...		
4.Co-PI-3……		

ANNEXURE 14

PARTICIPANT'S INFORMATION SHEET

IHEC-CDCRI Approval No: _____ Date: _____

1. Public Title: in simple layman terms – should mention the term that the project is a Research
2. Scientific Title: should be exact terms as mentioned in proposal.
3. Purpose of the Research: mention in simple terms
4. Objectives of the Research: in simple terms – what all will be measured
5. Expected Duration: frequency of contact with estimated number of participants to be enrolled, types of data collection and methods.
6. Benefits to the Participant / Community: as an outcome of the research
7. Risks: Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study.
8. Alternative Treatments: Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected
9. Confidentiality: limits to which the researcher would be able to safeguard confidentiality - Include plan for publication and post research data sharing.
10. Payment/reimbursement for participation: payment of incidental expenses, of compensation for loss of pay etc.
11. Compensation for harm / injury: providing free treatment for any injury/ harm arising out of the study and for ancillary care.
12. Insurance Coverage: if any for research related harm / injury
13. Freedom of Participation: to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled
14. Contact Details: research team and contact persons with addresses and phone numbers of PI, Co-PI and any other helpline number.

ANNEXURE 15

INFORMED CONSENT FORM

Proposal No.: _____ **Date:**_____

Title of the Project:

_____

Participant Declaration	**Tick**
The contents of the information sheet dated _____ that was provided have been read carefully by me / explained in detail tome, in a language that I comprehend, and I have fully understood the contents.	
I confirm that I have had the opportunity to ask questions.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.	
The nature and purpose of the study and its potential risks / benefits and expected duration of the study	
I give permission for these individuals to access and publish my records/ data collected for the purpose of this study.	
All compensation agreements have been discussed with me	
I agree to take part in the above study.	

(Signatures /Left Thumb Impression of Participant)

Name of the Participant: _____ _____

Son / Daughter / Spouse of: _____

Complete Postal Address: _____

Date: _____ Place: _____

This is to certify that the above consent has been obtained in my presence.

	Name	Signature	Date and Place
Principal Investigator	_____	_____	_____
Witness -1	_____	_____	_____
Witness -2	_____	_____	_____

1. **Three copies should be made, for (a) Participant, (b) Researcher, (c) Institution**
2. **This form must be translated to the local language as applicable.**

ANNEXURE 16

Letter Head

APPROVAL OF PROTOCOL FROM SCIENTIFIC COMMITTEE

Letter Ref. No:_____ **Date:**_____

This is to certify that the research proposal titled _____ submitted by_____, Student/Faculty of _____ has been reviewed and approved by the Scientific Committee of Chettinad Dental College and Research Institute.

Chairperson/ Convener Research
Scientific Committee
Chettinad Dental College and Research Institute,
Rajiv Gandhi Salai, Kelambakkam,
Kancheepuram Dt, TN- 603103

ANNEXURE 17

APPLICATION FORM FOR EXPEDITED REVIEW

Title of the Study	
PI Details	

1. Choose why expedited review is requested:

Reason	**Tick**
Involves non-identifiable specimen and human tissue from blood banks, tissue banks, left over clinical samples	
Involves clinical documentation materials that are non-identifiable (documents, records, data)	
Modification or amendments to approved protocol (only administrative changes, typographical errors and change in researcher)	
Minor deviation from approved protocol which causes no or minimal risk	
Multicentre study where one of the participating EC's has already approved the proposal	
Research during emergency	
Any other:	

2. Is waiver of consent being requested? YES/ NO

3. Does research involve vulnerable population? YES/ NO

If yes, please provide details

_____

Signature of the PI with date: …….

Comments of the EC: ……

Signature of the Member Secretary: ……...……

ANNEXURE 18

APPLICATION FORM FOR EXEMPTION FROM REVIEW

Title of the Study	
PI Details	

1. Choose why expedited review is requested:

Reason	**Tick**
Research on data in public domain – systematic review, meta-analysis	
Observation of public behaviour/ information recorded without linked identifiers and disclosure would not harm the interest of the observed person.	
Quality control and quality assurance audits in institution	
Comparison among instructional techniques, curricula, or classroom methods.	
Consumer acceptance study related to taste and food quality	
Public health programs by Govt. agencies	
Any other:	

Signature of the PI with date: …….

