STANDARD OPERATINGPROCEDURES

ETHICS REVIEW COMMITTEE

FACULTY OF DENTAL SCIENCES,

UNIVERSITY OF PERADENIYA

Version 2.0

Compiled by the Ethics Review Committee,
Faculty of Dental Sciences,
University of Peradeniya.

Approved by:

Dean, Faculty of Dental Sciences
Peradeniya

Date:

STANDARD OPERATING PROCEDURES
ETHICS REVIEW COMMITTEE
FACULTY OF DENTAL SCIENCES

Name and Position in ERC	Signature	Date
Prof. B.M.H.S.K. Banneheka, Chairman		
Dr. R.M. Jayasinghe,Secretary		
Prof. S.L. Ekanayake, member		
Prof. A. Tilakaratne, member		
Prof. A.K.S. Arambawatta, member		
Prof. R.W. Pallegama, member		
Dr. W.B.M.C.R.D. Weerasekera, member		
Dr. D. LeukeBandara, member		
Dr. P.V.K.S. Hettiarachchi, member		
Dr. M.P. Paranagama, member		
Prof. B.S.M.S. Siriwardena- Co-ordinator, PG Division		
Prof. R.D. Jayasinghe, Chairman, Faculty Research Committee		
Mr. A.N.M. Salgado, External Member		
Prof. M.A.M. Sitheeque, External Member		
Dr. D. Herath, External Member		

Approved by

Name and Position	Signature	Date
Dr. JAVP Jayasinghe Dean/Faculty of Dental Sciences, University of Peradeniya		

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1. Purpose :

To describe the overall function and scope of responsibilities of the ERC of the Faculty of Dental Sciences (ERC-FDS), University of Peradeniya (UOP) to maintain ethical standards of research conducted in the institution or collaborated by its researchers conforming to the three basic ethical principles: respect for people, beneficence and justice, thereby safeguard the dignity, rights, safety, and well-being of all actual or potential research participants.
Further, the process ensures that the proposed research design is scientifically sound and appropriate for addressing the research questions and will not unnecessarily expose research participants to risk.
In its function, the ERC-FDS follows the guidelines set by World Medical Association in Declaration of Helsinki,the Council for International Organization of Medical Sciences (CIOMS) and the operational Guidelines set for Ethics Committees that Review Biomedical Research by the World Health Organization.

2. Scope of the SOPs:

The SOP applies to all activities under the ERC-FDS/UOP.

3. Responsibility of the members of the ERC:

It is the responsibility of the members of the ERC-FDS/UOP, to read and understand and respect and act according to the rules set by ERC.

4. Functions of the ERC:

4.1. Overall function

The primary objective of the Ethics Review Committee, Faculty of Dental Sciences (ERC-FDS), University of Peradeniya (UOP) is to protect the welfare, rights, dignity and safety of human participants used in researchconforming to the three basic ethical principles: respect for people, beneficence and justice. The research should never be permitted to override the health, well-being, and care of research participants. Benefits and burdens of research should be distributed evenly among all groups and classes in society, taking age, gender, economic status, culture and ethnic considerations into account. The Ethical Review Committee (ERC) provides an independent, competent and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, the ERC needs to have independence from political, institutional, professional, and market influencesandsimilarly, they need to demonstrate competence and efficiency in their work. The ERC is responsible for carrying out a review of the proposed research and also ensure that there is regular evaluation of ethics of ongoing studies that have been approved.

The ERC is responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, with due regard for the requirements stipulated by aforementioned guidelines (section 1 of SOP001/01.1).

4.1.1. The functions of the ERC are:

4.1.1.1. To provide independent, competent and timely review and monitoring of the ethics of research projects involving humans.

4.1.1.2. To work out the principles and procedures that govern research projects involving biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and related substances; and the development of new applications of health technology

4.1.2. The ERC shall review only research proposals submitted by students and staff of the University of Peradeniya, except as provided hereunder:

4.1.2.1. The ERC-FDS/UOP,may accept as valid, an ethics approval given by the recognized ERC of another institution, for the purpose of approving the commencement of a project.

4.1.2.2. The ERC may review research proposals from researchers outside the Faculty of Dental Sciences, University of Peradeniya provided a valid and current Memorandum of Understanding between the Faculty of Dental Sciences, University of Peradeniya and the institution to which the researcher is accredited exists.

4.1.2.3. The ERC may review proposals related to dental, oral and maxillofacial diseases of researchers attached to the Ministry of Health when submitted through the administrative authority of the institution where the research would be carried out.

4.1.2.4. The ERC may review proposals of research related to dental, oral and maxillofacial diseases submitted by postgraduate trainees when submitted through the relevant supervisor.

4.2. The terms “human research participants” applies to a participant who is a living person who takes part in a research study and cadavers. Research involving humans includes, but not limited to:

4.2.1. surveys, interviews, focus groups or ethnographic observations.

4.2.2. studies of a physiological, biochemical, pathological or social process among human populations;

4.2.3. review of medical record where there is access to personal information.

4.2.4. collection of data from registries, repositories or databases where personal medical information are stored;

4.2.5. use of biological specimens (tissues, biopsies, organs, blood, urine, saliva, faeces);

4.2.6. response to a specific intervention including diagnostic, preventive or therapeutic measures, or studies designed to determine the consequences for individuals and communities of implementing preventive or therapeutic measures;

4.2.7. studies concerning human health-related behaviour in a variety of circumstances and environments;

4.2.8. research involving children or other vulnerable populations;

4.2.9. research involving quasi-experimental or experimental intervention, drugs and devices;

4.3. The ERC shall assess projects submitted for review conforming to the FERCSL,FERCAP and other national and international guidelines and with national and international laws to determine their acceptability on matters of ethics. It shall include an examination of the scientificvalidityof the proposal.

4.4 The ERC may review projects involving quality assurance including audits.

5. Glossary:

5.1. SOP (Standard Operating Procedure)

Detailed, written instructions, describing all activities and actions undertaken by an organization to achieve uniformity of the performances of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the documentation of operations, whilst maintaining high standards of Good Clinical Practice.

5.2. ERC- FDS/ UOP

The Ethical Review Committee, Faculty of Dental Sciences, University of Peradeniya

5.3. FERCSL

The Forum of Ethical Review Committees in Sri Lanka

5.4. FERCAP

The Forum of Ethical Review Committees in the Asia Pacific region

5.5. Guideline

Any suggestion, rulesetc.,intended as a guide for specific practice

5.6. CIOMS

Council for International Organizations of Medical Sciences

6. References:

6.1. Declaration of Helsinki, World Medical Association. 64th WMA General Assembly, Fortaleza, Brazil, 2013.(http://www.wma.net/en/30publications/10policies/b3/)

6.2. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organizations of Medical Sciences. Geneva 2002. http://www.cioms.ch/publications/layout_guide2002.pdf

6.3. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.4. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Composition of membership
	SOP – 002 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   To describe the composition of membership of the ERC-FDS.

   The ERC-FDS/UOP consists of both scientists and non- scientists. It is independent in its reflections, advice and decisions. ThisSOP describes the framework for the constitution of the ERC.

2. **Scope:**

   This SOP applies to functions of the Faculty Board of Dental Scienceswhich appoints the members to the ERC-FDS/UOP.

3. **Responsibilities:**

   It is the responsibility of the Faculty Board of Dental Sciencesto read and understand and act accordingly in appointing members to the ERC

4. **Detailed instructions:**

   4.1. The composition of the ERC shall be in accordance with the FERCSL and other relevant national and international guidelines.

   4.2. Members shall be appointed to ensure the ERC has the expertise required to assess the applications submitted for consideration.

   4.3. Membership consists of a maximum of 15 members and, among them, there should be a lawyer, a social scientist and a lay member who are preferably not faculty members.

   4.4. The Dean of the Facultyand Heads of institutions shall not be members.

   4.5. The composition of the ERC shall be diverse and,gender, language and age balance be maintained.

   4.6. With a committee of 15, the quorum for meetings shall be seven.

   4.7. All members and the staff of the secretariat should sign the “confidentiality agreement”

5. Glossary :

5.1 ERC Members- Individuals serving as regular and alternative members on the ERC board. Theboard is constituted in accordance with the membership requirement of the FERCSL guidelines.

5.2. Non-faculty Members
ERC members who are not permanent staff members of the Faculty ofDental Sciences, University of Peradeniya.

6. References:

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/accessed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

6.3. Fernando M, Dissnayake VHW and Corea E. (2007). Ethics Review Committee Guidelines. A Guide for Developing Standard Operating procedures for Committees that Review Biomedical Research Proposals, Sri Lanka

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Appointment and responsibilities of members
	SOP – 003 - 2020 **Version 2.0, November 2020.**

1. **Purpose** :

   These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for theappointment of members and the responsibilities of members of ERC-FDS/UOP.

2. **Scope :**

   This SOP applies to the Faculty Board of Dental Sciencesand members of ERC-FDS/UOP.

3. **Responsibility:**

   It is the responsibility of the ERC members and the Faculty of Dental Sciencesto read and understands and respect the rules set by ERC of the Faculty of Dental Sciences, University of **Peradeniya.**

4. **Detailed instructions:**

   4.1. Members shall be appointed by the Faculty Boardbased on their knowledge, qualities and experience and not as representatives of any organisation, group or opinion. A prospective member who wishes to be appointed shall make a request to the Faculty Board.

   4.2. The letters of appointment shall be issued by the Dean.

   4.3. The Chairperson and secretary shall be nominated by the ERC from among its members. An individual should have at least three years' experience as a member of the ERC-FDS/UOP to be eligible to be elected to the post of Chairperson. The Dean shall issue the letters of appointment.

   4.4. Members are appointed in their individual capacity and not by designation.

   4.5. The letter of appointment (AF/01– 003/02.0) shall include the date of appointment, length of tenure, responsibilities/terms of references and the circumstances whereby membership may be terminated.

   4.6. Members shall agree to their name and profession being made available to the public, including being published on the ERC website.

   4.7. Members shall be required to sign a confidential agreement (AF/02– 003/02.0) and a declaration of conflicts of interest stating interalia, that all matters of which he/she becomes

aware during the course of his/her work on the ERC shall l be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the ERC shall be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a ERC member.

4.8. Upon appointment, members shall be provided with the following documents:
4.8.1.Terms of Reference of the ERC;
4.8.2. Standard Operating Procedures of the ERC;
4.8.3. Up-to-date list of members' of the ERC and their contact information.
4.8.4.Any other relevant information about the ERC's processes, procedures and proposals.

4.9. Members shall be appointed for a period of three years, renewable at the discretion of the Faculty Board. At the end of three (03) years the committee shall be reconstituted and the new committee shall comprise of at least five (05) who have a minimum of two years' experience as members of previous ERC's to maintain the expertise with the view to facilitate the efficient functioningof the ERC. Members who wish to be reappointed shall make a request to the Faculty Board.

4.10. Appointments shall allow for continuity, the development of expertise within the ERC, and the regular input of fresh ideas and approaches.

4.11. All members shall be encouraged to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions shall be met by the ERC.

4.12. Members shall not be remunerated. Members shall be reimbursed for legitimate expenses incurred in attending ERC meetings, such as travelling and parking expenses.

4.13. However, the non-affiliated members can claim subsistence and travelling expenses.

4.14. Members may seek leave of absence from the ERC for a period not exceeding six months.

4.15. Membership shall lapse if a member fails to attend three consecutive meetings of the ERC without reasonable excuse/apology, unless under exceptional circumstances . Such circumstances should be notified to the ERC in writing. In the event that the membership has lapsed, the Chairperson shall notify the member of such a lapse of membership in writing.

4.16. Membership shall lapse if a member fails to attend, in full, at least two thirds of all scheduled ERC meetings in a given year, barring exceptional circumstances. Such circumstances need be notified to the ERC in writing.

4.17. To ensure independence of the Committee and the ability of its members to exercise their judgement concerning matters coming before the Committee, the members may only be removed by the Dean of the Faculty in;

4.17.1. failure to attend three consecutive meetings without informing the secretariat in advance ,
4.17.2. failure to attend at least 40% of the Committee meetings in any given year
4.17.3. flagrant departure from SOPs of ERC-FDS.

4.18. Except in the case of removal for cause, members shall serve for a period of three years. until their successors are named.

4.19. Members shall be expected to participate in relevant specialised working groups as required. The Chairperson shall be expected to be available to participate in subcommittee meetings when required.

4.20. A member may resign from the ERC at any time upon giving notice in writingto the Chairperson/ERC and the Dean/ FDS. Steps shall be taken to fill the vacancy.

5. Glossary :

5.1. Chairperson

A member of the ERC who presides over a board meeting. He/ She is nominated and selected by members of the ERC andresponsible for expedited approvals on behalf of the board.

5.2. Secretary

The Secretary is nominated and selected by members of the ERC and responsible for all secretarial work of the ERC.

6. **References**:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Functions of the ERC members
	SOP – 004 - 2020 **Version 2.0, November 2020.**

1. Purpose:

These standard operational procedures describe the Terms of Reference (TOR) whichprovides the framework for functions of the members of ERC-FDS/UOP.

2. Scope:

The SOP is applied to all activities under the ERC-FDS/UOP.

3. Responsibility:

It is the responsibility of the ERC members to read and understand their functions as members of the ERC.

4. Detailed instructions:

4.1. The responsibilities of ERC officials are as follows:

4.2. Chairperson

4.2.1. Perform duties assigned to the Chairperson according to the SOPs.

4.2.2. Conduct all meetings of the ERC according to the SOPs. If for reasons beyond control, the elected Chairperson is not available, an alternate Chairperson nominated by a majority vote from the members present shall conduct the meeting.

4.2.3. Conduct the business of the ERC according to the SOPs.

4.2.4.Provide guidance to ERC members and staff.

4.2.5.Periodically review and formulate existing or new ERC policies and guidelinesin consultation with the members of ERC.

4.2.6.Review applications if assigned.

4.3. Secretary

4.3.1.Organizing the meetings, maintaining records and communicating with all concerned parties.

4.3.2.Prepare the minutes of the meetings and general correspondence with applicants and communicate with the members/applicants with the approval of the Chairperson.

4.3.3. Perform duties assigned to the Secretary according to the SOPs.

4.3.4. Assign reviewers for applications in consultation with the Chairperson and co-ordinate the review process.

4.3.5.Supervise office staff in preparing minutes of meetings and correspondence regarding applications.