Comments of the EC: ……

Signature of the Member Secretary: ……...……

ANNEXURE 19

CHECK LIST FOR REVIEW OF PROPOSAL

No.	Item	Yes / No	EC Remarks
1	Cover letter		
2	Brief CV of all Investigators		
3	Good Clinical Practice (GCP) training of investigators in last 3 years		
4	Approval of scientific committee		
5	EC clearance of other centres*		
6	Agreement between collaborating partners*		
7	MTA between collaborating partners*		
8	Insurance policy/certificate		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification		
10	Copy of contract or agreement signed with the sponsor or donor agency		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol		
12	Research Protocol		
13	Investigator Brochures/ Advertisements		
14	Participant information sheet and consent form		
15	Proforma/ Questionnaire		
16	CTRI Registration		
17	Other Documents as applicable:		

ANNEXURE 20

Letter Head

FORMAT FOR COMMUNICATING THE EC DECISION

To **Date:**

Principal Investigator Name

Address, Institute

Respected Sir / Madam,

Sub: Your Proposal Reviewed - Communication of Decision - Regarding

IHEC-CDCRI Ref No: _____

The Institutional Human Ethics Committee - Chettinad Dental College and Research Institute (IHEC-CDCRI) has reviewed your proposal titled "_____" on "_____" and the following decision has been taken based on the deliberations and discussions.

Decision:

Comments:

Yours Sincerely

Member Secretary

IHEC-CDCRI.

ANNEXURE 21

APPLICATION / NOTIFICATION FORM FOR PROTOCOL AMENDMENTS

Title of the Study	
PI Details	
IHEC-CDCRI Approval No.	

1. Date of EC Approval: _____ Date of Start of Study: _____
2. Details of Amendments:

S.No.	Existing Provision	Proposed Amendment	Reason	Location in the Protocol (Page No.)

3. Impact on benefit-risk analysis? YES/ NO

   If yes, give details: _____

4. Is any re-consent necessary? YES/ NO

   If yes, have necessary changes been made in the consent form? YES/ NO

5. Type of review requested for amendment:

   - ☐ Expedited Review (no alteration in risk to participants)
   - ☐ Full review (there is an increased alteration in the risk to participants)

Signature of the PI with date: …….

ANNEXURE 22

CONTINUING REVIEW / ANNUAL REPORT FORMAT

Title of the Study	
PI Details	
IHEC-CDCRI Approval No.	

1. Date of EC approval: _____
2. Date of start of study: _____ Proposed date of completion: _____
3. Annual report period: From _____ to _____
4. Does study involve recruitment of participants? YES / NO
   a) If yes, Total expected: ____ Total screened: _____ Total enrolled:_____
      Number completed: _____ No on follow-up: _____
5. Have any patients withdrawn from the study? YES / NO
   a) If yes, total number withdrawn: _____
   b) Reason for withdrawal: _____
6. Will the study to extend beyond the stated period? YES / NO
   If yes, state the reason: _____
7. Have there been any amendments in the research protocol? YES / NO
   a) If yes, provide date of approval of the amended protocol: _____
   b) Details of re-consent from participants: _____

Signature of the PI with date: ……

ANNEXURE 23

PROTOCOL VIOLATION / DEVIATION REPORTING FORM

Title of the Study	
PI Details	
IHEC-CDCRI Approval No.	

1. Date of EC approval: _____
2. Date of start of study: _____ Proposed date of completion: _____
3. Participant ID: _____ Date of occurrence: _____
4. Total no. of deviations/violations reported till date in the study: _____
5. Deviation / violation observed by:
   - ☐ PI and study team
   - ☐ Sponsor
   - ☐ Monitor
   - ☐ SAE sub-committee / EC
6. Provide details of violation:

   ……

   ……
7. Corrective action taken by PI/Co-PI:

   ……

   ……
8. Impact on: ☐ Study participants ☐ Quality of data
9. Any changes in the study protocol is required? YES / NO

   If yes, provide details: ……

Signature of the PI with date: ……

ANNEXURE 24

SERIOUS ADVERSE EVENT REPORTING FORMAT

Title of the Study	
PI Details	
IHEC-CDCRI Approval No.	

1. Participant details:

Initials and ID …… Age ……. Gender ……. Weight …… Height ……...

2. Suspected SAE diagnosis: …….

3. SAE details:

Date of onset of SAE: ……..

Date of reporting SAE: …….

Describe the event: …….