4.3.6.Ensure that the membership file is current and up to date.

4.3.7.Provide guidance and supervision to the ERC office staff.

4.3.8. Perform any other duties assigned by the Chairperson.

4.3.9. Review applications if assigned.

4.4. Members

4.4.1. Attend meetings on a regular basis and remain until meetings are adjourned.

4.4.2. Shall be willing to publicize his/her full name, profession and affiliations.

4.4.3. Shall sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters.

4.4.4. Maintain strict confidentiality regarding protocol information, reviews and decisions and all matters discussed at committee meetings.

4.4.5. Disclose conflicting interests and where conflict does exist abstain from reviewing that protocol or leave the room during discussion and voting on the protocol.

4.4.6. Respect each others' views in the deliberative process.

4.4.7. Decide independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare.

4.4.8. Remain impartial and objective when reviewing protocols.

4.4.9. Maintain confidentiality of committee discussions and all meeting materials.

4.4.10. Perform expedited reviews of minimal risk research.

4.4.11. Review applications assigned to them and lead the discussion on the applications at full committee meetings.

4.4.12. Complete the assessment of study proposals assigned as primary reviewers prior to meetings and handover the completed application forms to the administrative assistant.If unable to attend, the forms should be sent to Secretary ERC two (2) working days before the scheduled ERC meeting.

4.4.13. Serve as principal reviewers for research in their areas of expertise.

4.4.14. Decide by vote or consensus, whether to approve, request revisions, not approve or defer studies following deliberation at full committee meetings.

4.4.15 Keep up-to-date with national and international research ethics and regulatoryguidance.Take part in research ethics-related continuing education.

4.4.16 Perform any other duties assigned to members according to the SOPs.

4.4.17 Perform any other duties assigned by the Chairperson.

4.5. Administrative assistant of the ERC

4.5.1. Coordinate collection and process all initial, resubmitted and continuing review proposals

4.5.2. Maintain the ERC-FDS/UOP documentation and archive as well as the electronic database of the ERC.

4.5.3.Check all application for completeness

4.5.3.1. If incomplete request submission of required documents and hold registration till the application is complete.

4.5.3.2. Schedule the review as soon as possible after submission; inform the Chairperson/Secretary or a committee member within 24 hours.

4.5.3.3. Consult Chairperson, Secretary to schedule the ERC meeting date.

4.5.4. Agenda preparation, meeting procedure and minutes

4.5.4.1. Prepare the meeting agenda according to the standard format.

4.5.4.2. Reserve a place (Faculty board room) for the scheduled meeting date and time.

4.5.4.3. Check whether the room, equipment and facilities are in good condition for the meeting.

4.5.4.4. Send the approved minutes to all ERC members.

4.5.5. Follow strict procedures to maintain the confidentiality of ERC documents.

4.5.6. Perform any other duties assigned by the Chairperson and Secretary.

5. Glossary :

5.1 Administrative assistant

He/She is responsible for the day-to-day administrative functions and duties which support the activities and responsibilities of the ERC members.

6. References :

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Orientation of new ERC members and training
	SOP – 005 - 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   To describe the procedures for orientation of new members and to inform them about the need for training and the importance of regularly attending training programmes or workshop to update their knowledge on the progress of technology, information and ethics. Further as the Faculty recognizes the importance of training and continuing professional development, the institution shall provide funding for specific training and study visits for ERC members.

2. **Scope:**

   These standard operating procedures describe the Terms of reference (TOR) which describe the procedure of orientation of new members of ERC-FDS/UOP and trainingofmembers of the ERC.

3. **Responsibility:**

   It is the responsibility of the new ERC members to read and understand their functions as members of the ERC-FDS/UOP. Further all members shall educate and train themselves periodically. The Chairperson and Secretary shall be responsible for organizing such training programs at regular intervals or inform members of possible training opportunities.

4. **Detailed instructions:**

   4.1. New ERC members shall be provided with adequate orientation.

   4.2. New member orientation will include the following:

   4.2.1. Introduction to other ERC members prior to the ERC meeting.

   4.2.2. Informal meeting with the Chairperson, Secretary and Officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.

   4.2.3. An opportunity to sit in at ERC meetings before their appointment takes effect.

   4.2.4. Priority given to participate in training sessions.

   4.3. New members will receive training in:

   4.3.1. Research ethics review

   4.3.2. Standard Operating Procedures of the ERC

   4.4. New members may be required to observe proceedings or be partnered with another ERC member for the review process for a maximum of three meetings /proposals before undertaking independent ethics review.

4.5. New membersshall be provided information about training courses, workshops, conferences Members shall select those appropriate and inform the Secretary/secretariat.

4.6. Members shall keeprecords of training/workshop/conference attended(AF/03-005) in chronological order and a copy to be retained in the ERC office.

4.7. New members will receive a copy of SOPs and TORs of the ERC.

5. Glossary :

5.1. TOR

Terms of reference

6. References :

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Independent Consultant/s for Review
	SOP – 006 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   To describe the procedure of appointing independent consultants and their roles and responsibilities.

2. **Scope:**

   If the Chairpersonor the ERC determines that a study involves procedures or information that is outside the area of expertise of its members, the Chairperson or the ERC shall invite individuals with competencies in those areas to assist in the review of issues that require expertise beyond or in addition to those available in the ERC.

3. **Responsibility:**

   Upon the advice or the recommendation of the Secretary or any other ERC member, it is the responsibility of the ERC to nominate and approve the names of the special consultants with the endorsement ofthe Chairperson.

4. **Detailed instructions:**

   4.1. The ERC shall be free to consult any person(s) considered by the ERC to be qualified to provide advice and assistance in the review of any research proposal submitted, , provided that the person(s) has/have no conflict of interest and maintain confidentiality. Such person(s) shall not be entitled to vote on any matter.

   4.2. Appointment of Independent Consultant(s)

   4.2.1. Independent Consultant(s) are appointed by the Chairperson based on the expertise needed to review the proposal and shall receive a formal notice of appointment.

   4.2.2. The letter of appointment shall include the date of appointment, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as an Independent Consultant to the ERC, and the conditions of appointment.

   4.2.3. The appointed consultants shallbe professionals in the areas of community and/or patient representation, medicine, statistics, social science and law.

   4.2.4. Independent Consultant(s) shall be appointed for the period sought or for a specific proposaland is not a continuous ongoing appointment/service.

   4.3. Conditions of Appointment

   4.3.1. Independent consultant(s) shall be appointed to the ERC under the following conditions:

   Willingness to publicize his/her full name, profession, and affiliation;l financial accountability, reimbursement for work and expenses, if any, within or related to the ERC should be recorded and made available to the public upon request;

4.3.2. All ERC Independent Consultants(s) shall sign Confidentiality/ Conflict of Interest agreements (AF/02-003) regarding meeting deliberations, applications, information on research participants, and related matters.

4.3.3. Responsibilities of the Independent Consultant is to review applications assigned to him/her and send a report to the Secretary/ ERC.

4.3.4. The consultant shall be invited to attend the ERC meeting, present the report and participate in the discussion if required as decided by the ERC members.

4.3.5. The consultant shall not participate in the decision making process of the proposal under review or on any other matter of the ERC.

4.3.6. The ERC shall maintain a roster of consultants.

5. Glossary:

5.1. Independent consultant

A non-member reviewer appointed to review, where additional or specialised expertise is needed to review a specific proposal.

6. References :

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Submission procedure for new applications
	SOP – 007 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   To describe the procedure for submission of new applications to the ERC secretariat

2. **Scope :**

   Protocol submission include; initial submission, resubmission of protocols with corrections/amendments and continuing review of approved protocols.

3. **Responsibility:**

   It is the responsibility of the ERC Secretary /administrative assistant to receive, record and distribute the review protocol and other relevant documents received by the ERC-FDS/UOP.

4. **Flow Chart :**

Research protocol and related documents received by the administrative assistant of the ERC

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Verify as per document checklist by the administrative assistant

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Day stamp the complete documents and handover to the Chairperson, Secretary or nominated ERC member

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Chairperson/Secretary or nominated ERC member check for completeness, if incomplete return to the PI to complete and resubmit

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Issue Complete Document Receipt form, Register in the ERC with a registration number

↓

Decide the review type and appoint primary reviewers

5. **Detailed instructions:**

5.1. Applications shall be submitted in the format prescribed by the ERC, **(**common application approved by FERCSL2019**)** which is available on the Faculty of Dental Sciencesweb site and shall include all necessary documentation.Application shall accompany a declaration by the applicant that all required documents have been submitted by completing and signing the application checklist.Necessary information required to fill the application form is available on the same web site. All applications shall be addressed to the Secretary, ERC, Faculty of Dental Sciences, University of Peradeniya.

5.2. Applications for ethical clearance shall be submitted in the application form provided by the ERC andshall accompany the following documents

5.2.1. One hard copy of the complete research proposal.

5.2.2. One hard copy of Information sheets and informed consent forms (ICFs)- in English, Sinhala and Tamil where appropriate.

5.2.3. One hard copy of other relevant documents, such as, questionnaires check listsc - in English, Sinhala and Tamil where appropriate.

5.2.4. Soft copy of updated Curriculum Vitae (CV) of all investigators; CV of the supervisor of research proposals related to postgraduate/ undergraduate degrees.

5.2.5. For study proposals submitted by postgraduates– Letter from the relevant postgraduate institute/board of study stating that the research proposal has been evaluated and has been found to be satisfactory for the purpose of postgraduate research.

5.3. Non-faculty members shall pay a handling charge as decided by the Faculty Board.This has to be paid to Dental Faculty Development Fund, University of Peradeniya account. Handling charges for undergraduate student protocols conducted as direct requirement of course work shall l be waived at the discretion of the ERC.

5.4. The ERC accepts duely filled applications from Monday to Friday during office hours.

5.5. Information about the closing date for receipt of new applications shall be y available for prospective applicants on the ERC website

5.6. Applications shall be checked by the administrative assistant of the ERC using a checklist.

5.7. The Chairperson, Secretary or a designated member of the ERC shall scrutinise the applications and the incomplete applications shall be returned to the applicant. Once the application is complete, ERC office shall date stamp all documents

5.8. For complete applications, the ERC office shall l issue a receipt to the Principal investigator (AF/05 – 007/02.0).

5.9. Only applications submitted at least 2 weeks prior to the next ERC meeting shall be included in the next ERC agenda.

5.10. Once an application has been accepted for ethics review, the administrative assistant shall assign an identification number to the proposal. The proposal shall be included in the ERC's register of received applications.A protocol specific file shall be maintained to file all documents relevant to the protocol.

5.11. Chairperson, Secretary or a nominated member of the ERC shall assessthe risk level of the research proposal (SOP 13 &14) and decide whether the research proposal needs to be reviewed or not, if required to be reviewed whether it is expedited or full board review .

5.12. For applications requiring full board review, the person assessing the research proposal, shall appoint 3 primary reviewers. The Primary reviewers shall include a subject specialist where ever possible and a non-medical member. The primary reviewers shall be appointed by the Chairperson/Secretary or a nominated member of the ERC.ERC members/consultants with no conflict of interest shall be considered reviewers. Nonmedical reviewer shall review the ICFs.

5.13. For applications qualifying for expedited review (SOP 14): the person assessing the research proposal shall appoint 2 primary reviewers. One person should be a non-medical member of the ERC. Reviewers for expedited review shall be appointed by the Chairperson/Secretary or a nominated ERC member. ERC members with no conflict of interest shall be considered as reviewers.

5.14. Applications not requiring ERC review (SOP 13) shall be issued a letter of exemption signed by the Chairperson and the Secretary of the ERC (AF/06 – 013/02.0).

6. Glossary :

6.1. New Application

A study protocol including the informed consent, investigator's qualifications, information on drug or device and advertisements (if applicable) presented to the ERC for approval for the first time and not previously approved by the Board. This includes re-application for those studies previously denied approval by the ERC.

6.2. Document

Document may be of any form, eg., paper, electronic mail, faxes, audio or video tape etc.

7. References:

7.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

7.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

7.3. Ethical guidelines for biomedical research on human subjects, 2000.

	Ethics Review Committee, Faculty of Dental Sciences University of Peradeniya.
	Subject : Preparation of agenda
	SOP – 008 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**
   To describe the format and the process of developing the agenda for the ERC meeting
2. **Scope:**
   The Secretary, ERC shall prepare the agenda for the meeting considering the previous minutes, new protocols and other documents pertaining to protocols under consideration.
3. **Responsibility :**
   It is the responsibility of the Secretary ERC to prepare the agenda.
4. **Detailed instructions:**
   4.1. An application shall be included on the agenda for the next available ERC meeting, provided it is received prior to the closing date for submission of applications and is deemed to be complete.
   4.2. The Secretary of the ERC shall preparethe agenda for the sERC meeting.
   4.3. All complete applications together with the relevant documents and all correspondence received by the Secretary shall be included in the agenda for consideration at the next meeting.
   4.4. The meeting agenda and associated documents shall be prepared by the Secretary and circulated among ERC members one week prior to the meeting and include information relating to the date, time and venue of the meeting
   4.5. Agenda items shall include the following items:
      4.5.1. Excuses
      4.5.2. Conflict of interest declaration
      4.5.3. Announcements,
      4.5.4. Minutes of the previous meeting,
      4.5.5. Business arising from the previous minutes,
      4.5.6. New applications,
      4.5.7. Applications awaiting clarification
      4.5.8. Previously unapproved applications,
      4.5.9. Amendments to approved proposals,
      4.5.10. Extensions,
      4.5.11. Progress reports
      4.5.12. Correspondence,
      4.5.13. Any other business,
      4.5.14. Close of meeting and date of next meeting

5. **Glossary :**
   5.1. Agenda
      A list of things to be done; a programme of business at a meeting

6. **References :**

   6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).
   6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Conduct of meetings
	SOP – 009 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   To describe the format of meetings of the ERC

2. **Scope:**

   These standard operational procedures describe the procedures for conduct of the ERC meetings.

3. **Responsibility:**

   It is the responsibility of the Chairperson and Secretary / administrative assistant to inform members and facilitate the conduct of regular and special meetings of the ERC

4. **Detailed instructions:**

   4.1. The ERC shall meet on a regular basis on a predetermined date, once a monthexceptduring the months of April and December. Dates of the ERC meetings for a given year shall be pre-decided and be availableon the ERC website.