4. Suspected intervention causing the SAE: ……...

5. Report type: Initial Follow-up Final

6. Have any similar SAE occurred previously in this study? YES/ NO

If, yes provide details: ……

Signature of the PI with date: …….

ANNEXURE 25

PREMATURE TERMINATION / DISCONTINUATION REPORT FORMAT

Title of the Study	
PI Details	
IHEC-CDCRI Approval No.	

1. Date of EC approval: _____ Date of start of study: _____
2. Date of last progress report submitted to EC: _____
3. Date of termination / discontinuation/ suspension: _____
4. Reason for termination / discontinuation / suspension:

   ……

   ……
5. Action taken post termination / discontinuation / suspension:

   ……

   ……
6. Plans for post-study follow up / withdrawal:

   ……

   ……
7. Details of study participants:

   Total to be recruited: _____ Screened: _____ Enrolled:_____

   Consent Withdrawn:_____ Withdrawn by PI: _____

   Reason: ……

Signature of the PI with date: ……

ANNEXURE 26

STUDY COMPLETION / FINAL REPORT FORMAT

Title of the Study	
PI Details	
IHEC-CDCRI Approval No.	

1. Date of EC approval: _____ Date of start of study: _____
2. Date of completion of study: _____
3. Provide details of:

   Total recruitment approved by EC: _____ Total Enrolled:_____

   Consent Withdrawn: _____ Withdrawn by PI: _____
4. Describe in brief publications/ presentations / dissemination plans:

   ……

   ……
5. State the number of violations / deviations / amendments made:

   ……
6. Describe plans for archival of records / record retention:

   ……

   ……
7. Describe the positive and negative effects of your findings on community:

   ……

   ……

   ……

Signature of the PI with date: ……

ANNEXURE 27

DRAFT of MoU BETWEEN IHEC-CDCRI AND EXTERNAL SITE

1. PARTIES

This MoU made and entered into on_____ (effective date) between **AAA,** "_____" and having its registered office "_____" of the **FIRST PART**,

AND

Institutional Human Ethics Committee- Chettinad Dental College and Research Institute, Chettinad Health City, Raji Gandhi Salai (OMR), Kelambakkam, Kancheepuram Dt, Tamil Nadu – 603103. (Herein after called "IHEC-CDCRI" which expression shall, where the context so admits, include its successors, and permitted assigns) of the **SECOND PART**.

2. BACKGROUND

2.1 WHEREAS IHEC-CDCRI and AAA are desirous of collaborating with each other using the facilities and expertise that is specific to the collaborative work proposed (**hereinafter called the PROJECT**) as per the scope of the work detailed in section 3.2

2.2 The parties have identified that a strong relationship between them is mutually beneficial and wish to establish a more formal relationship through this MoU.

3. SCOPE OF THE MOU

3.1 The MoU details the terms and conditions, financial arrangements, modalities of collaboration, responsibilities, and obligations of IHEC-CDCRI and AAA pertaining to the collaboration undertaken under the PROJECT.

3.2 AAA will submit their clinical trial study protocols to IHEC-CDCRI for ethical review. The submission, review and decision making will be in compliance to the guidelines stipulated in "New Drugs and Clinical Trials Rules, 2019", "National Ethical Guidelines for Biomedical Research Involving Human Participants, 2017" and Guideline for Good Clinical Practice ICH E6(R2)".

4. FINANCIAL ARRANGEMENTS

4.1 AAA has decided to accept IHEC-CDCRI as its Ethics Committee to execute the clinical trial or study together, each party contributing their knowledge and expertise to the project.

4.2 AAA will provide fee to IHEC-CDCRI to cover the costs of services which may be decided by both the parties from time to time.

4.3 IHEC-CDCRI and AAA are to undertake this project at their own risk.

5. MODALITIES OF COLLABORATION

5.1 IHEC-CDCRI will enjoy all the rights of an institutional ethics committee and AAA is agreeable to have IHEC-CDCRI as their ethics committee to achieve the goals of the PROJECT.

5.2 The IHEC-CDCRI hereby agrees that it will be acting, in the performance of this MOU, as an independent contractor. The services will be performed directly by the IHEC-CDCRI who will provide the services in a timely, competent, and professional manner having at all times due regard to the AAA business operations.

6. RESPONSIBILITIES

6.1 Both the parties shall engage the necessary manpower, infrastructure, materials, etc., required for undertaking the PROJECT.