   4.2. Members shall attend ERC meetings in person. Members who are unable to attend a meetingshallsend a written excuse to the Secretary of the ERC. The minutes shall record the submission of written excuses.

   4.3 There shall be a quorum of of seven (7) members including the Chairperson, Secretary and at least one non-medical member. It is necessary to have the quorum in order to reach a final decision on any agenda item.

   4.4 If the quorumis not met, the Chairperson under exceptional circumstances shall decide whether to proceed with the meeting. In such circumstances, decisions made by the ERC must be ratified by at least one lay representative.

   4.5 If the meeting does not have a quorum, the Chairperson shall cancel it and the ERC shall convene a meeting within ten (10) working days of the cancelled meeting.

   4.6 Meetings shall continue until all agenda items have been considered. In the event that the meeting has to be concluded prior to all agenda items being considered, the ERC shall a reconvene the meeting within 10 working days to complete the agenda.

   4.7 The ERC meeting shall be conducted in a manner to ensure confidentiality and open discussion.

4.8 The ERC may agree to the presence of visitors or observers at a meeting. However, they need to sign the declaration forms of confidentiality and conflicts of interest before they present at the meeting.

4.9 Any member of the ERC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the ERC must declare such interest beforehand. Such matters shall l be dealt in accordance with SOP 010.

4.10 All deliberations shall be conducted in a non-offensive, unbiased, sensitive and inclusive manner.

4.11 In circumstances where reviewers cannot be present, they shall provide a written review to be tabled at the meeting.

4.12 In circumstances where members cannot be present, they shall provide written comments to be tabled at the meeting.

5 . Glossary:

5.1 Minutes

An official record of the business discussed and transacted at a meeting, conference, f.

5.2 Quorum

Number of ERC members required to act on any motion presented to the board for action.

6 . References:

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Conflict of interest
	SOP – 010- 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   The purpose of this SOP is to describe the procedure for reporting and handling of conflict of interest of ERC members.

2. **Scope:**

   This SOP covers the agreement on conflict of interest concerning information and procedures followed by the ERC-FDS/UOP.

3. **Responsibility:**

   It is the responsibility of all ERC members to understand, accept and report any conflict of interest before the ERC meeting to protect the rights of study participants.

4. **Detailed instructions:**

   4.1 An ERC member shall inform the Chairperson if he/she has conflict of interest, financial or otherwise, with regards to a project or other related matter(s) to be considered by the ERC prior to the commencement of the meeting.

   4.2 The ERC shall determine if the concerned matter results in conflict of interest for the member and, if so, whether the member should withdraw from the meeting until deliberations on the relevant matter is completed. The member shall not be permitted to be an adjudicator of that research proposal.

   4.3 Declarations of conflict of interest by the member , resolutions, and his/her withdrawal from the meeting shall be minuted.

5. **Glossary :**

   5.1. Conflict of interest

   Conflicting interest of a Research Ethics Committee member generally includes the following:

   - Participation in a study where the Research Ethics Committee member is listed as an investigator or is a member of the research team.
   - Supervision of a study where the Committee member is the faculty supervisor.
   - Financial interest where the Research Ethics Committee member holds significant equity or stock options, receives or expects to receive compensation with a value that may be affected by the outcome of the study, has an ownership interest (including patent, trademark or copyright interest) in the drug, product or technology that is the subject of the research, or receives a significant amount annually as a salary, consulting income or other compensation from the sponsor.
   - The Committee member has a 'personal relationship' with the investigator. This means the member has an immediate family relationship or other close relationship with the

investigator ('immediate' family' means the Committee member's spouse or domestic partner and dependent children).

- The Committee member has a fiduciary relationship to the sponsor. This means the Committee member serves as an executive to a company sponsoring the research or serves on the company's board of directors.
- Other examples of conflicting interests include but are not limited to the following:
  - Research Ethics Committee member has an interest that he or she believes conflicts with the member's ability to review a project objectively.
  - Research Ethics Committee member is in direct competition with the investigators for limited resources, funding, sponsorship or research participants, or the Committee member is considered a personal or professional adversary of the investigators. Since such situations may depend on the circumstances, the Committee member should raise such a situation as soon as possible with the Chair. The standard used by the Chair is whether an independent observer could reasonably question whether the individual's actions or decisions would be based on factors other than the rights, welfare and safety of participants.
  - Any other reason for which the Committee member believes he or she has a conflicting interest with the research.

6. References:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

6.3. Ethical guidelines for biomedical research on human subjects, 2000

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Processing applications for ethics review
	SOP – 011- 2020 **Version 2.0, November 2020.**

1. Purpose :

To describe the process of consideration of initial applications for ethics review

2. Scope:

This SOP applies to the review process of a study protocol submitted for the first time.

3. Responsibility:

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observations and comments to the ERC in the application form (AF/04-007/02.0) and return to the ERC office on the due date. The Secretary / administrative assistant are responsible for receiving, verifying and managing the content of application forms. In addition, the administrative assistant shall create a protocol specific file, distribute the proposals and other documents and get them reviewed by the ERC and deliver the review results to the applicants.

4. Flow chart :

Protocol- Assign reviewers and reserve reviwers
Initial review by all members
↓
Examine the qualifications of investigators/supervisors and study sites
↓
Assess conflicts of interest
↓
Review study participants
↓
Examine the risks and benefits of the study
↓
Assess the confidentiality of data and autonomy of the participants
↓
Make decision and report to the ERC
↓
ERC meeting- record the ERC discussion and decision
↓
communicatethe ERC decision to the PI
↓
ERC Secretary/administrative staff store all original documents and forms pertaining to the proposal in protocol specific file

5. Detailed instructions:

5.1. The ERC shall consider/assess new applications at its monthly meeting provided that the completed application is received at least one week before the scheduled meeting.

5.2. Each application shall be scrutinized by the Chairperson / Secretary or an assigned member.

Once the application is accepted and registered with the ERC, the Chairperson/Secretary or the nominated member decides whether the application could be exempted from review or subjected to expedited reviewin accordance with SOP 13 and 14. Other applications shall be reviewed by full board review system.

5.3. Other applications shall be reviewed by two reviewers with at least one subject specialists relevant to the proposal and a non-medical reviewer. Reviewersshall
5.3.1. Review the application in details prior to the meeting.
5.3.2. Non- medical member shall review particularly the ICFs
5.3.3. Submit written comments about the application to the Secretary and initiate discussion regarding the application at the committee meeting.
5.3.4. When necessary, request the applicant to submit the necessary documents or revised version of the proposal through the ERC.

5.4. A protocol specific file shall be created to file all documents relevant to the protocol. A Soft copy of the protocolshall be uploaded to a Google drive folder which could be accessed by all ERC members**.**

5.5. If requested, all proposals shall be circulated to members of the ERC for review prior to themeeting

5.6. Applications shall be discussed at the meeting by members present. Written submissions made by those not present shall also be considered.

5.7. The ERC shall assess proposals submitted to it for review in accordance with the FERCSL and other national and international guidelines and with national and international laws to determine their acceptability on matters related to ethics. The ERC shall ensure that it is sufficiently
informed on all aspects of a research proposal, including its scientific validity, to make an assessment. The ERC shall deal with multi-centre research applications in accordance with SOP 025.

5.8. The ERC may invite an investigator to the meeting to clarify issues related toan application. The applicant shall be asked to leave the meeting prior to deliberation and decision-making about the application.

5.9. The ERC may invite a member of an advocacy group representing the interests of the participants to the meeting to clarify relevant issues.

5.9.1. The ERC, after considering an application shall decide on one of the following :
5.9.2. **Approved -** the proposal as being ethically acceptable, no changes requested.
5.9.3. **Minor revisions needed** – would be eligible for Chairperson's approval once revisions are done.
5.9.4. **Major revisions needed** – would require full board review once the revisions are done.
5.9.5. **Disapproved/ rejected** – reasons for rejection shall be conveyed to the applicant. .

5.10. The ERC decision shall s be by consensus. Where there is no consensus, a vote shall be taken and a two-thirds majority that includes at least one nonmedical person is required to implement the decsion. Any significant dissenting view/s or concern/s shall be noted in the minutes.

5.11.For proposals which the ERC considers ethically acceptable with minor revisions , it may delegate the authority to review the applicant's response and give final approval to one of the following:

5.11.1. Chairperson alone; or

5.11.2. Chairperson in oral or written consultation with one or more named members who were present at the meeting or who submitted written comments on the application.

5.12.In such circumstances, the ERC shall be informed at the next meeting of final decision taken on its behalf and this shall be ratified by the full ERC committee at its next meeting.

5.13. Prior to sending the relevant documents, all nominated reviewers shall first be enquired whether they are in a position to handover the review report within a period of three (03) weeks

5.14.The consented reviewers shall be requested to submit the report within a period of three (03) weeks from the date of receipt of the ERC application and documents

5.15.If any of the reviewers fail to submit the review report by the end of three weeks, ERC shall arrange to review the proposal by a reserve reviewer identified by the ERC.

5.16. Undergraduate research projects –for those following the BDS degree programme

4.16.1. Following submission of research proposals to the ERC by the Faculty Research Committee, they shall be assigned to a ERC subcommittee for evaluation for granting ethical clearence. This subcommittee shall consist of three (03) members.

4.16.2.The subcommittee/s shall be appointed by the ERC and the outcome of proposal review of the subcommittee shall be forwarded to the ERC.

4.16.3.Date/s of ERC subcommittee meetings shall be decided by the ERC.

4.16.4. If there are any concerns arising from the research proposal, the subcommittee shall discuss about them with the research supervisor and/ co- supervisor.

4.16.5. Decision regarding granting ethical approval shall be notifed to the applicant within a period of not more than six (06) weeks from the initial submission.

5.17. Undergraduate research projects –for those following degree programmes other than the BDS programme

5.17.1. If the applicants from other Faculties/ Universities have received ethical clearance from any Ethics Review Committee/s recognized by the FERCSL, they shall only need the approval from the Dean, Faculty of Dental Sciences to conduct the research utilizing physical resources of the Faculty of Dental Sciences.

5.17.2. The standard process for granting ethical clearance shall apply to the applicants from other Faculties/Universities/ HEIs whose research shall involve human resources of the Dental Faculty/Hospital, University of Peradeniya.

6.. All reviewers shall be sent a letter of appreciation signed by Chairman/ Secretary upon completion of the review process

7. References :

7.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

7.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996

7.3 Ethical guidelines for biomedical research on human subjects, 2000.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Review of resubmitted protocols
	SOP – 012- 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   This procedure describes how resubmitted study protocols are managed, re-reviewed and approved by the ERC.

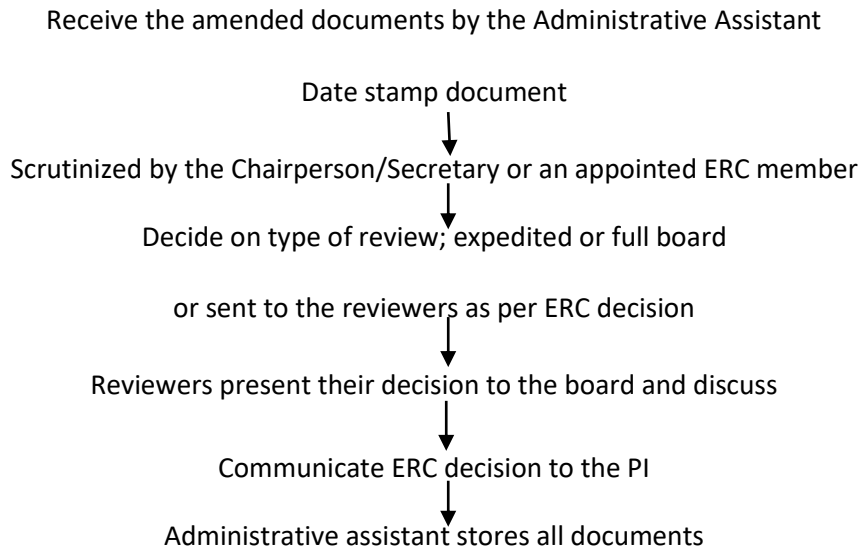
2. **Scope:**

   This SOP applies to study protocols that have been recommended for revision during the initial review process.

3. **Responsibility:**

   It is the responsibility of the ERC Secretary/ administrative assistant to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the ERC for reconsideration. A re-submitted protocol may be reviewed and approved by either the Chairperson or some ERC members/reviewers or full committee. The method of review would have been determined by the ERC at the time of the initial review.

4. **Flow chart:**



5. **Detailed instructions:**

   5.1. The resubmission shall consist of a document addressing the revisions , revised version of the protocol, related documents such as informed consent document, data collection instruments .

   5.2 Upon receipt of the documents, the administrative assistant shall date stamp them

5.3 The Chairperson / Secretary or an ERC member shall review the revised protocol, refer to the meeting minutes as guidance for the review and consider whether Chairperson's approval or a full review at the ERC committee meeting is required. Those that required major revisions shall l be resent to the primary reviewers for their observations and shall undergo a full board review.

5.4 For protocols which the ERC considers ethically acceptable with minor amendments, the ERC may choose to delegate the authority to review the applicant's response and give the final approval to the Chairperson in oral or written form in consultation with the Secretary and one principal reviewer who was present at the meeting or who submitted written comments about the application.

5.5 If recommendations have beensatisfactorilyaddressed,the Chairperson's approval shall l l be given and communicated to the Principal Investigator. Chairperson's approval thus given shall be ratified by the ERC at its next scheduled meeting.

5.6 If the recommended changes have not been addressed sufficiently, the principal investigator shall be informed in writing.

5.7 Revisions that reach the Secretary/ ERC at least 3days beforethe scheduled date of the next ERC meeting shall be considered for deliberation at that ERC meeting.

5.8 Investigators who do not respond to the recommended revisions shall be reminded twice in writing and those proposals for which no response is received within 3 months of the initial review shall be deleted from the meeting agenda. The period may be extended upon request by a PI, if the ERC considers the reasons for extension valid

5.9 If the ERC previously decided to review the revisions (major revisions), the revisions shall be sent to the original primary reviewers for their comments. The revised protocol shall be discussed at the next scheduled ERC meeting and the primary reviewers shall present (oral or in writing) a brief summery and lead the discussion on the protocol revision. Further recommendations for modifications to the protocol, consent form as requested by the committee shall be noted in the meeting minutes and also communicated to the principal investigator. Once the major revisions are accepted and approved by the ERC, the PIshall be informed. 5.11.The original completed documents along with the revised documents, the completed re-reviewed report and the assessment forms shall be stored.

6 . References:

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

6.3 Ethical guidelines for biomedical research on human subjects, 2000

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Exemption from review
	SOP – 013 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**
   To describe the procedure to identify research proposals that qualify for exemption from review.

2. **Scope:**
   This SOP applies to protocols that may be exempted from review at the initial scrutiny.

3. **Responsibility:**
   The Chairperson, Secretary or nominated ERC member at the initial scrutiny may assess the suitability of projects to be exempted from review and the suchprotocols shall be issued with the review exemption letter (AF/06-013/02.0).

4. **Detailed instructions:**

4.1 Research proposals may be exempted from review at the initial scrutiny in the following instances;

4.1.1. Research to be conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular or special education instructional strategies or research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods. Such research shall be exempted from review provided one or more of following conditions have been met:

4.1.1.2.The research is conducted in a commonly accepted educational setting (e.g., school or university).

4.1.1.3.The research involves normal educational practices (e.g., comparison of instructional techniques).

4.1.1.3 The study procedures do not cause a significant deviation in time or effort from the usual educational practices at the study site.

4.1.2 The study procedures do not increase the level of risk or discomfort associated with routine educational practices.

4.1.3 The study procedures do not involve sensitive subjects (e.g., sex education).

4.1.4 Provisions are made to ensure the existence of a non-coercive environment for students who choose not to participate.

4.1.5 The school or other institution grants written approval for the research to be conducted (Note: This exemption is not applicable to children or individuals with mental disability).

4.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless:

4.2.1 information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

4.2.2 any disclosure of the human participants' responses outside the research that could place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

NOTE A: Sensitive survey research is not exempted. A sensitive survey is one that deals with sensitive or highly personal aspects of the subject's behaviour, life experiences or attitudes. Examples include substance abuse, sexual activity or attitudes, sexual abuse, criminal behaviour, sensitive demographic data, detailed health history, . Sensitivity shall be determined on the risk to the subject in terms of a negative emotional reaction. An additional risk shall be l the possibility of breach of confidentiality.

4.3 Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

4.4 Research conducted by or subject to the approval of departmental or institutional heads and designed to study, evaluate or otherwise examine:

4.4.1 public benefit or service programs;
4.4.2 procedures for obtaining benefits or services under those programs;
4.4.3 possible changes in or alternatives to those programs or procedures; and/or
4.4.4 possible changes in methods or levels of payment for benefits or services under those programs.

4.5 Taste and food quality evaluation and consumer acceptance studies:

4.5.1 if wholesome foods without additives are consumed; or
4.5.2 if a food is consumed that contains a food ingredient at or below the recommended level and for a use found to be safe or agricultural chemical or environmental contaminant at or below the level found to be safe by the relevant Sri Lanka Governmental agency.

4.6 A standard approval letter shall be issued stating the reasons for exemption, in the format set out in annexure (AF/06– 013/02.0**)** and the ERC shall be informed at the next meeting.

5 . Glossary :

5.1 Vulnerable subjects

A category of research participants that includes children, prisoners, pregnant women, handicap or mentally disabled person and economically and educationally disadvantaged persons who are likely inclined to coercion or undue influence.

6 . References :

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).
6.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.
6.3 Ethical guidelines for biomedical research on human subjects, 2000.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Expedited review
	SOP – 014 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**
   To describe the procedure for expedited review of research proposals.

2. **Scope:**
   This SOP applies to the review and approval of study proposals with minimal risk to participants, protocol amendments, or informed consent changes of currently approved studies.

3. **Responsibility:**
   It is the responsibility of the ERC members to define which study protocols should be reviewed and approved through expedited review process.

4. **Flow chart:**

Determine the type of review needed for the protocol by chair person, Secretary or a nominated ERC member

↓

Appoint two reviewers for expedited review process by the Chairperson/Secretary or nominated ERC member

↓

Assess the proposal within a two week period

↓

Communicate reviewers' decision to the Secretary

↓

Final decision is communicated to the PI and the ERC

5. **Detailed instructions:**

5.1. Receive the submitted documents.
   5.1.1. Receive the application documents submitted by the investigators
   5.1.2. Check the items received
   5.1.3. Stamp the receiving date on the documents
   5.1.4. Sign the receiver's name on the receiving documents
   5.1.5. Handover the received documents to the Secretary.

5.2. Determine protocols for expedited review
   5.2.1. Chairperson, Secretary or nominated member of the ERC shall determine whether a study is qualified for expedited review according to the following criteria.
   5.2.2. Modification/amendments of protocols such as administrative revisions, addition or deletion of non- procedural items, non- significant risk research activity and research activity including minor changes to previously approved protocols.

5.2.3. Proposals involving interviews of non- confidential nature, not likely to harm the status or interests of the individual and not likely to offend the sensitivities of the people involved.

5.3. Following guidelines based on categories of research studies shall be used to fulfil the above requirements.

5.3.1. Research involving material (data, documents, records or specimens) that has been collected or would be collected solely for non-research purposes (such as medical treatment or diagnosis).

5.3.2. Collection of data from voice, video, digital or image recordings made for research purposes.

5.3.3. Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies where the investigator does not manipulate the participants' behaviour and the research would not involve stress to the participant.

5.3.4. Continuing review of research projects previously approved by the ERC as follows: where

5.3.4.1. the research is permanently closed to the enrolment of new participants;

5.3.4.2. all participants have completed all research-related interventions; and

5.3.4.3. the research remains active only for long-term follow-up of participants; or where no new participants have been enrolled and no additional risks have been identified; or where the remaining research activities arelimited to data analysis.

5.3.4.4 Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, which was determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

5.3.5. Research with the potential for physical or psychological harm should generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues and research dealing with vulnerable groups.

5.3.6. Expedited review of research protocols may be undertaken between scheduled meetings, at the discretion of the Chairperson, by the Chairperson and the Secretary. They may seek advice from other ERC members or suitably qualified experts, as appropriate, before arriving at a decision.

5.3.7. The decision of this review shall be tabled for ratification at the next ERC meeting.

5.3.8. Where the chair person, Secretary or the nominated ERC member considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the proposal shall be considered by the full ERC and cannot be dealt with by expedited review.

5.4. Expedited review process

5.4.1. Chairperson/ Secretary or2 ERC members nominated by the ERC each month shall review the eligible protocols.

5.4.2. The administrative assistant shall send the protocols to the selected members along with the application form which includes the assessment columns for reviewers.

5.4.3. If the two reviewers are not in agreement, the Chairperson shall refer the protocol for full board review.

5.4.4. Reviewershall not take more than 2 weeks to submit their reports.

5.4.5. Inform the members about the proposals approved for expedited review at its regular meetings.

5.4.6. If any ERC member raises concerns about a proposal presented for expedited review, that proposal shall undergo full board review.

5.4.7. The Chairperson and Secretaryshallissue the ethical clearance certificate.

6. Glossary:

6.1. Expedited approval

An ERC approval granted only by the Chairperson of the ERC or a designated ERC member (not the full Board) for "minor" changes to current ERC – approved research proposals and for research which involves no more than minimal risk.

6.2. Expedited review

A review process, by only two designated ERC members who then report their decision at the full board meeting. An expedited review is a quick review for minor changes to the approved protocol and for research proposal with minimal risk in nature.

6.3. Vulnerable subjects

A category of research participants that includes children, prisoners, pregnant women, handicap or mentally disabled person and economically and educationally disadvantaged persons who are likely inclined to coercion or undue influence.

7. References:

7.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

7.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

7.3 Ethical guidelines for biomedical research on human subjects, 2000

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Amendments and extensions to approved proposals
	SOP – 015 - 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   The purpose of this procedure is to describe how l amendments and extensions to approved protocols should be managed and reviewed by the ERC.

2. **Scope:**

   This SOP applies to previously approved study protocols that require approval for amendments or extension of validity of ethical clearance. Amendments or extensions to protocols shall not be implemented until reviewed and approved by the ERC.

3. **Responsibility:**

   It is the responsibility of the Secretary ERC to manage amendments and extensions to protocols. Investigators may amend the content, questionnaires, and consent forms from time to time. They may also request a period of extension to complete the research.

4. **Detailed instructions:**

   4.1. The principal investigator may seek approval for amendments to proposals that have been approved, including changes to the manner of conduct of the research and extension of the period for which approval has been given. Such requests shall be made in writing and include:

   4.1.1. details of the nature of the proposed amendments and/or reasons for request for extension; annexure (AF/07-015/02.0& AF/08-015/02.0)

   4.1.2. an assessment of the ethical implications, if any, that arise as a result of the amendment or extension;

   4.1.3. a set of documents incorporating the amendments identified by the revised version numbers and dates. The amendments should be highlighted.

   4.2. All requests for amendments shall be reviewed by the ERC at its next meeting, provided the request has been received by the ERC office by the agenda closing date, except as follows:

   4.2.1. the ERC initial reviewer may undertake expedited review of requests for minor amendments between scheduled meetings at the discretion of the Chairperson and in accordance with SOP 012, provided that his/her decisions are ratified at the next scheduled ERC meeting.s

4.2.2. The Chairperson/Secretary may review and approve urgent protocol amendments requested for safety reasons, provided that the ERC reviews the decision at its next scheduled meeting.

4.3. The ERC shall report in writing to the principal investigator within five (5) working days of the meeting at which the request was considered (the scheduled ERC meeting).

4.3.1. Approval of amendments requested shall be as in the approval letter set out in annexure (AF/08-015/02.0).

4.3.2. Approval of extension of the period of validity shall state the new period for which approval has been given with dates. Standard ethical clearance certificate shall be issued in the format set out in annexure (AF/09 – 016/02.0).

4.4. If the ERC finds that further information, clarification or modification is required for the consideration of the request for amendment or extension, the applicant shall be informed giving reasons and the information requested clearly set out. Wherever possible, requests for additional information/clarification/modification shall refer to the FERCSL Guidelines. The letter shall be in the format set out in attachment H.

4.5 If the requested amendment or extension is rejected, a letter including the reasons for the decision with reference to the FERCSL Guidelines or other relevant documents or legislation shall be issued.

4.6 All reviewed and approved requests for amendments and extensions shall be recorded in the relevant proposal file and where appropriate in the ERC's register of received and reviewed applications.

5. Glossary:

5.1. Amendment protocol document.

A set documents consisting of amended parts and related documents of the protocol, previously approved by the ERC. In the course of the study, the PI may decide to make changes to the protocol.

5.2. Expedited approval

ERC approval granted only by the Chairperson of the ERC or a designated ERC member (not the full Board) for "minor" changes to current ERC – approved research activities and for research which involves no more than minimal risk.

6. References:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

6.3. Ethical guidelines for biomedical research on human subjects, 2000.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Notification of decisions of the ERC for new applications
	SOP – 016 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   To describe the procedure for notification of decisions of the ERC regarding review of new applications.

2. **Scope:**

   This SOP applies to all communications related to the studies under review of the ERC-FDS/UOP.

3. **Responsibility:**

   It is the responsibility of all ERC members, secretariat and the Chairperson conducting activities of the ERC to complete a written communication record of telephone, or interpersonal discussions related to past, present and/or future studies and/or processes involving the ERC.

4. **Detailed instructions:**

   4.1. Decisions of the ERC with regard to all applications discussed shall be conveyed in writing, to the principal investigator, within seven (7) working days of the meeting unless notified otherwise. ERC decisions shall be in the form: Approved, resubmission with minor corrections, resubmission with major corrections or Rejected.

   4.2. If approved, any conditions stipulated should be made clear.

   4.3. A proposal shall be approved only after all outstanding requests (if any) for further information, clarification or modification has been satisfactorily resolved.

   4.4. the approval shall be in writing and shall contain the following information:

   4.4.1. the title of the proposal;
   4.4.2. the name of the principal investigator(s);
   4.4.3. the ERC proposal identification number;
   4.4.4. the version number and date of all documents reviewed and approved by the ERC Including clinical protocols, patient information sheets, consent forms, advertisements, questionnaires etc;
   4.4.5. the date of the ERC meeting at which the proposal was first considered;
   4.4.6. the date of the ERC's approval;
   4.4.7. the conditions, if any, to which approval is subject to;
   4.4.8. the period of validity of the ERC's approval;
   4.4.9. the frequency of progress reports; and
   4.4.10. the date of submission of the final report.

   4.5. In all instances, data collection shall not commence until written notification has been received by the applicant confirming approval.

4.6. A standard ethical clearance certificate shall be issued in the format set out in annexure (AF/09 – 016/2.0).

4.7. If further information, clarification or modification of the proposal is required, it should be clearly stated. Wherever possible reference should be made to the FERCSL guidelines or other relevant documents or legislation to support the request.

4.8. The ERC shall promote active communication with applicants to speedily resolve outstanding requests for further information, clarification or modification of proposals. It may nominate one of its members to communicate directly with the applicant (PI) or invite the applicant to attend an ERC meeting to enable verbal discussion.

4.9. The letter shall be in the standard format set out in annexure (AF/10 -016/02.0).

4.10. If the proposal is rejected on ethical or other grounds, the letter of rejection shall include the reasons for the decision with reference to the FERCSL Guidelines or other relevant documents or legislation.

4.11. The letter shall be in the standard format set out in annexure (AF/11 -016/02.0).

5. Glossary:

5.1. Ethical clearance certificate

This is a certificate issued by an ERC after reviewing research proposal, informed consent form and other relevant documents, to certify that the research proposal conforms to the ethical guideline of the FERCSL for a defined period of time.

6. References:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

6.3. Ethical guidelines for biomedical research on human subjects, 2000.

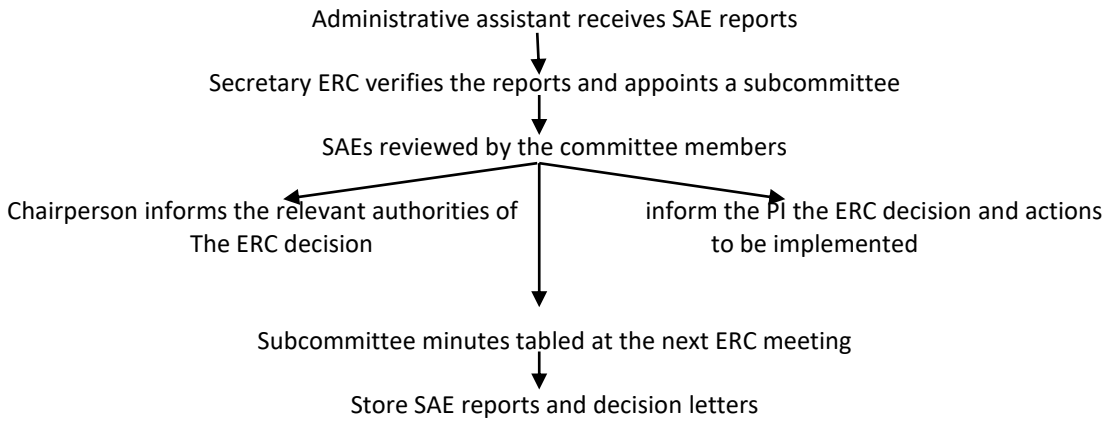
	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Handling of Adverse Events
	SOP – 017 - 2020 **Version 2.0, November 2020.**

1. **Purpose:**
   To describe the procedure for reporting and handling of adverse events

2. **Scope:**
   This SOP applies to all communications and actions related to a serious adverse event (SAE) defined as undesirable clinical responses to an intervention, including treatment or diagnostic procedures of studies under the approval of the ERC-FDS/UOP, that have resulted in harm/death of participants.

3. **Responsibility:**
   The Principal investigator (PI) shall immediately report all serious adverse events in clinical trials to the ethics committee of the institution responsible for the conduct of research in accordance with the reporting conditions required by the ERC.
   The Principal investigatorshall report all adverse events and the responses to those events in the periodic and final reports of the projects.
   The Chairperson shall take an appropriate course of action for those adverse events deemed serious and requiring immediate attention.

4. **Flow chart:**



5. **Detailed instructions:**
   5.1 The ERC shall require, as a condition of approval of each proposal, that researchers immediately report Suspected Unexpected Serious Adverse Events (SUSAR) or Serious Adverse Events (SAE) to the ERC.
   5.2 This requirement includes those that have occurred at other sites in the case of Multicentre Studies.
   5.3 The current guidelines of the Sri Lanka Drug Regulatory Authority stipulate the following timelines for reporting such events occurring at local trial sites:
      5.3.1 death or life threatening event in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than five days.

5.3.2 events, other than fatal and life threatening, in a patient on a trial or within 30 days off trial: report as soon as possible, but no later than seven days.

5.4 Notifications of Serious Adverse Events (SAE) must be submitted in the format as set out in annexure (AF/13 – 018/02.0) and shall include all the documents required. These documents shall include at least:

5.4.1 A statement from the principal investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device;

5.4.2 A statement from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the patient information sheet/consent form.

5.5 The procedure and format for notification of adverse events to the ERC shall be readily available to investigators.

5.6 Adverse events may be reviewed by a special subcommittee of the ERC empowered to review such events, which shall determine the appropriate course of action.

5.7 The special subcommittee will consist of the following

5.7.1 Chairperson ERC

5.7.2 Secretary ERC

5.7.3 Clinical pharmacologist

5.7.4 A clinician with special training /interest in the clinical discipline.

5.8 The review shall take place within one week of notification of the event. The special committee shall determine the appropriate course of action and inform the ERC of its recommendations. This may include:

5.8.1 a notation on the proposal file of the occurrence;

5.8.2 increased monitoring of the research;

5.8.3 a request for an amendment to the protocol and/or patient information sheet/consent form;

5.8.4 suspension of ethics approval; or

5.8.5 termination of ethics approval.

5.9 All adverse events reviewed under this section shall be reported to the ERC at the next meeting.

5.10 The Chairperson may take a course of action as he/she feels fit in the circumstances for those adverse events deemed serious and requiring immediate attention. This may include:

5.10.1 Referral to the Clinical Trials Sub-committee of the Ministry of Health

5.10.2 Immediate request for additional information;

5.10.3 Immediate suspension of ethics approval;

5.10.4 Immediate termination of ethics approval.

5.11 The ERC shall inform the investigator that it has received notification of the serious or unexpected adverse event, and the course of action is necessary.

5.12 The Chairperson shall immediately notify the Dean, Faculty of Dental Sciences, University of Peradeniya, if a research study has been suspended or terminated because of a serious adverse event.

6 Glossary :

6.1 Adverse Event

Any untoward medical occurrence in a patient or clinical investigation participant administered with an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavourable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

6.2. SAE (Serious Adverse Event)

The SAE is serious and should be reported when patient outcome is:

Death – Report if the patient's death is suspected as being a direct outcome of the adverse event.

Life Threatening - Report if the patient was at substantial risk of dying at time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.

Hospitalization (initial or prolong) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.

Disability – Report if the adverse event resulted in a significant, persistant, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activity or quality of life.

Congenital Anomaly – Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

Requires Intervention to Prevent Permanent Impairment or Damage – Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.

6.3. Unexpected ADR (Adverse Drug Reaction) – Unexpected Adverse Drug reaction, the nature or severity of which is not consistent with the informed consent/ information sheets or the applicable product information.

7. References:

7.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

7.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Monitoring of approved research studies
	SOP – 018 - 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   To describe the procedure for monitoring research studies approved by the ERC to ensure compliance with conditions of ethics approval

2. **Scope:**

   This SOP applies to all studies under the approval of the ERC-FDS/UOP.

3. **Responsibility:**

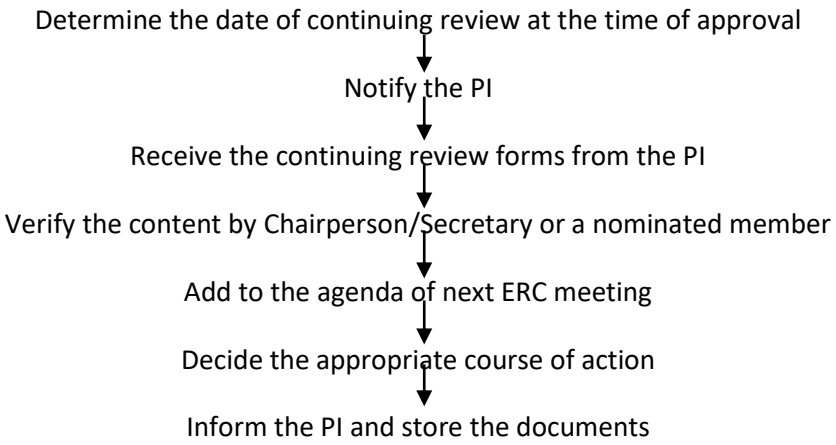
   The Principal investigator shall send periodic progress reports to ERC-FDS/UOP. The frequency of reports shall be decided by the ERC depending on the nature and duration of the study. The principal investigator shall send the final report to ERC on completion of the study.

   The Principal investigator shall immediately report all serious adverse events in clinical trials to the ERC.

   The Principal investigator shall report all adverse events and the response to those events periodically and final reports of the project.

   The Chairperson shall sh appropriate course of action for those adverse events deemed serious and requesting immediate action.

4. **Flow chart:**



5. **Detailed instructions:**

   5.1. The ERC shall monitor approve research studies to ensure compliance with its approval.

   5.2. It may request, at any time, information on any relevant aspects of the study and discuss any issue of relevance with the researchers.

   5.3. It shall require applicants (PI) to provide progress reports, at least annually, and a final report at the conclusion of the study(Annexure; AF/15 – 019/02.0 & AF/16 -020/02.0).

   5.4. In the case of clinical trials, the ERC shall require quarterly reports which shall be reviewed by the ERC committee.

   5.5. The progress reports shall contain at least the following information:

5.5.1. progress to date or outcome in the case of completed research;
5.5.2. statements regarding maintenance and security of records;
5.5.3. statements supporting compliance with the approved protocol;
5.5.4. statements supporting compliance with any conditions of approval.
5.5.5. Extension of approval for a further period shall l be subject to the principal investigator submitting progress reports as called for in the letter of approval.

5.6. In determining the frequency and type of monitoring required for approved studies, the ERC shall give consideration to the degree of risk to participants in the research. The ERC may adopt measures that it considers appropriate for monitoring, such as:
5.6.1. Written reports;
5.6.2. Random inspections of research sites, data and signed consent forms etc

5.7. The ERC shall require, as a condition of approval of each proposal, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:
5.7.1. proposed changes to the protocol;
5.7.2. any unforeseen events that might affect continued ethical acceptability of the study; and
5.7.3. new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

5.8. The ERC shall require, as a condition of approval of each proposal, that investigators inform the ERC, giving reasons, if the research study is discontinued before the expected date of completion.

5.9. Should the ERC become aware, on good grounds, of circumstances that have arisen which prevents a research study from being conducted in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the principal investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research study be discontinued or suspended, or that other necessary steps be taken.

6. Glossary:

6.1. Monitoring Visits

An action that ERC or its representatives visit study sites to assess how well the selected investigators and the institutions are conducting the research taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the sites. Normally monitoring visit shall be arranged in advance in concurrence with the principal investigators.

7. References:

7.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

7.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Intervention in Non- Compliance and Violation
	SOP – 019 - 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   To provide instructions for taking action and maintaining records that identify investigators / institutes who fail to follow the procedure written in the approved protocol or to comply with national, international guidelines for conduct of human research, including those who fail to respond to ERC request.

2. **Scope:**

   This SOP applies to all research protocols approved by the ERC-FDS/UOP involving human subjects.

3. **Responsibility:**

   Designated member/s or the Secretary are responsible for collecting and recording non compliances.

4. **Detailed instructions:**

   4.1. Ensure that issues as well as details of non-compliance involving research investigators are included in the agenda of the ERC meeting.

   4.2. Maintain a file that identifies investigators who are found to be non- compliant with national and international regulations or who fail to follow protocol approval stipulations or to respond to the ERC request for information or action.

   4.3. The ERC Board may decide to suspend or terminate approval of current studies or refuse to accept and review subsequent applications from the investigators cited. This decision shall be based on the category of deviations/violations (major and minor)

   4.4. The Chairperson notifies the ERC action in writing to the investigator as follows:

   4.4.1. Temporary suspension

   4.4.2. Termination of approval of the current study

   4.4.3. Refuse to accept and review subsequent applications from the investigator cited for major violations by the investigator without informing the ERC.

   4.5. Make 4 copies of the notification letter signed by the Chairperson and Secretary ; original copy to the investigator, a copy to the relevant national authorities and institutes, third copy to the sponsor of the study, the last copy in the 'noncompliance' file of the ERC

   4.6. Follow up action after reasonable time.

5. **Glossary :**

   5.1. Deviation/ noncompliance/ violation

   The ERC monitors whether the investigators do not conduct the study in compliance with the approved protocol according to the national and international guidelines and/or fail to respond to the ERC request for information/action.

5.2. Major protocol deviations

Major protocol deviations are deviations which affect a participant's safety, condition or status, the integrity of the study data, pose a significant risk of harm and change the balance of risks and benefits and a participant's willingness to continue participation.

If a deviation meets any of the following criteria it should be classified as major (the list is not comprehensive):

5.2.1. The deviation has harmed or posed a significant or substantive risk of harm to a participant:

5.2.1.1. A participant received the wrong treatment or incorrect dose.

5.2.1.2. A participant met withdrawal criteria during a study but was not withdrawn.

5.2.1.3. A participant received an excluded related medication.

5.2.2. The deviation compromises the scientific integrity of the study data:

5.2.2.1. A participant was enrolled but does not meet the protocol's eligibility criteria

5.2.2.2. Failure to treat participants per protocol procedures that specifically relate to primary efficacy outcomes (if it involves participant's safety, it meets the category above)

5.2.2.3. Changing the protocol without Ethics Committee approval

5.2.2.4. Inadvertent loss of samples or data

5.2.3. The deviation is a deliberate or knowing violation of ethical or regulatory policies or guidelines:

5.2.3.1. Failure to obtain informed consent

5.2.3.2. Falsifying research or medical records

5.2.3.3. Performing tests or procedures beyond the investigator's professional scope

5.2.3.4. Failure to follow the safety monitoring plan

5.2.4. The deviation involves serious or continuing non-compliance with institutional or regulatory policies:

5.2.4.1. Working under an expired professional license

5.2.4.2. Repeated minor deviations

5.3. Minor protocol deviations

Minor protocol deviations are deviations which do not affect a participant's safety, compromise the integrity of study data or affect a participant's willingness to continue taking part in the study.

Examples of minor deviations include:

a) Missing pages of a completed consent form
b) Inappropriate documentation of informed consent such as missing signatures
c) Using an expired consent form that has not changed significantly
d) Participant did not receive a copy of a signed consent form (but on discovery, a copy is given to participant)
e) Study procedure conducted out of sequence

6. References:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Site Monitoring Visits
	SOP – 020 - 2020 **Version 2.0, November 2020.**

1. Purpose:

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored for its performance or compliance.

2. Scope:

This SOP applies to any visit/or monitoring of any study site as stated in the ERC approved study protocol that identify the places/s where the study and/or laboratory procedures are being carried out or performed.

3. Responsibility:

It is the responsibility of the ERC-FDS/UOP to perform or designate some qualified agents to perform on its behalf on- site inspection of the research projects it has approved. The Chairperson/Secretary or the members may initiate an on- site evaluation of a study site for cause or routine audit.

4. Detailed instructions:

4.1. Selection of the study site is based on following criteria:
- 4.1.1. New study sites
- 4.1.2. Reports of remarkable serious adverse events
- 4.1.3. Number of studies carried out at the study site
- 4.1.4. Frequency of protocol submission for ERC review
- 4.1.5. Non- compliance or suspicious conduct
- 4.1.6. Frequently fail to submit progress reports/final reports

4.2. Before the visit
- 4.2.1. Contact the site and notify them about the visit
- 4.2.2. Make appropriate travel arrangements
- 4.2.3. Review the ERC files at the office and make appropriate notes

4.3. During the visit
- 4.3.1. Use the “Checklist of a Monitoring Visit” form (AF/16 -020/02.0)
- 4.3.2. The ERC members shall
  - 4.3.2.1. Review the informed consent forms
  - 4.3.2.2. Review randomly the subject files to ensure that the subjects are signing the correct informed consent forms
  - 4.3.2.3. Observe the laboratory and other facilities of the study
  - 4.3.2.4. Obtain immediate feed back

4.4. After the visit

4.4.1. Write a report within 2 weeks

4.4.2. Forward a copy of the site visit report to the 'site monitoring file' for full board review

4.4.3. Send a copy of the report to the PI

5. Glossary:

5.1. Monitoring Visit:

An action that ERC or its nominated member/s visit study sites to assess how well the selected investigators and the institutes are conducting research, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Monitoring visits shall be arranged in advance in concurrence with the principal investigator.

6**. References :**

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Study Termination
	SOP – 021 - 2020 **Version 2.0, November 2020.**

1. Purpose:

This procedure describes how the ERC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the ERC based on serious adverse events, protocol deviation, noncompliance and violation of national and international regulations.

2. Scope:

This SOP applies to any study approved by the ERC-FDS/UOPthat is being recommended for termination before its scheduled completion.

3. Responsibility:

It is the responsibility of the ERC Chairperson to terminate within 24 hours in case of SAE, and any study that the ERC has previously approved when the safety or benefit tothe study participants is in doubt or at risk. The secretariat is responsible for management of the termination process.

4. Detailed instructions:

4.1. Receive recommendation for study termination.

4.1.1. Receive recommendation and comments from ERC members, sponsor or other authorized bodies for study protocol termination.

4.1.2. Request principal investigator to prepare 'Study Termination Memorandum' and the original continuing review application form .

4.1.3. Administrative assistant to initial and date the documents upon receipt.

4.2. Review and discuss the Termination process

4.2.1. Notify the Chairperson regarding the recommendation for study protocol termination with a date by the administrative assistant.

4.2.2. Chairperson reviews the results, reasons and accrual data.

4.2.3. Chairperson calls for an emergency meeting within 5 working days to discuss about the recommendation.

4.2.4. Chairperson signs and dates the continuing review application form in acknowledgement and approval of the termination.

4.3. Notify the principal investigator the decision within 7 working days.

4.4. Keep the original version of the request memorandum for termination and the original version of the continuing review application form in the protocol file.

4.5. Store the protocol documents indefinitely.

5. References:

5.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

5.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Minutes of meetings
	SOP – 022 - 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   The purpose of this procedure is to identify the administrative process and provide instructions for preparation, review, approval, and distribution of meeting minutes of ERC-FDS/.

2. **Scope:**

   This SOP applies to the administrative process concerning the preparation of minutes of ERC meetings.

3. **Responsibility:**

   It is the responsibility of the Secretary/administrative assistant to prepare the minutes and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson shall review and approve the minutes sent to him/her.

4. **Detailed instructions:**

   4.1. The Secretary of the ERC shall prepare and maintain minutes of all meetings.

   4.2. The format of the minutes shall include at least the following items:

   - 4.2.1.attendance;
   - 4.2.2.excuses;
   - 4.2.3.confirmation of minutes of the previous meeting;
   - 4.2.4.business arising from the previous minutes;
   - 4.2.5.conflicts of interest;
   - 4.2.6.new applications;
   - 4.2.7.applications awaiting clarification;
   - 4.2.8.amendments to approved proposals;
   - 4.2.9.correspondence;
   - 4.2.10. other business;
   - 4.2.11. close and next meeting.

   4.3. The minutes shall include a record of decisions taken by the ERC. Any relevant discussion including views expressed by those not present, may be included.

   4.4. In relation to new applications or amendments, the minutes shall record the ERC's decision and any requests for additional information, clarification or modification of the proposal.

   4.5. In recording a decision on a proposal, any significant dissenting view or concern shall be noted in the minutes.

   4.6. To encourage free and open discussion and to emphasise the collegiate character of the ERC deliberations, particular views shall not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

   4.7. Presence of primary reviewers of a protocol is essential before initiating the decision process.

4.8. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC consideration of the relevant application shall be minuted regarding a member's declaration of a conflict of interest.

4.9. Whenever voting occurs, the voting method shall be documented as follows

4.9.1. Voting shall take place after the observers/presenters/board members with conflicts of interest leave the meeting room

4.9.2. The Chairperson determines if the number of voting board members is sufficient to constitute a quorum.

4.9.3. Chairperson makes a motion to recommend action on a protocol or issue being discussed

4.9.4. The motion is seconded and voting takes place

4.9.5. A motion is carried out once the majority of ERC members vote in favour of the motion.

4.10. Minutes shall be produced as soon as practicable and shall be checked by the Chairperson for accuracy.

4.11. The minutes shall be circulated to all ERC members at least one week before the date of meeting. All members shall be given the opportunity to seek amendments to the minutes prior to their confirmation.

4.12. The original copy of minutes of each meeting shall be retained in a 'Minutes' file.

4.13. A summary of the confirmed minutes of each meeting shall be forwarded to the Dean and the Faculty Board for their information. The extracts shall consist of the titles of the approved protocols and the names of investigators and any other decision of the ERC that would need Faculty Board approval for implementation.

5. Glossary:

5.1. Minutes

An official record of the business discussed and transacted at a meeting, conference, .

6. References:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Complaints about the conduct of a research project
	SOP – 023 - 2020 **Version 2.0, November 2020.**

1. **Purpose:**
   The purpose of this SOP is to describe the mechanism of receiving, handling and responding to complaints concerning the participant's rights and conduct of a research approved by the ERC

2. **Scope:**
   This SOP applies to all studies under the approval of the ERC-FDS/UOP.

3. **Responsibilities:**
   The ERC shall require, as a condition of approval of each project, that the researchers indicate the details of the Chairperson/Secretary of ERC to receive complaints about the conduct of the research at the time of submission of the application form.

4. **Detailed instructions:**
   4.1. The ERC maintains a complaint register at the ERC office to receive written complaints from research participants, researchers or other interested persons about the conduct of the approved research. In addition, they can post written and signed complaints to the Chairperson/Secretary of ERC directly. The contact details of the ERC should be included in the participant information sheet and consent forms.

   4.2. Any complaints received by the ERC office about the conduct of research approved by the ERC shall be investigated by a member appointed by the ERC. That person is responsible for obtaining details of the complaint, in writing, especially in the case of verbal complaints, including the grounds for the complaint and shall notify the Chairperson as soon as possible.

   4.3. If the Chairperson considers the complaint to be of a sufficiently serious nature, he/she shall bring it to the attention of the Dean as soon as possible.

   4.4. Where the complaint concerns a serious matter that lies within the jurisdiction of the Ministry of Health or other institution, the Dean shall consider referral of the complaint to that body.

   4.5. The Chairperson or Secretary shall send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator in all cases, outlining the nature of the complaint and the mechanism for inquiring into the complaint, as set out below.

   4.6. The Chairperson shall inquire into the complaint and confirm its validity, or appoint suitable persons to inquire into the complaint, and make recommendationsabout the course of action to be taken at the next meetingof the ERC. If the complaint is substantiated, action may include:
   4.6.1. amendments to the proposal, including increased monitoring by the ERC;
   4.6.2. suspension of the research till remedial action has been taken;
   4.6.3. termination of the study; or
   4.6.4. Other actions to address issues raised by the complainant.

4.7. If the complainant is not satisfied with the outcome of the Chairperson's inquiry, then he/she can appeal against the decision with reasons and refer the complaint to the Dean or his/her nominee, or request that the Chairperson does so, with a request for re-appraisal.

4.8. In such an instance as in (4.7) above, the Chairperson of the ERC shall provide the Dean or his/her nominee with all relevant information including:

4.8.1. the nature of the complaint;
4.8.2. material reviewed at the Chairperson's inquiry ;
4.8.3. the decision of the Chairperson's inquiry; and
4.8.4. any other relevant documentation and pertinent information.

4.9. The Dean shall determine whether there are sufficient grounds to review the decision of the Chairperson and if so, whether a further inquiry of the complaint is warranted. If there is no indication for further inquiry, the Dean shall inform the complainant and the Chairperson of this.

4.10. If the Dean determines that there are grounds to review the decision of the initial inquiry, then he/she shall establish a panel to consider the complaint

4.10.1 The panel shall include, at least, the following members:
4.10.2 the Dean or his/her nominee, as convenor of the panel;
4.10.3 two nominees of the Dean (who are not members of the ERC);
4.10.4 the ERC Chairperson or his/her nominee.

4.11 The panel shall give afford the ERC and the complainant the opportunity to make submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with an opportunity to make submissions.

4.12 The panel shall have access to all documents relating to the research and may interview other parties, and seek internal and external expert advice, as it deems fit.

4.13 The Dean shall notify the complainant, the Chairperson and the investigators (if an allegation has been made against them) of the outcome of the inquiry in the following terms: either the appeal is dismissed and the decision of the Chairperson upheld; or the Dean directs suitable action to be taken to resolve outstanding issues mentioned in the appeal.

5. Glossary :

5.1 Participant's Rights

Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family. It is essential that human rights should be protected by the rule of law.

6. References:

6.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Complaints concerning review process the ERC
	SOP – 024- 2020 **Version 2.0, November 2020..**

1. Purpose :

The purpose of this SOP is to describe the procedure for receiving and handling concerns or complaints from investigators about the ERC's review process.

2. Scope:

This SOP applies to the conduct and actions of the ERC-FDS/ UOP with regards to the review process of applications submitted

3. Responsibility:

Any concern or complaint about the ERC's review process should be directed to the attention of the Chairperson of the ERC and /or Dean, FDS/UOP. The preliminary investigation is the responsibility of the Chairperson and the Dean, FDS/UOP. They shall decide if a further inquiry is necessary.

4. Detailed instructions:

4.1 Any concern or complaint about the ERC's review process should be directed to the attention of the Chairperson of the ERC, detailing, in writing, the grounds of the concern or complaint. Complaints may also be made to the Dean.

4.2 The Chairperson shall l inform the Dean as soon as possible of any complaints received by him/her. The Dean shall inform the Chairperson as soon as possible of any complaints received by him/her. The Dean shall send a letter of acknowledgement to the complainant, outlining the following mechanism.

4.3 The Chairperson or nominee shall l investigate complaint and its validity, and make a recommendation to the ERC on the appropriate course of action to be taken at its next meeting.

4.4If the complainant is not satisfied with the outcome of the ERC investigation, he/she can then refer the complaint to the Dean or his/her nominee.

4.5 The Chairperson of the ERC shall provide the Dean with all relevant information about the complaint/concern, including:

4.5.1 the complaint;
4.5.2 material reviewed at the Chairperson's or the nominee's investigation
4.5.3 thedecision of the Chairperson's or the nominee's investigation and
4.5.4 any other relevant documentation.

4.6 The Dean shall determine whether there is to be a further investigation about the complaint.

4.7 If the Dean determines there is to be a further investigation, then he/she shall appoint a panel to consider the complaint/concern.

4.8 The panel shall include, at least, the following members:

4.8.1 The Dean or his/her nominee, as convenor of the panel.

4.8.2 Two nominees of the Dean (not members of the ERC).

4.9 The panel shall request the ERC and the complainant to make submissions.

4.10 The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advice. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with the FERCSL Guidelines, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or biased manner.

4.11 The Dean shall notify the complainant and the ERC of the outcome of the investigation. The outcome of this process may include:

4.11.1 The complaint/concern is dismissed.

4.11.2 The complaint/concern is referred back to the ERC for consideration, bearing in mind the findings of the panel.

4.11.3 The application may be referred for external review by an independent ERC if the Dean concludes that due process has not been followed by the ERC in reaching its decision.

4.12 The panel may also make recommendations about the operation of the ERC including actionssuch as:

4.12.1 a review of the Terms of Reference and Standard Operating Procedures;

4.12.2 a review of the ERC's membership

4.12.3 other such action, as appropriate.

5**. References :**

5.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

5.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Record Keeping
	SOP – 025- 2020 **Version 2.0, November 2020.**

1. **Purpose:**

The purpose of this SOP is to identify the administrative process and provide instructions for presentation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of ERC-FDS/UOP meetings.

2. **Scope:**

This SOP applies to administrative process concerning the preparation of the agenda for all regular ERC-FDS/UOP meetings.

3. **Responsibility:**

It is the responsibility of the Secretary ERC to prepare the agenda for the ERC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agenda and minutes sent to him/her.

4. **Detailed instructions:**

4.1. The Secretary of the ERC shall prepare and maintain written records of the ERC's activities, including agendas and minutes of all meetings of the ERC.

4.2. The administrative assistant of the ERC shall prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:

4.2.1. the proposal identification number;
4.2.2. the principal investigator(s);
4.2.3. the name of the responsible institution or organisation;
4.2.4. the title of the project;
4.2.5. date of review at the ERC meeting and the decision;
4.2.6. the approval or non-approval of any changes to the proposal;
4.2.7. the terms and conditions, if any, of approval of the proposal;
4.2.8. type of approval whether approval was by expedited review; and
4.2.9. action taken by the ERC to monitor the conduct of the research.

4.3. The paper file shall contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the ERC, all approved documents and other material used to inform potential research participants.

4.4. All relevant records of the ERC, including applications, membership, minutes and correspondence, shall be kept as confidential files.

4.5. To ensure confidentiality, all documents provided to ERC members, which are no longer required, should e disposed in a secure manner.

4.6. All records pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention shall be five (5) years from the date of approval. Files which are required for longer retention shall be electronically archived. Retention periods shall be ten (10) years from the date of approval.

4.7. A register of all the applications received and reviewed shall be maintained in accordance with the FERCSL Guidelines.

5. Glossary:

5.1. Administrative Documents

Documents include official minutes of board meeting and the SOPs, and other relevant documents.

5.2. Inactive Files

Approved documents and supporting documents , records containing communication and correspondence with the investigator, and reports that corresponds to each study approved by the ERC board for which a final report has been received and accepted.

6. References:

6.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

6.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : ERC reporting requirements
	SOP – 026- 2020 **Version 2.0, November 2020.**

1. **Purpose:**

   The purpose of this SOP is to describe the reporting requirements of the ERC to the Faculty Board.

2. **Scope:**

   This SOP applies to minutes of meetings, annual report and Terms of Reference, Standard Operating Procedures and membership of the ERC-FDS/UOP.

3. **Responsibility:**

   It is the responsibility of the Secretary to forward the summery of minutes and any other communication to the Faculty Board on behalf of the ERC.

4. **Detailed instructions**:

   4.1. The minutes of every ERC meeting, in summary form, shall be forwarded to the Faculty Board through the Dean.

   4.2. The ERC shall provide an annual report to the Faculty Board at the end of each calendar year on its progress, including;

   4.2.1. membership changes

   4.2.2. number of meetings

   4.2.3. number of proposals reviewed, approved, rejected

   4.2.4. monitoring procedures for ethical aspects of research in progress

   4.2.5. description of any complaints received and their outcomes

   4.2.6. description of any research where ethical approval has been withdrawn and reasons for withdrawal of approval and

   4.2.7. general issues raised

   4.3. The ERC Terms of Reference, Standard Operational Procedures and membership shall be available upon request to the general public, and shall be posted on the website.

   4.4. The ERC shall maintain records of all financial transactions and audited accounts shall be reviewed by the ERC annually.

5. **References:**

   5.1. WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

   5.2. International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Handling multi- site research studies
	SOP – 027- 2020 **Version 2.0, November 2020.**

1. **Purpose :**
   To describe the procedure for the handlingof multi-centre research by the ERC

2. **Detailed instruction:**
   2.1. To facilitate the review of multi-centre research, the ERC may:
      2.1.1. communicate with any other ERC;
      2.1.2. accept a scientific/technical and/or ethical assessment of the research by another ERC;
      2.1.3. share its scientific/technical and/or ethical assessment of the research with another ERC.
      2.1.4. It shall follow review procedures and after review procedures as per the SOPs for studies at PU.

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Review of Terms of Reference and Standard Operating Procedures
	SOP – 028- 2020 **Version 2.0, November 2020.**

1. **Purpose :**

   The purpose of this SOP is to describe the procedure for the amendment of Terms of Reference and Standard Operating Procedures of the ERC.

2. **Scope:**

   This SOP covers the procedures of writing, reviewing, distributing and amending SOPs of the ERC-FDS/UOP.

3. **Responsibility:**

   It is the responsibility of the Chairperson and Secretary to appoint a SOP team to formulate the SOPs by following the same procedure, format, and coding system when drafting or editing any SOP of the institute.

4. **Detailed instructions:**

   4.1 Terms of Reference and Standard Operating Procedure shall be reviewed at least every three years and amended as necessary.

   4.2 The Terms of Reference and Standard Operating Procedures may be amended consequent to proposals made by ERC members to the Faculty Board.

   4.3 For those proposals made by an ERC member:

   4.3.1 The proposal must be in writing and circulated to all ERC members for their consideration.

   4.3.2 The views of the members shall be discussed at a scheduled meeting of the ERC. Any member unable to attend such a meeting may register his/her views in writing.

   4.3.3 The proposal shall be ratified if two thirds of the members agree to the amendment.

   4.3.4 The Chairperson shall send the amendment to the Faculty Board for review and approval.

   4.4 For those proposals made by the Faculty Board:

   4.4.1 The Dean shall send the proposal in writing to the ERC

   4.4.2 The proposal shall be circulated to all ERC members for their consideration.

   4.4.3 The views of the members shall be discussed at a scheduled meeting of the ERC. Any member unable to attend such a meeting may register his/her views in writing.

   4.4.4 The proposal shall be ratified if two thirds of the members agree to the amendment.

   4.4.5 The decision of the ERC shall be conveyed to the Faculty Board.

   4.5 Process of maintaining history of SOP revisions

   4.5.1 Previous official versions of SOPs, tables of content, relevant information regarding changes shall be conserved at the ERC.

5 References:

5.1 WHO Operational Guidelines for Ethical Review Committee that review biomedical research (Geneva 2000 www.who.int/tdr/publications/aceseed on 25th August 2014).

5.2 International conference on harmonization, guidance on Good Clinical Practice (ICH GCP) 1996.

Annexures

Annexur: **(AF/01- 003/Version 2.0, November 2020)**

The letter of appointment

Date:

Name:

Address

Dear ……..,

Appointment to the Ethics Review Committee

I am pleased to inform that you have been appointed as a member of the Ethics Review Committee of the Faculty of Dental Sciences, University of Peradeniya for a period of three (3) years with effect from …….

As a member of the committee, you would be entrusted with the task of reviewing proposals submitted for ethics approval as per the standard procedures of the ERC and relevant national and international guidelines.

The Faculty of Dental Sciences, University of Peradeniya will provide the indemnity in respect of all liabilities that may arise in the course of bona fide conduct of your duties. The TOR and the SOPs are attached herewith.

Please sign the attached confidentiality agreement and hand it over to the ERC office.

Yours sincerely

……..

Dean

Annexur: **(AF/02- 003/Version 2.0, November 2020)**

Confidentiality agreement

This agreement is made and entered into on this …….. Day of …… …….. by and between Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya (hereinafter referred to as ERC) and ……
(Holder of NIC number ……) of ……..
(Hereinafter referred to as the "member")

Whereas the member has agreed to serve on the aforesaid ERC and in which capacity the member will have access to confidential Information in the ERC;
AND WHERE AS the member has acknowledged and agreed that the committee has and shall continue to have sole rights to the confidential Information and has agreed to hold the same in strict confidence during and after the member's period of service within the ERC.

1. Interpretation

"Confidential information" shall include all information of a confidential and proprietary nature provided or made available to the member by the ERC including but not limited to the research proposal and documents. Techniques, intellectual property and processes and such other information related to the ERC but shall not include information which is or becomes publicly available other than through the faults of the member.

2. Obligations of the member

The member hereby undertakes:

a) to maintain the highest degree of secrecy and keep as confidential any Confidential Information which the member may be granted access to or which may be available to or which member receives on behalf of the ERC or in the capacity of the member ERC by any means and to use such confidential information only in duty authorized manner in the interest of the ERC and for the purpose of fulfilling function and responsibility arising a as member of the ERC.

b) not at any time during or after service within the ERC, for any reason, disclose or permit to be disclosed any Confidential Information to any third party or to use such confidential information for personal use without the express prior written approval of the ERC.

c) on termination of the period of membership within the ERC, for whatever reason to the ERC all property, documents and paper in the members possessions or control relating to the inter alia of the ERC.

d) that in the event of break of any of the conditions mentioned above, the ERC shall be entitled to injunctive relief and or specific performance to enforce the conditions set out above.

3. Legal compulsion to disclose

In the event that the member becomes legally compelled to disclose any Confidential Information the member shall give prompt notice in writing of such facts to the ERC so that ERC has an opportunity to seek a protective order or other remedy. In the event that such protective order or other appropriate remedy is not sought by the ERC or is sought but is not obtained, the member will nevertheless disclose only that portion or the confidential information as is necessary to comply with its obligations under law and shall use reasonable endeavors to obtain any appropriate court order or other reliable assurance that confidential treatment will be accorded to confidential information so disclosed.

4. ***The member hereby unconditionally accepts and acknowledges that having regard to the nature of the ERC and the functions and duties of the member of the ERC the member considers the terms and conditions imposed herein has being fair and reasonable.***

..... ……..

Signature of the member date

…….. ……

Signature of the Chairperson of the ERC date

Annexur: **(AF/03- 004/Version 2.0, November 2020)**

Training Record of …….(Name) ERC FDS, UOP

Name of training session	Date	Conducted by

Annexure: **(AF/04- 007/Version 2.0, November 2020)**

Ethics Review Application Form
Common Application Format-FERCSL

For office use only

Application No:		Checked By:	
Date Received:		ERC Meeting Date:	

Level of Risk: No Risk/Minimal Risk/Greater than Minimal Risk
Review Type: Exempted/Expedited Review/Full Board Review
Names of the Reviewers:

1)	2)
3)	4)

Date Informed:

Part-I: Basic Information

1.1.Title of Project

1.2. Details of Investigator (s)

Name	Qualifications	Designation & Affiliation of	Role	Signature
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	

Attach separate sheet if needed

1.3. Contact details of the Principal Investigator

Address for communication	
Telephone No(s)	
Fax No	
Email Address	

1.4. Is this a post graduate protocol

Yes ☐ No ☐

If yes, give following details

Course/degree	
Institution	

1.5. Has this protocol been subjected to scientific review by any other institution/board/committee/Boss?

Yes		No	

if yes, give derails

Name of the institution/board/committee/BoS

Outcome of the review and date

1.6. Funding

Is this project funded

Yes		No	

Name & Address of the Funding Source (s)†	Amount

†*Please complete Annexure-1 for research funded*

1.7. Proposed starting & Ending dates †,‡

Starting Date				Ending Date			

† From initial recruitment of participants until completion of all data collection

‡ Retrospective approval will Not be given for the projects already started or completed

1.8. Location/s where the study would be conducted

1.9. Has ethics approval for this protocol been requested from this ERC or another ERC

Yes		No	

If yes, give details(name of the committees and outcome)

1.10. Conflict of interest

a. Does any member of the research team have any Conflict of

Yes		No	

If yes, please give details (investigator, co- investigator, collaborator)	
Commercially	
Financially	
Intellectually	
Other(explain)	

C. If there is a duality of interest stated above describe how the conflict/s would be addressed.

Part –II: Project Overview

2.1. Study type (mark with "✓")

	Epidemiological study/Non-interventional study
	Survey/Audit
	Clinical trial (*Please complete Annexure-2*)
	field Trial/Community Trial
	Case study
	Qualitative study
	Health System Research
	Implementation Research

	Complementary and alternative medicine (CAM) research
	Experimental study
	Other (please specify)

2.2. Nature of the Protocol (mark all appropriate with a "✓")

	Research with Human Participants
	Research using stored human biological material
	Research involving medical devices
	Research using Medical Records, Registers or Databases
	Establishment and maintenance of research database *(Please complete Annexure 4)*

Part-III: Scientific Validity and Ethical Conduct

Please include the following information as given in your protocol indicating the page number(s) relevant to each section in the box.

3.1. Justification		Applicable		Section in Protocol & page
		Yes	No	
1)	The scientific importance of your study in relation to improving health care and/or knowledge on the subject.			
2)	The justification for a replication study, if this is a replication study.			

3.2.Scientific validity		Applicable		Section in Protocol & page
		Yes	No	
1)	Justification for conducting the study in this population			
2)	Study design			
3)	Objectives: General and specific			
4)	The inclusion and exclusion criteria			
5)	How the sample size was calculated			
6)	Plan for selection of the sample			
7)	Details of data collection tools, methods, investigations, etc.			

† Please complete Annexure-3, if this is a community based study

3.3. Consent		Applicable		Section in Protocol & page
		Yes	No	
1)	The procedure for approaching the relevant community and initial contact of with the participants+			
2)	The procedure for obtaining informed consent			
3)	The information (written/oral) provided to participants			
4)	The procedure for ensuring that subjects have understood the information provided.			
5)	The procedure for obtaining proxy consent.			
6)	The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited. (for children aged 12-18 years in addition to parental consent, children's assent must be sought)			
7)	The procedure for withdrawing consent and withdraw from the research			
8)	The procedure for re-consenting			

3.4. Confidentiality		Applicable		Section in Protocol & page
		Yes	No	
1)	How the data and samples will be obtained			
2)	How long data and samples will be kept			
3)	Justification for collection of personal identification data			
4)	Who will have access to the personal data of the research participants			
5)	How the confidentiality of participants be ensured			
6)	The procedure for data and sample storage			
7)	The procedure for data and sample disposal			

3.5. Vulnerability and Inducement		Applicable		Section in Protocol & page
		Yes	No	
1)	Justification for including vulnerable populations			
2)	Compensation provided to participants.			

3.6. Collaborative partnership		Applicable		Section in Protocol & page
		Yes	No	
1)	The collaborations you have established with institutions where the study is to be conducted			
2)	The collaborations you have established with the community where the study is to be conducted			
3)	Patient and public engagement and involvement (PPEI) in research			
4)	Benefit due to this collaboration to individual, institution, society, etc.			

3.7. Social Value		Applicable		Section in Protocol & page
		Yes	No	
1)	The beneficiaries of your research and the benefit to them			
2)	The plan for dissemination of study findings			

3.7. Rights of the participants		Applicable		Section in Protocol & page
		Yes	No	
1)	Procedure for subjects to ask questions and register complaints			
2)	The contact person for research participants			
3)	Provisions for participants to be informed of results			

3.8. Assessment of Risks/Benefits		Applicable		Section in Protocol & page
		Yes	No	
1)	The risks to research participants (physical, psychological, etc.)			
2)	Benefits to research participants			
3)	Steps taken to minimize risks			
4)	Support provided to the research participants (medical, psychological and other)			
5)	Risk-benefit analysis/discussion			

3.9. Responsibilities of the researcher		Applicable		Section in Protocol & page
		Yes	No	
1)	Declaration of conflicts of interests and how the investigators plan to manage the conflicts			
2)	The ethical/legal/social and financial issues relevant to the study			

Part-IV: Information Sheet (IFS)/Informed Consent Form (ICF) Check List

4.1. List the sections and page number in IFS/ICF where you have dealt with the following

		Section in IFS/ICF & page
1)	Purpose of the study	
2)	Voluntary participation	
3)	Duration, procedures of the study and participant's responsibilities	
4)	Potential benefits	
5)	Risks, hazards and discomforts	
6)	Collection and fate of biological samples	
7)	Reimbursements	
8)	Confidentiality	
9)	Termination of study participation	

Part-V: Document Check List & Declaration

I declare that I have attached the following documents (Please tick and confirm):

	Document	version/ Date	Application	No. of copies
1)	Covering Letter			
2)	Application Form (Part I, II, III, IV & V)			
3)	Annexure-1 (Research funded by foreign agencies/companies)			
4)	Annexure-2 (Clinical trials)			
5)	Annexure-3 (Community based research)			
6)	Annexure-4 (Establishment and maintenance of research database)			
7)	The complete research protocol including a section on ethics considerations			
8)	Information sheet for research participants (IFS)			
	English			
	Sinhalese			
	Tamil			
9)	Informed Consent Form (ICF)			
	English			
	Sinhalese			
	Tamil			
10)	Assent Form			
	English			
	Sinhalese			
	Tamil			
11)	Data collection booklets/forms/questionnaires			
	English			
	Sinhalese			
	Tamil			
12)	Approval letter from BOS, institutions			
13)	Ethics approval letter (if any)			
14)	Indemnity/Insurance coverage (required for clinical trials)			
15)	Clinical Trials Contract (required for clinical trials)			
16)	Certificate of GAP training for relevant member of the research study			

17)	Materials Transfer Agreement (required for all research involving transfer of biological samples abroad)			
18)	Brief curriculum vitae of all investigators			
19)	A receipt of payment (if applicable)			
20)	Soft copies of the documents			
21)	Approval letter from BOS, institutions			
22)	Ethics approval letter (if any)			

Declaration of applicant

1) As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
2) I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
3) I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
4) I affirm that I will submit all relevant documents such as progress reports, final reports, Saes, etc. as required by the ERC
5) I declare that I am not seeking approval for a study that has already commenced or has already bee Completed.
6) I certify that the information given above is true and correct to the best of my knowledge. I understand that if this information is found to be incorrect the ERC approval if given will be withdrawn.

	Date:			

Signature of Principal Investigator

Full name of the Principal Investigator

Annexur: **(AF/05- 007/Version 2.0, November 2020)**

Document Receipt Form
ERC Faculty of Dental Sciences, University of Peradeniya.

Protocol No:		Date of submission:
Type of submission:	1. Initial review 2. Protocol Amendments	3. Continuing review of Approved Protocol
Protocol Title :		
Principal investigator:		
Telephone Number:		Email:
Institution:		
Document submitted: 1. Complete	2. Incomplete, will submit on	
Documents to be submitted :		
Received by :		
Date of received:		
This proposal will be considered by the ERC at its meeting on ...../...../2014 Secretary Date		

Annexure: **(AF/06 – 013/Version 2.0, November 2020)**

Exemption from Ethics Review
ERC Faculty of Dental Sciences, University of Peradeniya.

Protocol No:	Date of Submission :
Protocol Title :	
Name of the PI:	
Address:	

Dear Prof/ Dr /Mr/Ms

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting of held on ……. /……../……..

This proposal is exempted from ethics review for the following reasons.

1.

2.

The following documents have been reviewed by the committee.

1. Project proposal
2. Study instrument – English

Please note that this exemptionis valid to the submitted protocol only and any alteration or deviation should be notified to the ERC.

Chairperson Secretary

Annexure:**(AF/07-015/ Version 2.0, November 2020)**

Protocol Extension Submission Form
Ethical Review Committee, Faculty of Dental Sciences, University of Peradeniya.

Protocol No:	Submitted date:
Protocol Title:	
Principal Investigator:	
Institute:	Telephone No:
Approved date:	Extension submission date:
Extension period: from ...../...../..... to ...../...../.....	
Reason for extension:	
Signature:..... Date:	

Annexure: **(AF/08-015/ Version 2.0, November 2020)**

Protocol Amendment Submission Form
Ethical Review Committee, Faculty of Dental Sciences, University of Peradeniya.

Protocol No:	Submitted date:
Protocol Title:	
Principal Investigator:	
Institute:	Telephone No:
Approved date:	No of amendment:
Reason for amendment:	
Amendments are attached with this form	
Type of review requested: ☐ Expedited (minor changes) ☐ Full Review (more than minor changes or the amendment "materially affects risk of subjects") Signature:..... Date:	

Annexur: **(AF/09 – 016/ Version 2.0, November 2020)**

ETHICAL CLEARANCE CERTIFICATE

The Institutional Ethical Review Committee, Faculty of Dental Sciences, University of Peradeniya has reviewed and discussed the protocol / protocol extension / protocol amendment of Research Project No …….. titled.....
.....
....".submitted by Prof/Dr .....on .....

The committee has decided to approve the version …… of the referenced protocol at its …….. meeting held on …/…/….., subject to the following conditions:-

- It is understood that the study is being conducted at .....
  .....
- Any amendment or deviation to this study protocol should not be implemented until it is reviewed and approved by the ERC, Faculty of Dental Sciences, Peradeniya. The required amendments/deviations should be submitted to the ERC, Faculty of Dental Sciences, Peradeniya using the **Amendment Submission Form.**
- This certificate is valid until....., and if an extension is required; a properly filled **Protocol Extension Submission Form** should be submitted to the ERC, Faculty of Dental Sciences, Peradeniya, one month before the termination date.
- Any Serious Adverse Event that occurs during the conduct of the study should be reported to the ERC Faculty of Dental Sciences, Peradeniya immediately.
- The study should be conducted after obtaining informed consent from patients/guardians/participants.
- Submission of a progress report to the ERC, FDS, Peradeniya on ethical issues at the end of one year is mandatory.
- Submission of the final report to the ERC, Peradeniya at the end of the study is mandatory.
- The study has to be conducted in compliance with the approved protocol; failing to oblige may lead to cancellationofapproval.

....

Secretary ERC Chairperson ERC

Annexure **:(AF/10 - 016/Version 2.0, November 2020)**

Letter Requesting Additional Information
ERC Faculty of Dental Sciences, University of Peradeniya.

Protocol No:	Date of Submission :
Protocol Title :	
Name of the PI:	
Address:	

Dear Prof/ Dr /Mr/Ms

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting of held on ……../……../……..

The following additional information is requested:

You are advised that you should not commence this study until the final approval has been granted. Please highlight the changes made to the documents to assist the Committee inchecking the amended documents. **(delete if not applicable).??**

In order to table your response at the next Ethics Review Committeemeeting, this information should be forwarded to the ERC Office by ……./……./……..

Yours sincerely,

Secretary

Ethics Review Committee

Annexure : **(AF/11 -016/Version 2.0, November 2020)**

Letter for Rejection of an Application
ERC Faculty of Dental Sciences, University of Peradeniya.

Protocol No:	Date of Submission :
Protocol Title :	
Name of the PI:	
Address:	

Dear Prof/ Dr /Mr/Ms

Thank you for submitting the above research proposal, which was considered by the Ethics Review Committee, at its meeting of held on ……./……../…….

The Committee, which operates in accordance with the relevant guidelines of theForum of Ethics Review Committees in Sri Lanka (FERCSL) and the InternationalConference on Harmonisation Good Clinical Practice (ICH GCP), has decided not toapprove your project for the following reasons:

You may discuss the ERC's decision regarding your proposal with the chairperson or me by appointment.

Yours sincerely,

Secretary

Ethics Review Committee

Annexure : **(AF/12 -017/Version 2.0, November 2020)**

Letter for APPRECIATION TO THE REVIEWER

Date .....

.....
.....
.....

Dear Sir/ Madam,

This is to express our deep appreciation and gratitude for your contribution in reviewing the following research proposals submitted to the Ethics Review Committee of the Faculty of Dental Sciences, University of Peradeniya:
Title .....

Your unbiased reviews with constructive comments were very useful in improving the standards of the research carried out by the members of the Faculty and those of the profession who are from external institutions.

We very much appreciate and are very thankful for your contribution and look forward to your continued support in improving the ethical aspect and quality of our research in the future.

Chairman / Ethical Review Committee
Faculty of Dental Sciences
University of Peradeniya.

Annexure**: (AF/13– 018/Version 2.0, November 2020)**

……/ ……../ Year
Secretary
Ethics Review Committee,
Faculty of Dental Sciences,
University of Peradeniya.

Notification of Serious Adverse Event (SAE)

I herewith send the duly filled three monthly/ six monthly serious adverse event reporting form for consideration of the EthicsReview Committee.

Chief Investigator's Comments -

Yours sincerely,

.....

Chief Investigator

Annexure: **(AF/14– 018/Version 2.0, November 2020)**

Serious Adverse Event (SAE)Report

Principal investigator: .....
Protocol No: .....

Study Title:
.....
.....

Name of the studied medicine/device: .....
Period from ..... to.....

Sponsor:.....

No.	Description of unexpected adverse event	Date of Event	Date start and end of treatment	sex	Age	Seriousness (Y/N)	Related to study (Y/N)	Concomitant medication	Intervention	Remarks

Comments:

Reviewed by.....
Date: .....

Annexure: **(AF/15 -019/Version 2.0, November 2020)**

Continuing Review form (quarterly / biannually / annually)
ERC, Faculty of Dental Sciences, University of Peradeniya.

Protocol Number:	
Principal Investigator:	
Telephone No.	Email:
Protocol Title:	
Number of participants enrolled	
Number of participants who withdrew.	
Number of participants lost to follow-up.	
A summary of any complaints about the research since the last Committee review.	
A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last Committee review.	
Signature of PI	Date

Annexure: **(AF/16 – 020/Version 2.0, November 2020)**

Final Report
Ethical Review Committee, Faculty of Dental Sciences, University of Peradeniya.

Protocol No:	Assigned No:
Protocol Title:	
Principal Investigator :	
Phone No:	E mail Address:
Sponsor's Name:	
Address:	
Phone No:	E mail address:
Study site(s):	
Total number of study participants:	
Number of study arms:	
Objective(s):	
Study materials and method:	
Study dose(s):	
Duration of the study:	
Treatment form:	
Adverse events:	
Results and Conclusions:	
Signature of PI:	Date:

Annexure: **(AF/17 – 021/Version 2.0, November 2020)**

Deviation / Non Compliance / Violation Record

Application No.	Date:
Study Title:	
Name of the Investigator/s:	
Address:	Contact No.
Institution:	Contact No.
Sponsor:	Contact No.
☐ Deviation from protocol ☐ Non Compliance ☐ Major ☐ Minor ☐ Violation	
Description:	
ERC decision:	
Action taken:	Outcome:
Detected by. Date .	Reported by. Date.

Annexure: **(AF/18 – 008/Version 2.0, November 2020)**

CHECKLIST for SITE MONITORING VISIT

Protocol No.:	Date of visit:
Study Title:	
Name of the Principal Investigator:	
Phone:	Name of the Sponsor:□
Address:	Address of the Sponsor:
Total number of subjects expected: ☐ yes ☐ No	Total number of subjects enrolled:
Are site facilities appropriate? ☐ yes ☐ No	Comments:
Is informed consent up to date? ☐ yes ☐ No	Comments:
Any adverse event found? ☐ yes ☐ No	Comments:
Any protocol non-compliance/violence? ☐ yes ☐ No	Comments:
Are all case records, forms up to date? ☐ yes ☐ No	Comments:
Is storage of data and investigating products locked? ☐ yes ☐ No	Comments:
How well are participants protected? ☐ Good ☐ Fair ☐ Poor	Comments:
Any outstanding tasks or results of visits? ☐ yes ☐ No	Details:
Duration of visit:……hours.	Starting from:
Names of the ERC members 1. 2. 3.	
Date:	

Ethical Review Committee, Faculty of Dental Sciences,
University of Peradeniya.

Premature study termination report

1.Application number:	
2. Title:	
3. Name of PI:	
4. Contact number and email address:	
5. Study site:	
6. Sponsor:	
7. ERC approval date:	8. Last progress report submission date:
9. Study start date:	10. Original study termination date:
11. Study participants: (provide number) 11.1 Target accrual of study/trial: 11.2 Total patients to be recruited: 11.3 Screened: 11.4 Screen failure: 11.5 Enrolled:	

11.6 Consent withdrawn and reasons:

11.7 Withdrawn by PI and reasons:

11.8 Active on treatment:

11.9 Completed treatment:

11.10 Patients on follow up:

11.11 Patients lost to follow up:

11.12 Any other

12. Any impaired participants: 12.1 None: 12.2 Physically: 12.3 Mentally: 12.4 Both:
13. SAE total numbers:
14. SAE events:
15. PI signature and date:

Annexure: **(AF/20 – 009/Version 2.0, November 2020)**

Template for ERC Agenda

1. Excuses
2. Announcements
3. Minutes of the previous meeting
4. Business arising from the previous minutes,
5. New applications:
   5.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

6. Resubmissions
   6.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

7. Continuing review
   7.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

8. Previously unapproved applications
   8.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

9. Amendments to approved proposals
   9.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

10. Extensions

10.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

11. Serious Adverse Events

11.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

12. Deviations

12.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

13. Violation /non compliance

13.1.

Protocol No.:	Version:	Date:
Title :		
Names of investigators :		
Sponsor:		
Reviewers		

14. Any other business,

15. Close of meeting and date of next meeting

Annexure: **(AF/21 – 009/Version 2.0, November 2020)**

Template for ERC Minutes

1. **Attendance:**
2. **Excuses:**
3. **Confirmation of minutes of the previous meeting:**
4. **Business arising from the previous minutes:**
5. **Conflicts of interest:**

Chair requested members to declare COI regarding protocols under review before the commencement of the meeting

6. **New applications;**

6.1.

Protocol No.	**Date of Submission:**	
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:** **Ethical:** Vulnerability – Physical Risk – Psychosocial risk – Benefits – Consent – Confidentiality – Withdrawal rights –		
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove **Voting details:** **Detailed instructions:** Resubmission after correction of major methodological errors.		

7. **Resubmissions:**

7.1.

Protocol No.	**Date of 1st submission:**	**Date of re submission:**
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:**		

Ethical: Vulnerability: Physical Risk: Psychosocial risk: Benefits: Consent: Confidentiality: Withdrawal rights:
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove **Detailed instructions:**

8. Continuing review:

8.1.

Protocol No.	**Date of Submission:**	
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:** **Ethical:** Vulnerability: Physical Risk: Psychosocial risk: Benefits: Consent: Confidentiality: Withdrawal rights:		
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove **Detailed instructions:**		

9. Previously unapproved application:

9.1.

Protocol No.	**Date of Submission:**	
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:** **Ethical:** Vulnerability: Physical Risk: Psychosocial risk: Benefits: Consent:		

Confidentiality: Withdrawal rights:
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove **Detailed instructions:**

10.Amendments to approved proposals:

10.1.

Protocol No.	**Date of Submission:**	
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:** **Ethical:** Vulnerability: Physical Risk: Psychosocial risk: Benefits: Consent: Confidentiality: Withdrawal rights:		
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove **Detailed instructions:**		

11.Extensions to previously approved proposals:

11.1.

Protocol No.	**Date of Submission:**	
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:** **Ethical:** Vulnerability: Physical Risk: Psychosocial risk: Benefits: Consent: Confidentiality: Withdrawal rights:		
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove		

Detailed instructions:

12. Deviations :

12.1.

Protocol No.	**Date of Submission:**	
Title:		
Principal Investigator :		
Institution:	**Protocol Version:**	**ICF Version:**
Sponsor:	**Study Instrument Version:**	
Reviewers:		
Points discussed: **Science:** **Ethical:** Vulnerability: Physical Risk: Psychosocial risk: Benefits: Consent: Confidentiality: Withdrawal rights:		
Decision: □Approved; □Minor errors - resubmission; □ Major errors - resubmission; □ Disapprove **Detail instructions:**		

13. Serious Adverse Events (SAE):

14. Violations / Non Compliance :

15. Report of the Expedited review:

16. Other matters:

Starting time: **Adjourned at:**

Prepared by:

Chairperson, ERC Secretary,