6.2 Neither party shall be responsible for any damage to the property of the other party caused by its personnel during or consequent to the work carried out under this MOU.

7. COMPLETION

7.1 The work envisaged to be done by AAA/ IHEC-CDCRI shall be deemed to have been successfully completed by AAA/ IHEC-CDCRI on submission of the Final Report / fulfilment of its / their responsibilities as detailed in the PROJECT.

8. RESULTS OF PROJECTS

8.1 Any intellectual property rights patents / design / trademark / copyrights obtained by the parties hereto pertaining to the PROJECT prior to signing of the MOU shall remain the property of the respective party.

8.2 The procedural formalities for securing and maintaining the intellectual property rights (patents / trademark / copyright) if any, shall be the joint responsibility of AAA and IHEC-CDCRI.

9. CONFIDENTIALITY

9.1 During the tenure of the MOU and for six months thereafter both AAA and IHEC-CDCRI undertake on behalf of their subcontractors / employees / representatives / associates to maintain strict confidentiality and prevent disclosure thereof, of all the information and data exchanged / generated pertaining to work under this MOU for any purposes other than in accordance with this MOU.

10. FORCE MAJEURE

10.1Neither party shall be held responsible for non-fulfilment of their respective obligations under this MOU due to the exigency of one or more of the force majeure events such as but not limited to Acts of God, war, flood, earthquakes, strike, lockouts, epidemics, civil commotion, etc., provided on the occurrence and cessation of any such events, the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continue beyond 6 months, the parties shall then mutually decide the future course of action.

11. EFFECTIVE DATE, DURATION, TERMINATION OF THE MOU

11.1 The MoU shall be effective from the effective date written above and shall remain in force for a period of ---- years from the said date, in the first instance.

11.2 The MU shall terminate on the expiry of the period, as in clause 12.1, unless extended by both the parties.

11.3 During the tenure of the MoU, parties hereto can terminate the MoU either for breach of any of the terms and conditions of this MoU or otherwise by giving 1 months' notice in writing to the defaulting party. Failure of either party to terminate the MoU on account of breach or default by the other shall not constitute a waiver of that party's right to terminate this MoU.

11.4 In the event of termination vide clause 12.3, the rights and obligations of the parties thereto shall be settled by mutual discussion;

11.5 Even if the agreement is terminated, the indemnity clause will be binding on both the parties as defined in clause 16 with regard to the studies reviewed by IHEC-CDCRI.

12. NOTICES

12.1 All notices and other communications required to be served on IHEC-CDCRI under the terms of this MOU shall be considered to be duly served if the same shall have been delivered to, left with or posted by registered mail to IHEC-CDCRI at its address mentioned in this document. Similarly, any notice to be given to the AAA shall be considered as duly served if the same have been delivered to, left with or posted by registered mail to the AAA at its registered address mentioned in this document.

13. AMENDMENTS TO THE MOU

13.1 No amendment or modification of this MoU shall be valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to be an amendment of this MoU. The modifications / changes shall be effective from the date on which they are made / executed, unless otherwise agreed to

14. ASSIGNMENT OF THE MOU

14.1 The rights and / or liabilities arising to any party to this MOU shall not be assigned except with the written consent of the other party and subject to such terms and conditions as may be mutually agreed upon.

15. ARBITRATION

15.1 In the event of any dispute arising out of or in connection with this MOU, the parties wish to seek an amicable settlement as per the laws of India and Tamil Nadu within the legal jurisdiction of Chennai.

16. INDEMNITY

16.1 AAA indemnifies the current members of the IHEC-CDCRI and will keep indemnified all the current members of IHEC-CDCRI against all claims, liabilities, demands, charges, loss, injuries, costs and expenses in respect of all and any decisions taken in good faith and acts done as members of the towards the review and / or approval of the clinical trial, as detailed in the IHEC-CDCRI approved study protocol and documents.

16.2 This Indemnity will cover the said members during their tenure of office and also cover claims etc. made after their tenure.

16.3 As and when there are fresh nominations to the Ethics Committee this indemnity will cover such members also.

SEAL OF PARTIES

In witness whereof the parties hereto have signed this MoU on the day, month, and year mentioned hereinabove.

Parties

For and on behalf of **AAA** Signature: Name: Designation: Seal:	**For and on behalf of** **IHEC-CDCRI** Signature: Name: Designation: Seal: