TERMS OF REFERENCE

AND

STANDARD OPERATING PROCEDURES

Faculty of Dental Sciences

University of Peradeniya

2019

Terms of Reference and Standard Operating Procedures for Unit and Subcommittee of the Faculty of Dental Sciences

Approved by the Faculty Board of Dental Sciences

TERMS OF REFERENCE

UNDERGRADUATE DIVISION (UGD)

Terms of Reference
Undergraduate Division of Faculty of Dental Sciences

Purpose:

The Undergraduate Division (UGD) of the Faculty of Dental Sciences is responsible for implementation, conducting and monitoring of the undergraduate study program of FDS under the directives of the Dean of the Faculty and guidelines established by the Board of the Faculty of Dental Sciences.

Composition of the committee of UGD*:*

- Two Coordinators representing different phases of the study program
- Chairperson/Curriculum Committee (CCom)
- Chairperson/Faculty Quality Assurance Cell (FQAC)
- Director/ Unit for Development of Dental Education (UDDE)
- Coordinator/ Students' Welfare and Advisory Committee
- Academic Coordinator/ Examination Division
- Coordinator/ Faculty English Language Teaching Unit (FELTU)
- Four (04) elected members among academic staff of FDS

Invited members:

The committee of the UGD shall decide to invite any person/s to attend its meetings if the contribution of such person/s may advance its objectives. However such members shall be of non-voting capacity.

Meetings of the UGD:

One of the coordinators shall chair the meetings of the UGD. There shall be nine (09) meetings scheduled to be held each year, while a minimum of six (06) meetings per year would be compulsory. Meetings shall be held on the third Tuesday afternoon of a month unless otherwise directed and specified by the Dean and the Faculty Board.

Quorum and Voting:

The quorum for a meeting shall be 50% plus one. All members shall have the voting power at a time of a dispute. In the event of a tie, the Chair will cast the deciding vote.

Administrative Assistance: The office of the UGD under the Dean's Office and Assistant Registrar/FDS shall provide administrative assistance.

Specific Duties and Responsibilities of the UGD:

1. Advise the Dean on matters in relation to implementation and conducting of the undergraduate study program of the Faculty.
2. Report to the Faculty Board on academic matters in relation to implementation of the undergraduate study program.
3. Promote and ensure that academic standards are maintained at the highest possible level during implementation and delivery of all courses in the study program.
4. Prepare handbooks with clear guidelines and useful information to students to be distributed at the time of entering the FDS.
5. Prepare course-books for each segment of the study program.
6. Provide feedback and liaise with the Curriculum Committee and the Examination Division for periodic review of courses, course content, delivery, assessments and rules and regulations of the study program.
7. Establish mechanisms for effective delivery of courses across the study program.
8. Prepare annual calendar of dates to synchronize all academic years within the Faculty.
9. Compile and finalize all teaching schedules of the study program with the assistance of Course Coordinators and Semester Coordinators.
10. Ensure maximum horizontal and vertical integration within and between courses when preparing time tables.
11. Compile guidelines and protocols received from Course Coordinators for all clinical/laboratory/practical procedures carried out by students.
12. Ensure that the students follow the code of ethics as they follow the study program.
13. Organize and coordinate with the relevant sub-committees for orientation of new entrants and clinical induction of students as they advance into the clinical phase of training.
14. Prepare a calendar of assessments for all courses in all semesters, and keeping students informed in advance through semester time tables, email, Moodle and the web.

15. Ensure that all student records are securely arranged in a retrievable manner while maintaining confidentiality of records.
16. Promptly report to the Dean and the Faculty Board for necessary advice or action, for any matter which cannot be resolved within the committee of UGD.

Delegation of Tasks:

In addition to the specific duties and responsibilities of the UGD, it shall delegate other identified tasks and responsibilities for subcommittees appointed by the UGD, as and where necessary.

TERMS OF REFERENCE

FACULTY RESEARCH COMMITTEE (FRC)

Terms of Reference

Faculty Research Committee of Faculty of Dental Sciences

The Faculty Research Committee (FRC) is a sub-committee of the Faculty Board and will provide reports, recommendations and advice to the Faculty Board regarding research and development activities of the faculty. Further, the FRC shall be responsible for developing strategies that would help to maintain a healthy research culture in the Faculty and to promote cross-disciplinary research and scholarly output. Therefore, the FRC aims to develop and promote the conduct of quality research in a scholarly environment in the faculty. In this endeavor, the FRC shall implement and manage research activities in line with the rules and regulations of the Senate Research Committee (SRC) of the University of Peradeniya.

1. Membership

- Chairman
- Secretary
- All Heads of Departments
- Chairman/Higher Degrees Committee
- Five academic staff members appointed by the Faculty Board
- Two external members with experties in research

2. Frequency of meetings

The FRC meetings shall be held at least once in two months. The quorum for a committee meeting shall be one third of the membership.

3. Conflict of interest

Committee members are required to declare to the Chair any real, perceived or potential conflict of interest that they may have with any item on the Committee's agenda. If the Chair or Committee deems a member to have a conflict of interest in a matter before the Committee, the member will be excused from discussions and deliberations regarding that matter.

4. Activities of the FRC

4.1 Lectures and workshops on research related topics

The FRC shall be responsible for organizing lectures/workshops on research related topics for academic staff and postgraduate students.

4.2 University research grants

The FRC shall promote and foster a research culture among faculty members and also monitor research funded through university research grants. The FRC shall be responsible for the review of university research grant applications of faculty members and recommend suitable project proposals for consideration by the SRC for the award of university research grants. Further, the FRC shall monitor the progress of such research grants, review and submit biannual progress reports and the final reports of research grants to the SRC.

Matters pertaining to university research grants shall be dealt in accordance with the rules and regulations governing university research grants of the SRC (annexure.1).

4.3 Research allowance applications

The FRC following the review report of the subcommittee appointed by the Faculty Board shall recommend applications of academic members for the payment of the research allowance to the Vice Chancellor.

4.4 Undergraduate research symposium

The FRC shall organize an undergraduate research symposium annually where undergraduate students are provided with an opportunity to present their findings based on their research. The best three research presentations selected at this symposium shall be nominated to be presented at the annual iPURSE .

4.5 University research sessions

The FRC shall support the organizing committee of the annual iPURSE. Accordingly, the FRC shall liase with the subcommittees of the main organizing committee of iPURSE.

4.6 Recognition of researchers in the faculty

The FRC shall develop a scheme to recognise researchers of the faculty. A panel consiting of three members shall review the applications regarding research activities of academic staff based on predetermined criteria annually. Those academic members who receive the minimum required mark shall be awarded certificates of recognition for their research.

4.7 Development of policies and practices to improve research

The FRC shall develop and review policies and practices to improve the quality, impact and quantity of research activity in the faculty and monitor implementation of such policies and evaluate their outcomes.

TERMS OF REFERENCE
ENGLISH LANGUAGE TEACHING UNIT (ELTU)

Terms of Reference

English Language Teaching Unit (ELTU) of Faculty of Dental Sciences

Background

English Language Teaching Unit (ELTU) of the Faculty of Dental Sciences operates in liaison with the ELTU of the University of Peradeniya. ELTU of the Faculty of Dental Sciences is directly answerable to the Faculty Board and its functions shall be monitored by the committee of the ELTU appointed by the Faculty Board. There shall be a fulltime coordinator for the ELTU and a member of the academic staff who has been appointed by the faculty board shall act as the convener of the committee of the ELTU.

Committee of the ELTU

The Committee of the ELTU shall meet time to time and discuss the matters relevant to the functioning of the ELTU, the designing and conduct of the English language teaching programme.

Membership of the ELTU Committee

- Convener appointed by the faculty board
- Two academic staff members appointed by the Faculty Board
- Coordinator/ELTU
- Any other staff in the ELTU
-

Committee of the ELTU will specifically look into the following with reference to the ELTU activities.

1. Planning the Intensive English Course for the new entrants and monitoring its implementation with the ELTU staff.
2. Planning and organizing the variety entertainment at the completion of the Intensive English Course with the ELTU staff

3. Making suggestion to improve the English courses conducted for the BDS undergraduates during the curriculum revisions and preparation of the programme book.
4. Providing necessary advice to the ELTU staff regarding English language requirements of BDS undergraduates.
5. Monitoring proper conduct and assessments of English language courses in the BDS curriculum.
6. Making arrangements for additional English classes by the ELTU for the students who need extra support in English throughout the BDS programme.
7. Supporting the planning and implementation of the English language courses for the dental auxiliary trainees and non-academic staff of the Faculty of Dental Sciences.
8. Making suggestions to the Faculty board regarding the necessary facilities/requirements and infrastructure developments for the ELTU.

Activities of ELTU will be as follows.

1. **English for new entrants and the variety entertainment**

ELTU conducts Intensive English Course of 3-4 months duration for the new entrants each year. A placement test is held at the entry for all students in order to grade them according to their level of proficiency in English. The areas of English proficiency focused on are: reading and comprehension, speech, listening and writing.

Intensive Course in English aims to provide the students with an adequate knowledge and proficiency in the English language, which will enable them to follow the BDS program successfully. At the completion of the Intensive English Course, a variety entertainment concert shall be organized by the ELTU annually to showcase the numerous talents of the new entrants.

2. **English for the BDS undergraduates**

The primary mission of the ELTU is to assist students with their English, so that they can follow the BDS programme effectively. Accordingly, ELTU shall assist the Faculty to design and implement English courses identified in the BDS degree programme.

ELTU shall also provide advice regarding the development, implementation of teaching and learning related policies and procedures regarding English language teaching for the BDS undergraduates.

Currently ELTU is conducting the following courses for the new BDS curriculum and the ELTU coordinator is the course coordinator of these courses. Accordingly, delivery of the courses and assessments are conducted by the ELTU.

Further, modifications of the courses and the relevant amendments shall be suggested to the curriculum committee by the ELTU each year to be included in the programme book.

Semester	**Course No**	**Course name**	**Credits**
1	DS1107	English 1	non GPA
2	DS 1206	English 2	non GPA

3. English for students who request extra support

ELTU shall also help the students who need extra support in English throughout the BDS programme. Such requests should be directed to the Dean through the respective semester coordinator by the students upon which arrangements are made to cater the students' requests.

4. English for trainees in the dental auxiliary training school (DATS)

ELTU conducts courses for the trainees in the DATS each year. Course designing, conducting classes and the evaluation of the students are performed with the concurrence of the DATS curriculum and the Director/DATS.

5. English for non-academic staff

ELTU conducts English classes for the non-academic staff of the Faculty of Dental Sciences to support their office work and the teaching support activities.

6. Other activities

ELTU also provides English language support that includes editing of documents mainly for the Dean's office and other academic departments when the need arises.

ELTU shall send the reports of the work done by the unit to the Dean after the completion of the intensive course in English and the ongoing courses (semester 1 & 2) regularly.

TERMS OF REFERENCE

POST GRADUATE AND HIGHER DEGREES COMMITTEE (PGHDC)

Terms of Reference

Post Graduate and Higher Degrees Committee of Faculty of Dental Sciences

The terms of reference (TOR) and the functioning of the Post Graduate and Higher Degrees Committee (PGHDC) is as follows:

Responsibilities of the PGHDC include

1. To conduct the Post graduate and Higher Degrees Committee meetings (PGHDC)
2. It is the responsibility of the chairman and the secretary to conduct regular and special meetings of the Post Graduate and Higher Degrees Committee
3. The PGHDC meeting will be held every 3rd Wednesday of each month.

   It is expected that members attend PGHDC meetings in person. Members who are unable to attend a meeting should send a written excuse to the Chairman, Post Graduate and Higher Degrees Committee. The minutes should record the submission of excuses
4. Meetings will usually continue until all agenda items have been considered
5. Minutes are maintained in a file in an orderly manner

   Higher Degrees application must be submitted in the format prescribed by the HDC which is available in the Dean's Office. It shall include all necessary documentation and information required to complete the submission form that is available in the Dean's office. All applications should be addressed to the Secretary, PGHDC Faculty of Dental Sciences, University of Peradeniya.
6. Responsibilities of the Post Graduate and Higher Degrees Committee
   - Collecting applications for HD
   - Discuss the applications at the PGHDC meetings and appoint two (02) reviewers and forwarding applications to reviewers
   - After the review process is completed HDC approval for registration of MPhil, or PhD degree
   - Colleting progress reports every 6 months

- When submitted to conduct the thesis defence as instructed in the rules and regulations booklet (attached)
- Submission of names of graduates to the convocation for degrees and issue of any other relevant documents
- Assisting in formulation of new postgraduate degree programmes to be conducted by the Faculty
- Maintain a record of all postgraduate students attached to the Faculty of Dental Sciences at a given time including foreign postgraduate students
- Facilitate and assist in registration, orientation on the commencement of the programme
- Issuing a post graduate identity card from the Faculty (cost born by the student)
- Provision of Wi-Fi and library facilities if requested subjected to University rules and regulations
- Conducting regular educational activities for postgraduate students such as journal clubs, workshops and registrar forums
- Provision of infrastructure facilities within available resources (e.g. Postgraduate room)
- Coordinate with the PGIM or other relevant authorities (MOH, Armed forces etc) regarding any issues pertaining to post graduate matter through the Dean Faculty of Dental Sciences

Details of the Minutes of meetings of PGHDC

1. The secretary of the HDC will prepare and maintain minutes of all meetings.
2. The format of the meeting will include at least the following items;
   2.1. Attendance
   2.2. Excuses
   2.3. Absence
   2.4. Confirmation of the minuets of the previous meeting
   2.5. Business arising from the previous minutes
   2.6. Current applications

2.7. New applications

2.8. Progress reports

2.9. Title change

2.10. Appointment of examiners

2.11. Examination results

2.12. Correspondence

2.13. Matters pertaining to post graduate students

2.14. Any other matters

3. The minutes will be circulated to all PGHDC members at least one week before the date of the meeting
4. The confirmed minutes of each meeting will be filed
5. Confirmed minutes of each meeting shall be forwarded to the Faculty Board for their approval

TERMS OF REFERENCE

UNIT FOR DEVELOPMENT OF DENTAL EDUCATION (UDDE)

Terms of Reference

Unit for Development of Dental Education of Faculty of Dental Sciences

Amended Policy document, May 2019

The field of Dental education has evolved greatly globally and still progressing. In Sri Lanka there is lot of space for development of dental education. Currently, there is no dedicated unit or a body for the field of dental education in Sri Lanka. Dental education cannot be separated from medical education although there could be distinct differences.

Many years ago, a unit for enhancement of Dental Education was established in the Faculty of Dental Sciences. It was the "Centre for Development of Dental Education (CDDE)", which was later designated as Unit for Development of Dental Education (UDDE). The original objectives of the UDDE entailed the following.

1. Research on dental education
2. Dental Curriculum development
3. Staff development
4. Improvement of Student assessments
5. Enhancement of Learning
6.

However, with subsequent changes which took place with the development of the 5 year curriculum, some of the above mentioned tasks were assigned to distinct committees which have been carrying out the respective tasks up to present. Keeping abreast with these changes the amended policy of the UDDE is as follows.

Unit for Development of Dental Education (UDDE)

Faculty of Dental Sciences, University of Peradeniya

Mission

To provide leadership in planning and developing **dental education** and to facilitate sustainable resource development in the field of Dental Education both nationally and in the South Asian Region.

Focus

1. Identification of newer areas for improvement in Dental education
2. Developing linkages among different sectors related to Dental education
3. Collaborating with national and international centres of excellence in medical and dental education
4. Enhancing sustainability of relevant institutions
5. Promoting innovations in both undergraduate and post graduate dental education and policy and quality standard formulation
6. Promoting multidisciplinary research in Dental education

Span of activities of the UDDE include

1. Conducting workshops and lectures for continuing professional development of academic staff, trainers of health professions education.
2. Gathering and analysis of required information for the development of dental education
3. Facilitating dialogue on trends in dental education
4. Carrying out educational research
5. Providing consultancy services
6. Publishing educational material

Resources and manpower

The Dean Faculty of Dental Sciences will be facilitating the assignment of the manpower and resources to the UDDE.

Human Resources:

The unit will consist of two committees, namely the main Planning committee and an Action committee.

The Planning committee, which will function at a coordination level, will consist of eight (08) Ex-officio members, the Director/UDDE and the Secretary of the UDDE. The main aim of the Planning Committee will be to give the basic inputs in accomplishing the focus areas of the UDDE and also to critique the tasks carrying out by the UDDE.

Thus, the membership of the Planning committee should consist of:

1. Dean Faculty of Dental Sciences
2. Director UDDE
3. Chairman/ Curriculum committee
4. Coordinator/ Undergraduate Division
5. Chairperson/ Quality Assurance cell
6. Coordinator/ Examination Division
7. Chairman/ Student Welfare and Advisory Committee
8. Director/ Dental E-Learning Unit
9. Chairperson/ Faculty Research committee
10. Coordinator/ Postgraduate division

The planning committee will meet once a month.

The Action committee will comprise of eight academic staff members and several non-academic staff members to execute the tasks needed to be completed by the UDDE.

This will be headed by the Director UDDE and the committee will meet more frequently depending on the tasks assigned to the UDDE.

In addition to aforementioned members, considering the multiple tasks that is planned to carry out by the UDDE, recruitment of a permanent non-academic staff member to the unit for secretarial work would be necessary.

Physical resources:

Existing physical facilities allocated to the unit can be utilised for the future functions and the additional facilities if required would be requested according to the need.

TERMS OF REFERENCE

FACULTY QUALITY ASSURANCE CELL (FQAC)

Terms of Reference of Faculty Quality Assurance Cell

- **Responsibilities and duties of FQAC coordinator**

a. Liaise with the Director, internal Quality Assurance Unit (IQAU) of the University to coordinate university level Quality Assurance Unit (QA) activities.
b. Organize Faculty level QA meetings on two months basis.
c. Attend to specific issues as recommended by the University Quality Assurance Management Committee from time to time.
d. Monitor the collation and analysis of Faculty level QA data as peer review forms and student feedback forms.
e. Coordinate with other related committees and units within the Faculty on matters related to QA activities.
f. Prepare the Faculty for programme reviews conducted by the QAS and implementation of their recommendations.
g. Submit recommendations to uplift the status of the faculty based on the stakeholder feedbacks, public surveys, statistics and other information.
h. Providing information requested by the IQAU in order to operate its activities efficiently and effectively.
i. Cooperate with the IQAU in reviewing and monitoring the quality academic programmes, research and services provided by the faculties.
j. Maintenance of records pertaining to finance at the faculty level.

CURRICULUM DEVELOPMENT POLICY AND KEY GUIDELINES OF THE FACULTY OF DENTALSCIENCES

Curriculum Development Policy and Key Guidelines of Faculty of Dental Sciences

Policy code: CDP/FDS/2019

Established Date: May/2019

Reviewed Date:May/2019

This document relates to the curriculum development policy of the Faculty of Dental Sciences, University of Peradeniya and describes the procedure to be followed when study programs and courses are, added, deleted or amended. The curriculum development policy shall ensure that the Faculty develops curricula to meet national and international standards. By-laws, guidelines and practices shall be formulated based on this policy. In addition, the policy outlines the roles of administrators and key committees in the curriculum development process. This policy on curriculum development of the Faculty shall be referred to as the ***Curriculum Development Policy of the Faculty of Dental Sciences of the University of Peradeniya-2019 (CDP/FDS/2019)***. CDP-FDS-2019 is guided by the policies and procedures established by the Senate of the University of Peradeniya.

Abbreviations used throughout this policy document include the following:

ADPC: Academic Development and Planning Committee

BFDS: Board of the Faculty of Dental Sciences

CCom: Curriculum Committee

CD&R: Curriculum Development and Revision

CDP: Curriculum Development Policy

CRC: Curriculum Review Committee

ER&R: Examination rules and regulations

EU: Examination Unit

FDS: Faculty of Dental Sciences

PGD: Post Graduate Division of the Faculty

QAC: Quality Assurance Cell

SLQF: Sri Lanka Qualification Framework

UDDE: Unit for Development of Dental Education

UGC: University Grants Commission

UGD: Undergraduate Division of the Faculty

UoP: University of Peradeniya

1. The FDS shall be responsible for program design, development and deletion
2. Faculty members shall be key drivers of the CD&R process.
3. Being a state university, CD&R shall be done in the best interest of the socioeconomic development of the country through enhancing the quality of dental education.
4. The curricula developed by the Faculty shall give due consideration to ensure social justice, ethical values and gender equity
5. The programs shall be periodically reviewed and developed as and when necessary with a minimum of a 6-year gap between two review cycles.
6. A careful and meticulous review on the appropriateness of the graduate profile for the next decade shall be the starting point of any major review.
7. Curriculum development or revision may be required for the following reasons
    - Changes in academic and/or community needs;
    - Changes in pedagogy or instructional methodology;
    - Changing needs of students;
    - Changing international, national, provincial and professional association standards;
    - New directives and initiatives from relevant statutory bodies.
    - Or any other
8. Maximum transparency shall be maintained in the process of CD& R.
9. The CCom of the Faculty shall be responsible and accountable for the development of undergraduate curricula and the PGD is responsible and accountable for the development of curricula for postgraduate study programs of the Faculty.
10. The CCom shall be a standing committee of the BFDS and meet at least ten times per year.
    a. The CCom shall be chaired by a permanent academic staff member; Senior Lecturer Grade I or above of the Faculty.

b. CCom shall include the following members:
    i. All semester coordinators
    ii. Director of the UDDE
    iii. Coordinators of the UGD
    iv. Coordinator of the EU
    v. Two student members.
c. Members including outside experts shall be co-opted if and when necessary.

11. Stakeholders of the curricula of the FDS shall be students of respective study programs, members of students' unions, administrative bodies of the university, relevant state and non-state agencies, parents of students, patients, relevant professional bodies and practitioners and the public.
12. Views of all internal and external stakeholders shall be entertained in the process
13. Suggestions for curriculum/course amendments/new courses/programs shall be originated by any stakeholder. The CCom and the BFDS shall give due consideration to such suggestions and document the course of action to be taken in relation to such suggestions.
14. The Faculty shall uphold the following in relation to CD&R
    a. Adoption of an outcome-based approach as the philosophy of the process.
    b. Be consistent with the mission and vision of the Faculty and conforms to the mission and vision of UoP.
    c. Adoption of national guidelines stipulated in SLQF.
    d. Teaching and the learning process (T&LP) are learner centered.
    e. Course Intended Learning Outcomes (ILOs) are constructively aligned to the Program Learning Outcomes (PLO) and the graduate profile (GP).
    f. Learning outcomes define skills, knowledge, and attitudes that a student is expected to demonstrate following completion of a course or a program of study.
    g. Multiple summative and formative approaches shall be used for assessments and student grading.
    h. Modern IT based technology shall be incorporated in delivery, assessment and program management.

15. The CRC shall review the output of the CCom and the PGU in relation to CD&R for acceptability.
16. Course and program approval process shall follow guidelines stipulated by the UoP.
17. The Faculty shall ensure that members and all parties involved in the curriculum development process are thoroughly educated on the task and materials, instructions and guidelines are provided to those involved in the curriculum development process.
18. The Dean and the Assistant Registrar/Senior Assistant Registrar shall provide finance, infrastructure and physical facilities to carry out the process.
19. Members of the UDDE, PGD, UGD, CCom, CRC and members of any related committees shall be appointed by the Dean with the consent of the BFDS
20. Amendments to the curriculum and the process to be followed:
    a. Amendments to the duration of study programs or proposals to establish new study programs
        i. Be based on national needs and shall require feedback from all stakeholders
        ii. Following approval of the BFDS, the Office of the Dean shall submit such amendments to course specifications to the Senate for approval
        iii. Following the approval of the Senate, the University shall submit the proposal for approval of the UGC.
    b. Amendments to existing study programs that do not require a change in the duration of the study program
        i. Shall be proposed to the Dean of the Faculty in writing by any stakeholder or expressed at the meeting of BFDS. The Dean shall instruct the CCom and/or the PGD to take appropriate actions.
        ii. Shall be compiled by the CCom or the PGD and following approval of the BFDS, the Office of the Dean shall submit such amendments to the Senate for approval.
        iii. Such proposals shall be submitted to the Senate only once a year unless otherwise mandatory.

c. Amendments to curricula that do not require changes to already approved course specifications or the program structure by the Senate **but** require only the approval of the BFDS

   i. Such amendments shall be

      1. Changes to assessment structure without changing the breakdown of percentage marks listed in the course specifications
      2. Changes to the type/ number of questions and time durations of assessment components
      3. Changes to the distribution of lectures, practical classes, in-class assignments and clinical sessions.
      4. Any other changes to the curriculum documented in the student handbook and program manual which have already been approved by the BFDS

   ii. Shall be proposed to the Dean of the Faculty in writing by any stakeholder or expressed at the meeting of BFDS. The Dean shall instruct the CCom and/or the PGD to take appropriate action.

   iii. Shall be compiled by the CCom or the PGD following a thorough discussion at the committee and obtain the approval of the BFDS.

21. Examination rules and regulations (ER&R) pertinent to different study programs shall be compiled separately.
22. CCom shall compile new ER&R or introduce amendments to existing ER&R and following approval of the BFDS, submit it to the Senate for approval.
23. Concurrent with every revision of the curriculum at the levels of 20a and 20b, the ER&R shall be reviewed, and congruency be established.
24. All revisions to the curriculum and ER&R shall be communicated to students and staff promptly through faculty web-page.
25. Following implementation of the curriculum cohesion, efficiency and effectiveness shall be reviewed periodically with wider stakeholder participation.
26. The Faculty shall cancel a program after considering all aspects including national needs based on feedback obtained from all stakeholders.

27. CDP-FDS-2019 shall be reviewed and confirmed by BFDS with necessary amendments every ten years.

TERMS OF REFERENCE

INFORMATION TECHNOLOGY (IT), NETWORKING AND CENTRAL RECORD COMMITTEE

Terms of Reference of Information Technology (IT), Networking and Central Record committee

Introduction:

The IT, Networking and Central Record committee the Faculty of Dental Sciences (FDS) was re-constituted at the 302nd Faculty Board with broadened responsibilities constituting the up-liftment and maintenance of the IT, Networking and Central Record keeping in order to facilitate the study programs of FDS.

It is governed under the directives of the Dean of the Faculty and guidelines established by the Board of the Faculty of Dental Sciences.

Composition:

- The committee is chaired by the co-ordinator appointed by the faculty board, under the guidance of the Dean, Faculty of Dental Sciences.
- The Dean of the faculty of Dental Sciences shall be an ex-offcio – member of the committee.

- **Members of the committee: (Appointed by the Faculty Board)**
    - Six academic staff members
    - One computer programmer
    - Three technical officers
    - Invited member; non-voting (if necessary)

- **Administrative Assistance:** The Dean's Office and Assistant Registrar/FDS shall provide administrative assistance. (One management assistant)

- The committee shall where necessary appoint sub committees from its members and the invited members of the committee to carry out specific tasks. A member of the committee shall be appointed as a convener for the sub-committee/s

Meetings:

- Minimum of 6 meetings per year
- Call for the meetings by the coordinator

Quorum:

- Five members of the committee
- All the members of the committee shall have the voting power
- No voting power for the invited members
- In the event of a tie, the coordinator shall cast the deciding vote

Duties and responsibilities of the committee:

- To enhance the information technology facilities for the academic and non-academic staff members of the Faculty of Dental Sciences
- To introduce new updated technologies on information technology, Networking and record keeping to the Faculty of Dental Sciences.
- Collaborate with IT committee of the University of Peradeniya and to keep par with the developments of IT and networking in the University of Peradeniya.
- To improve the standards of IT knowledge of the academic and non-academic staff members of the faculty.
- To maintain and update the faculty website
- To maintain efficient data base system for the dental students
- To maintain efficient data base system for the patients of the Dental Hospital Peradeniya
- To introduce and maintain the proper storage system for the patient records
- To prepare guidelines on the use of IT, Networking and Central Records of FDS and submit to the Faculty Board.

STANDARD OPERATING PROCEDURES
ETHICS REVIEW COMMITTEE (ERC)

STANDARD OPERATING PROCEDURES

ETHICS REVIEW COMMITTEE

FACULTY OF DENTAL SCIENCES,

UNIVERSITY OF PERADENIYA

Version 1.0

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
Dr. R.W. Pallegama, Chairman		
Dr. N.S. Soysa, Secretary		
Prof. S.L. Ekanayake, member		
Prof. A. Tilakaratne, member		
Prof. P.R. Jayasooriya, member		
Prof. K.T. Silva, member		
Prof. M.A.M. Sitheeque, member		
Mr. Asoka B. Herath, member		
Dr. I. Gunaratne, member		
Dr. A.K.S. Arambawatta, member		
Dr. J.A.V.P. Jayasinghe, member		
Dr. H.R.D. Peiris, member		
Dr. B.M.H.S.K. Banneheka, member		
Dr. J.A.M.S. Jayathilake, member		

Approved by

Name and Position	Signature	Date
Prof. W.M Thilakaratne Dean/Faculty of Dental Sciences, University of Peradeniya		

TABLE OF CONTENTS

No.	List of SOPs	Code	Version	Effective date	Page
1	ERC Functions	SOP 001	01.0	01/04/2016	04
2	Membership composition	SOP 002	01.0	01/04/2016	07
3	Appointment and responsibilities of members	SOP 003	01.0	01/04/2016	09
4	Functions of the ERC members	SOP 004	01.0	01/04/2016	12
5	Orientation of new ERC members and training	SOP 005	01.0	01/04/2016	15
6	Independent Consultant/s for review	SOP 006	01.0	01/04/2016	17
7	Submission procedure for new applications	SOP 007	01.0	01/04/2016	19
8	Preparation of agenda	SOP 008	01.0	01/04/2016	22
9	Conduct of meetings	SOP 009	01.0	01/04/2016	23
10	Conflict of interest	SOP 010	01.0	01/04/2016	25
11	Consideration of initial applications for ethics review by the ERC	SOP 011	01.0	01/04/2016	27
12	Review of resubmitted protocols	SOP 012	01.0	01/04/2016	30
13	Exemption from review	SOP 013	01.0	01/04/2016	32
14	Expedited review	SOP 014	01.0	01/04/2016	34
15	Amendments and extensions to approved proposals	SOP 015	01.0	01/04/2016	37
16	Notification of decisions of the ERC for new applications	SOP 016	01.0	01/04/2016	39
17	Handling of Adverse Events	SOP 017	01.0	01/04/2016	41
18	Monitoring of approved research studies	SOP 018	01.0	01/04/2016	44
19	Intervention in noncompliance and violation	SOP 019	01.0	01/04/2016	46
20	Site Monitoring Visits	SOP 020	01.0	01/04/2016	48
21	Study Termination	SOP 021	01.0	01/04/2016	50
22	Minutes of meetings	SOP 022	01.0	01/04/2016	51
23	Complaints about the conduct of a research project	SOP 023	01.0	01/04/2016	53
24	Complaints concerning the ERC's review process	SOP 024	01.0	01/04/2016	55
25	Record Keeping	SOP 025	01.0	01/04/2016	57
26	ERC reporting requirements	SOP 026	01.0	01/04/2016	59
27	Handling of multi-centre research	SOP 027	01.0	01/04/2016	60
28	Review of Terms of Reference and Standard Operating Procedures	SOP 028	01.0	01/04/2016	61

TABLE OF ANNEXURE

No.	List of Annexure	Code	Version	Effective date	Page
1	Letter of appointment	AF/01 -003	1.0	01/04/2016	62
2	Confidentially agreement form	AF/02-003	1.0	01/04/2016	63
3	Training record form of members	AF/03 -005	1.0	01/04/2016	**65**
4	Ethics Review Protocol Submission Form with study assessment	AF/04 - 007	1.0	01/04/2016	66
5	Document Receipt Form	AF/05 - 007	1.0	01/04/2016	82
6	Exemption from Ethics Review	AF/06 - 013	1.0	01/04/2016	83
7	Protocol Extension Submission Form	AF/07 - 015	1.0	01/04/2016	84
8	Protocol Amendment Submission Form	AF/08 - 015	1.0	01/04/2016	85
9	Ethical Clearance Certificate	AF/9 - 016	1.0	01/04/2016	86
10	Letter Requesting Additional Information	AF/10- 016	1.0	01/04/2016	87
11	Standard letter for rejection of an application	AF/11 - 016	1.0	01/04/2016	88
12	Notification of Serious Adverse Event (SAE)	AF/12 -017	1.0	01/04/2016	89
13	Continuing Review form (quarterly / biannually / annually)	AF/13 - 018	1.0	01/04/2016	91
14	Final Report	AF/14- 018	1.0	01/04/2016	92
15	Deviation/Noncompliance/Violation Record	AF/15 - 019	1.0	01/04/2016	93
16	Checklist of a Monitoring Visit form	AF/16 - 020	1.0	01/04/2016	94
17	Premature study termination report	AF/17 - 021	1.0	01/04/2016	95
18	Template for ERC Agenda	AF/18 - 008	1.0	01/04/2016	98
19	Template for ERC Minutes	AF/19 - 009	1.0	01/04/2016	100

	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya
	Subject : ERC Functions
	SOP – 001 - 2016 **Version 1.0, April 2016.**

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 the ethical standards of research conducted in the institution or collaborated by its researchers in accordance with 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. Detailed functions:

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 research in accordance with 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 fairly among all groups and classes in society, taking age, gender, economic status, culture and ethnic considerations into account. Ethical Review Committee (ERC) provides independent, competent and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, ERC needs to have independence from political, institutional, professional, and market influences and similarly they need to demonstrate competence and efficiency in their work. The ERC is responsible for carrying out the review of proposed research before the commencement of the research and also to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision.
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 SOP 001/01.1).

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 of researchers who are doing research related to dental, oral and maxillofacial diseases submitted by the researchers attached to the Health ministry when submitted through the administrative authority of the institution where the research will be carried out.

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

4.1.2.5. The role of the ERC in providing ethics approval and monitoring of the research; the role of the institution to which the researcher is accredited in giving approval for the research to be conducted within its premises.

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 an 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 to it for review in accordance with the FERCSL, FERCAP and other national and international guidelines and with national and international laws to determine their acceptability on matters of ethics. This shall include an examination of the scientific validity of 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, rules etc.,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 : Membership composition
	SOP – 002 - 2016 **Version 1.0, April 2016**

1. Purpose :

To describe the membership composition of the ERC-FDS.

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

2. Scope:

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

3. Responsibilities:

It is the responsibility of the Faculty Board of Dental Sciences to read and understand and act accordingly in appointing members to 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 to it 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. Dean of the Faculty or Heads of institutions should 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 a “confidentiality agreement”

5. Glossary :

5.2. ERC Members Individuals serving as regular and alternative members on the ERC board. These boards are constituted in accordance with the membership requirement of the FERCSL guidelines.

5.3. Non faculty Members

ERC members who are not permanent staff members of the Faculty of Dental Sciences, University of Peradeniya.

6. References:

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

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

6.4. 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 - 2016 **Version 1.0, April 2016**

1. **Purpose** :

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

2. **Scope :**

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

3. **Responsibility:**

   It is the responsibility of the ERC members and the Faculty of Dental Sciences to 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 will be appointed by the Faculty Board based 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 will be issued by the Dean.

   4.3. Chairpersons and secretaries will 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 will issue the letters of appointment.

   4.4. Members are appointed in their individual capacity and not by designation (no ex-officio members).

   4.5. The letter of appointment (AF/01 – 003/01.0) 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 will be required to sign a confidential agreement (AF/02 – 003/01.0) 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 will be kept confidential; that any

conflicts of interest, which exist or may arise during his/her tenure on the ERC will 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 are appointed for a period of three years, renewable at the discretion of the Faculty Board. At the end of three (03) years the committee is reconstituted and the new committee should 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 functioning of the ERC. Members who wish to be reappointed shall make 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 are encouraged to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the ERC.

4.12. Members shall not be remunerated. Members will 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 a leave of absence from the ERC for a period not exceeding six months.

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

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

4.17.To ensure the 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 of the meeting,
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 until their successors are named for a period of three years.

4.19. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will 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 writing to 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 and responsible 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 in 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 - 2016 **Version 1.0, April 2016**

1. Purpose:

These standard operational procedures describe the Terms of Reference (TOR) which provides the framework for functions of 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 will conduct the meeting.

4.2.3. Conduct 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 guidelines in 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 with 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. Must be willing to publicize his/her full name, profession and affiliations.

4.4.3. Should 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 a conflict does exist with respect to a study abstain from reviewing the protocol or leave the room during discussion of and voting on the protocol.

4.4.6. Respect each others' views and 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 for the study proposals assigned as primary reviewers prior to meeting 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 main 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 regulatory guidance. 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 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. Make sure that the room, equipments and facilities are available 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 confidentiality of ERC documents.

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

5. Glossary :

5.2. 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 :

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

6.3. 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 - 2016 **Version 1.0, April 2016**

1. Purpose:

To describe the procedures for the orientation of new members and to inform the members why training is necessary and how the members should seek to regularly attend training or workshop programmes to update themselves on the progress of technology, information and ethics. Further the Faculty recognizes the importance of training and continuing professional development, therefore, the institution will 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 training all members 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. It is the responsibility of all members to have themselves educated and trained periodically and it is the responsibility of the Chairperson and Secretary to organize 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 on 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 review process for a maximum of three meetings /proposals before undertaking independent ethics review.

4.5. New members will be provided information on training courses, workshops, conferences, etc. And members should select the ones they need and inform the Secretary/secretariat.

4.6. Members should keep training/workshop/conference records (AF/03-005) in chronological order and a copy must 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 - 2016 **Version 1.0, April 2016**

1. Purpose :

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

2. Scope:

If the Chairperson or the ERC determines that a study will involve procedures or information that is not within the area of expertise of its members, the Chairperson or the ERC may invite individuals with competencies in special 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 to be endorsed by the 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 to it, subjected to that person(s) having no conflict of interest and providing an undertaking of 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 in accordance with the expertise needed to review the proposal and will 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 may be professionals in the areas of community and/or patient representation, medicine, statistics, social science and law.

4.2.4. Independent Consultant(s) are appointed for the period sought or for a specific proposal and is not a continuous ongoing appointment/service.

4.3. Conditions of Appointment

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

Willingness to publicize his/her full name, profession, and affiliation; all 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) must 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 them and send a report to the Secretary ERC be reviewed by the ERC at the time the study is reviewed at the ERC meeting. This will be reviewed by the ERC at the time the study is reviewed.

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

4.3.6. The ERC shall maintain a roster of consultants.

5. Glossary:

5.1. Independent consultant

A nonmember 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 - 2016 **Version 1.0, April 2016**

1. Purpose :

To describe the procedure for the 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

↓

Verify as per document checklist by the administrative assistant

↓

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

↓

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

↓

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 must be submitted in the format prescribed by the ERC, **(**AF/04 – 007/01.0**)** which is available in the Faculty of Dental Sciences web site and shall include all necessary documentation. Application should 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 in the same web site. All applications should be addressed to the Secretary, ERC, Faculty of Dental Sciences, University of Peradeniya.

5.2. Applications for ethical clearance must be submitted in the application form given by the ERC and should be accompanied by the following documents

5.2.1. Three copies of complete research proposal.

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

5.2.3. Three copies of other relevant documents, such as, questionnaires check lists etc - in English, Sinhala and Tamil where appropriate.

5.2.4. Updated Curriculum Vitae (CV) of the Principal Investigator; CV of the supervisor for the student projects and proposals for post graduate degrees.

5.2.5. For postgraduate study proposals – Letter from the relevant postgraduate institute/board 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 will incur 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 a direct requirement of course work will be waived at the discretion of the ERC.

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

5.5. Information about the closing date for receipt of new applications onto the next ERC agenda shall be readily available for prospective applicants in the ERC website

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

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

5.8. For complete applications, the ERC office will issue a receipt to the Principal investigator (AF/05 – 007/01.0).

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

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

5.11. Chairperson, Secretary or a nominated member of the ERC assesses the risk level of the research proposal (SOP 13 &14) and decide whether the research proposal needs to be reviewed or not, if needed the type of review; expedited or full board.

5.12. For applications requiring full board review, the person assessing the research proposal, appoints 3 primary reviewers. Primary reviewers shall include a subject specialist where ever

possible and a non-medical member. The primary reviewers will 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. Applications qualifying for expedited review (SOP 14): the person assessing the research proposal appoints 2 primary reviewers. One person should be a non-medical member of the ERC. Reviewers for expedited review will 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) will be issued an exemption letter signed by the Chairperson and the Secretary of the ERC (AF/06 – 013/01.0).

6. Glossary :

6.1. New Application

A study protocol including the informed consent, investigator's qualifications, information on the drug or device and advertisements (if applicable) presented to ERC for approval for the first time and not previously approved by this Board. This includes re-application for those studies denied approved 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 - 2014 **Version 1.0, April 2016**

1. **Purpose :**
   To describe the process and format of agenda for an ERC meeting
2. **Scope:**
   The Secretary, ERC will prepare the agenda for the next meeting considering the previous minutes, new protocols and other documents pertaining to the protocols under consideration.
3. **Responsibility :**
   It is the responsibility of the Secretary ERC to prepare the agenda.
4. **Detailed instructions:**

4.1. An application will be included on the agenda for the next available ERC meeting, provided it is received by the relevant closing date and is complete.

4.2. The Secretary of the ERC will prepare an agenda for each ERC meeting.

4.3. All complete applications together with relevant documents and all correspondence received by the Secretary of the ERC will be included on the agenda for ERC consideration at its next meeting.

4.4. The meeting agenda and associated documents will be prepared by the Secretary of the ERC and circulated to all ERC members one week prior to the next meeting. This will include information relating to the date, time and venue of the meeting

4.5. Agenda items will include the following items:

4.5.1. apologies,
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 - 2016 **Version 1.0, April 2016**

1. **Purpose :**

   To describe the format of meetings of the ERC

2. **Scope:**

   These standard operational procedures describe the procedures for the 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 ERC

4. **Detailed instructions:**

   4.1. The ERC shall meet on a regular basis on predetermined dates, which will normally be at monthly intervals except for the months of April and December. Dates of ERC meetings for the year shall be pre-decided and be publicly available in the ERC website.

   4.2. It is important for the members to attend ERC meetings in person. Members who are unable to attend a meeting should send a written excuse to the Secretary of the ERC. The minutes should record the submission of written excuses.

   4.3. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least seven (7) members are gathered including the Chairperson, Secretary and at least one non medical member present.

   4.4. If the meeting does not achieve quorum , the Chairperson shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the ERC must be ratified by at least one lay representative.

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

   4.6. Meetings will usually 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 will reconvene within 10 working days to complete the agenda.

   4.7. The ERC meeting will be conducted in such a manner as 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 their presence 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. This will be dealt with in accordance with SOP 010.

4.10. All deliberations will be conducted in a manner that is non offensive, unbiased, sensitive and inclusive.

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

4.12. In circumstances where members cannot be present, they may provide written comments. These will be tabled at the meeting.

5. Glossary:

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

5.2. Quorum
Number of ERC members required to act on any motion presented to the board of 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 - 2016 **Version 1.0, April 2016**

1. Purpose:

The purpose of this SOP is to describe the procedure for reporting and handling of conflict of interest of the 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, as soon as practicable during the ERC meeting, inform the Chairperson if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) to be considered by the ERC prior to the commencement of the meeting.

4.2. The ERC will determine if this results in a conflict of interest for the member and, if so, the member will withdraw from the meeting until the ERC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on the research.

4.3. All declarations of conflict of interest, resolutions of same and the absence of the member concerned will be minuted.

5. Glossary :

5.1. Conflict of interest

A 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 : Consideration of initial applications for ethics review by the ERC
	SOP – 011 - 2016 **Version 1.0, April 2016**

1. **Purpose :**

   To describe the process of the ERC's consideration of initial applications for ethics assessment.

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/04-007/01.0) 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 creates a protocol specific file, distributes the proposals and other documents and gets them reviewed by the ERC and delivers the review results to the applicants.

4. **Flow chart :**

Protocol- Assign primary reviewers
Initial review by all members
↓
Examine the qualifications of investigators/supervisors and study sites
↓
Assess the conflicts of interests
↓
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
↓
ERC decision communicate 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 will consider/assess new applications at its next monthly meeting provided that the completed application is received at least two weeks before the scheduled meeting.

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

Once the application is accepted and registered in the ERC, the Chairperson/Secretary or the nominated member decides the applications that may exempt from review or conduct expedited review of proposals in accordance with SOP 13 and 14. Other applications will be reviewed by full board review system.

5.3. Research proposals submitted by the undergraduates which are eligible for expedited review will be sent to the ERC subcommittee which include the Chairperson and Secretary for reviewing after registration at the ERC.

5.4. Other applications will be reviewed by three primary reviewers with at least one subject specialists relevant to the proposal and a non-medical reviewer. Primary reviewers would:

5.4.1. Review the application in detail prior to the meeting.

5.4.2.Non medical member pay more attention to review ICFs

5.4.3. Submit written comments on the application to the Secretary and initiate discussion on the application at the committee meeting.

5.4.4. Whenever necessary, request the applicant to submit the necessary documents or revised version of the proposal through ERC.

5.5. All proposals shall be circulated to all members of the ERC for review prior to the meeting. Applications will be discussed at the meeting by all members present. Written submissions made by those not present will be considered.

5.6. 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 of ethics. The ERC must ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific validity, to make an assessment. The ERC will deal with multi-centre research applications in accordance with SOP 025.

5.7. The ERC may invite an investigator to the meeting to clarify issues in relation to the application. The applicant will be asked to leave the meeting prior to ERC deliberation and decision-making concerning the application.

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

5.8.1.The ERC, after considering an application at a meeting, will make one of the following decisions:

5.8.2. **Approved -** the proposal as being ethically acceptable, no changes requested.

5.8.3. **Minor revisions needed** – would be eligible for Chairperson's approval once these are done.

5.8.4. **Major revisions needed** – would require full board review once the revisions are done.

5.8.5. **Disapproved/ rejected** – reasons will be conveyed to the applicant. .

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

5.10. 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:

5.10.1. Chairperson alone; or

5.10.2. 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.

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

6.3. 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 - 2016 **Version 1.0, April 2016**

1. **Purpose:**

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

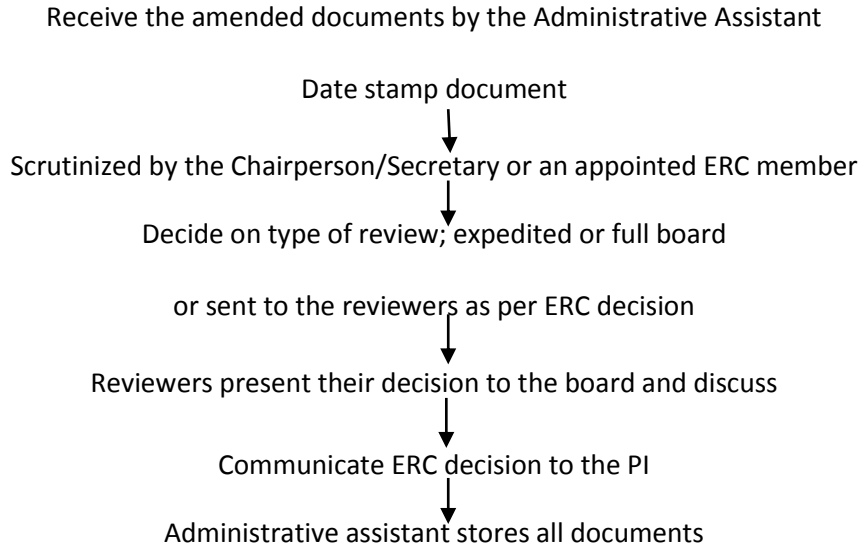
2. **Scope:**

   This SOP applies to study protocols that have been recommended corrections 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. How the protocol will be reviewed should have been determined by the ERC at the time of the initial review.

4. **Flow chart:**



5. **Detailed instructions:**

5.1. The resubmission should consist of a memorandum addressing the corrections, revised version of the protocol, related documents such as informed consent document, data collection instruments etc.

5.2. The administrative assistant should date stamp forms upon receiving the package.

5.3. The Chairperson / Secretary or an ERC member reviews the revised protocol, refers 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 have required major revisions will be resent to primary reviewers for observations and will 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 final approval for the project to proceed to the Chairperson in oral or written consultation with the Secretary and one principal reviewer who was present at the meeting or who submitted written comments on the application.

5.5. If recommendations have been met satisfactorily, Chairperson's approval will be given and this will be communicated to the Principal Investigator. Chairperson's approval thus given will be ratified by the ERC at its next scheduled meeting.

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

5.7. For proposals which the ERC has recommended resubmissions, making a decision until an issue is clarified or further information is provided or the project is modified, the project and the researchers' response will be considered at a subsequent meeting of the ERC.

5.8. The clarifications that reach the Secretary ERC at least 10 days before due date of the next ERC meeting of the month will be considered at that ERC meeting.

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

5.10. If the ERC previously decided to review the revisions (major revisions), the revisions will be sent to the original primary reviewers for comments. The revised protocol will be discussed at the next scheduled ERC meeting where; the primary reviewers presents (oral or in writing) a brief summery and lead the discussion on protocol revision. Further recommendations for modifications to the protocol, consent form etc as requested by the committee are noted in the meeting minutes as with modifications made by ERC and will be communicated to the principal investigator. Once the major revision is accepted by the ERC, then the approval will be communicated to the PI as given in the flow chart.

5.11. The original completed documents along with revised documents, the completed re-reviewed report and the assessment forms will 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 - 2016 **Version 1.1, April 2016**

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

2. **Scope:**
   This SOP applies to protocols that may be exempt 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 suitable protocols will be issued the review exemption letter (AF/06-013/01.0).

4. **Detailed instructions:**
   4.1 The initial scrutiny may exempt research proposals from review, in the following circumstances:
   4.1.1. Research 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 will be exempt provided the following conditions are 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 involve no increase in 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).

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

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

4.1.2. 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, etc. Sensitivity will be determined on the risk to the subject in terms of a negative emotional reaction. An additional risk will be the possibility of a breach of confidentiality.

4.2. 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.

4.3. Research which is conducted by or subject to the approval of departmental or institutional heads and which are designed to study, evaluate or otherwise examine:
4.3.1. public benefit or service programs;
4.3.2. procedures for obtaining benefits or services under those programs;
4.3.3. possible changes in or alternatives to those programs or procedures; and/or
4.3.4. possible changes in methods or levels of payment for benefits or services under those programs.

4.4. Taste and food quality evaluation and consumer acceptance studies:
4.4.1. if wholesome foods without additives are consumed; or
4.4.2. if a food is consumed that contains a food ingredient at or below the 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.

4.5. A standard approval letter will be issued stating the reasons for exemptions, in the format set out in annexure (AF/06 – 013/01.0**)** and the ERC will 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 - 2016 **Version 1.1, April 2016**

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. Hand the received documents to the Secretary.

5.2. Determine protocols for expedited review
- 5.2.1. Chairperson, Secretary or nominated member of the ERC determines 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 from previous 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 sensibilities of the people involved.

5.3. Following guidelines according to the categories of research studies would be used to fulfil the above requirements.

5.3.1. Research involving material (data, documents, records or specimens) that has been collected or will 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 will not involve stress to the participant.

5.3.4. Continuing review of research previously approved by the convened 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 reaching a decision.

5.3.7. The decision of this review must 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 must be considered by the full ERC and cannot be dealt with by expedited review.

5.4. Expedited review process

5.4.1. Chairperson nominates 2 ERC members in each month to review the eligible protocols.

5.4.2. The administrative assistant sends the protocols to the selected members along with the application from which includes the assessment columns for reviewers.

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

5.4.4. Review should not take more than 2 weeks.

5.4.5. Inform the ERC of the proposals approved by expedited review at its regular meetings.

5.4.6. If any ERC member raises concern about any of the proposals presented to it as expedited review, then the proposal shall undergo full board review.

5.4.7. The Chairperson and Secretary issue 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 activities 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 the decision to the full board meeting. An expedited review is a speedy one 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:

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

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

6.6. 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 - 2016 **Version 1.1, April 2016**

1. Purpose:

The purpose of this procedure is to describe how protocol amendments and extensions are managed and reviewed by the ERC.

2. Scope:

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

3. Responsibility:

It is the responsibility of the Secretary ERC to manage protocol amendments and extensions. Investigators may amend the content, questionnaires, and consent forms from time to time. They may 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 in the manner of conduct of the research and extension of the period for which approval has been given. Such requests shall be in writing and include:

4.1.1. details of the nature of the proposed amendments and/or reasons for request for extension; annexure (AF/07-015/01.0 & AF/08-015/01.0)

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 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 its decisions are ratified at the next scheduled ERC meeting.

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/08-015/01.0).

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 will be issued in the format set out in annexure (AF/07 – 015/01.0).

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 should be so informed with reasons and the information requested should be clearly set out. Wherever possible, requests for additional information/clarification/modification should refer to the FERCSL Guidelines. The letter shall be in the format as set out in attachment H.

4.5 If the requested amendment or extension is rejected, a letter of rejection including the reasons on which the decision was made 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 consist 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 in the protocol.

5.2. 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 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 - 2016 **Version 1.1, April 2016**

1. Purpose :

To describe the procedure for the notification of decision of the ERC concerning the 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 for telephone, or interpersonal discussions related to past, present and/or future studies and/or processes involving the ERC.

4. Detailed instructions:

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

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

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

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

5.4.1. the title of the proposal;
5.4.2. the name of the principal investigator(s);
5.4.3. the ERC proposal identification number;
5.4.4. 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;
5.4.5. the date of the ERC meeting at which the proposal was first considered;
5.4.6. the date of the ERC's approval;
5.4.7. the conditions, if any, to which approval is subject;
5.4.8. the period of validity of the ERC's approval;
5.4.9. the frequency of progress reports; and
5.4.10. the date of submission of the final report.

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

5.6. A standard ethical clearance certificate will be issued in the format set out in annexure (AF/09 – 015/01.0).

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

5.8. The ERC should 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.

5.9. The letter shall be in the standard format set out in annexure (AF/10 -016/01.0).

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

5.11. The letter shall be in the standard format set out in annexure (AF/11 -016/01.0).

6. Glossary:

6.1. 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 they are conformed to the ethical guideline of the FERCSL for a defined period of time.

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.

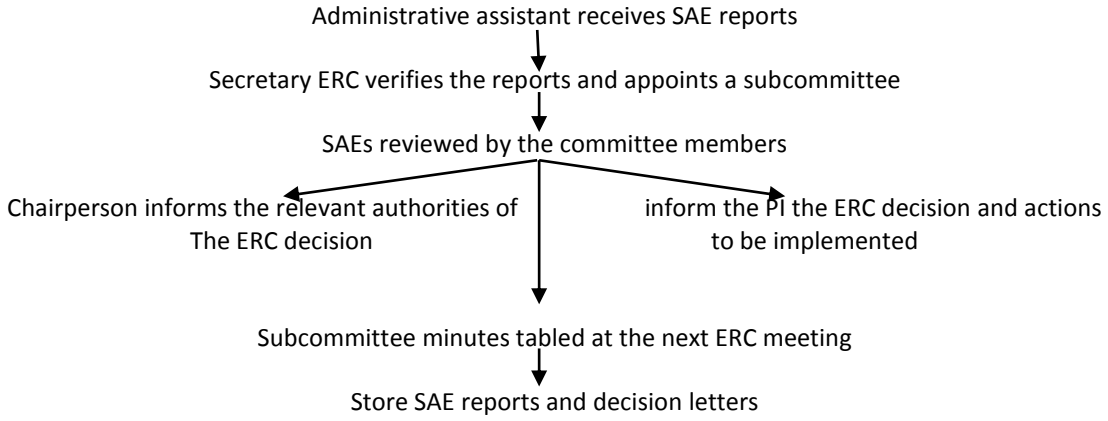
	Ethics Review Committee, Faculty of Dental Sciences, University of Peradeniya.
	Subject : Handling of Adverse Events
	SOP – 017 - 2016 **Version 1.1, April 2016**

1. **Purpose:**
   To describe the procedure for the 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 a 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) should 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 ERC.
   The Principal investigator should report all adverse events and the response to those events in the periodic and final reports for the projects.
   The Chairperson may take the 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/12 – 017/01.0) 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 :

6.10 Adverse Event

Any untoward medical occurrence in a patient or clinical investigation participant administered 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:

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

7.3. 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 - 2016 **Version 1.1, April 2016**

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:**

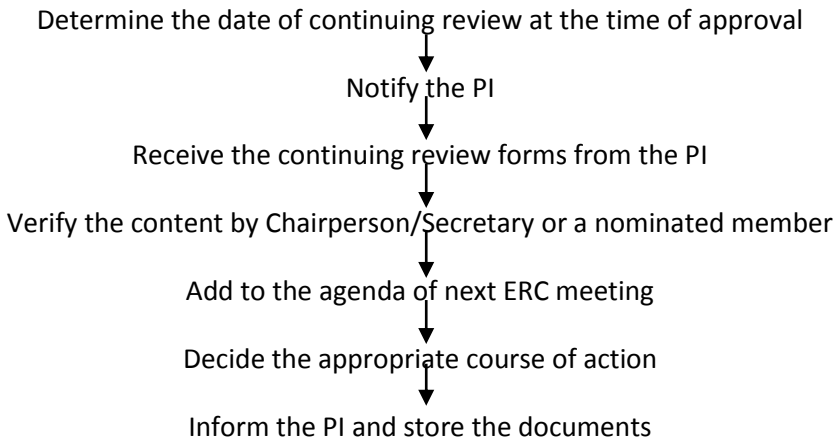
The Principal investigator should send periodic progress reports to ERC-FDS/UOP. The frequency of reports will be decided by the ERC depending on the nature and duration of the study. The principal investigator should send the final report to ERC at the completion of study.

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

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

The Chairperson may take the 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 will require applicants (PI) to provide progress reports, at least annually, and a final report at the conclusion of the study (Annexure; AF/13 – 018/01.0 & AF/14 -018/01.0).

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 will 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 will give consideration to the degree of risk to participants in the research. The ERC may adopt what measures 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 in 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 prevent 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 sited to assess how well the selected investigators and the institutions are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the sites. Normally monitoring visit will be arranged in advance 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 - 2016 **Version 1.0, April 2016**

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 the 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 the issues as well as the 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 fail 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 the approval of the current study
      4.4.3.Refuse to accept and review subsequent applications from the investigator cited for major violations by the investigation without informing the ERC.
   4.5. Make 4 copies of the notification letter sign 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 investigators do not perform 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):

5.10.3 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 - 2016 **Version 1.0, April 2016**

1. Purpose:

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of 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 for a 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 -020/01.0)

4.3.2. The ERC members will

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 for the study

4.3.2.4. Obtain the 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 will be arranged in advance following discussion with the principal investigator.

6**. References :**

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

1.2. 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 - 2016 **Version 1.0, April 2016**

1. Purpose:

This procedure describes how an 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/UOP that 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 of the study participants is doubtful 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 day 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 - 2016 **Version 1.1, April 2016**

1. Purpose:

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

2. Scope:

This SOP applies to administrative process concerning the preparation of minutes for all 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 should review and approve the minutes sent to him/her.

4. Detailed instructions:

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

4.2. The format of the minutes will 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 should 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 will be noted in the minutes.

4.6. To encourage free and open discussion and to emphasise the collegiate character of 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 the 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 will 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 will 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 will be produced as soon as practicable and will be checked by the Chairperson for accuracy.

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

4.12. The original copy of each meeting's minutes will 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 will consist of the titles of the approved protocols and the names of investigators and any other decision of 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, etc.

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 - 2016 **Version 1.1, April 2016**

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 will 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 complain register at the ERC office to receive written complaints from research participants, researchers or other interested persons about the conduct of 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 should 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 will 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 will inquire into the complaint and confirm its validity, or cause an inquiry by suitably qualified persons, and make a recommendation to the ERC a suitable course of action at its next meeting. 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 action 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 will 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 in the Chairperson's investigation inquiry;
4.8.3. the results of the Chairperson's inquiry; and
4.8.4. any other relevant documentation and pertinent information.

4.9. The Dean will 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. Where there is to be no further inquiry, the Dean will inform the complainant and the Chairperson of this.

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

4.11. The panel will include, at least, the following members:
4.11.1. the Dean or his/her nominee, as convenor of the panel;
4.11.2. two nominees of the Dean (who are not members of the ERC);
4.11.3. the ERC Chairperson or his/her nominee.

4.12. The panel will 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.

4.13. 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 sees fit.

4.14. The Dean will notify the complainant, the Chairperson and the investigators (if an allegation has been made against them) of the outcome of the review 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 rose 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 the ERC's review process
	SOP – 024 - 2014 **Version 1.1, September 2014.**

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 made.

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

   4.3 The Chairperson or nominee will instigate complaint and its validity, and make a recommendation to the ERC on the appropriate course of action at its next meeting.

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

   4.5 The Chairperson of the ERC will provide the Dean with all relevant information about the complaint/concern, including:
   4.5.1 the complaint;
   4.5.2 material reviewed in the Chairperson's or the nominee's investigation
   4.5.3 the results of the Chairperson's or the nominee's investigation and
   4.5.4 any other relevant documentation.

   4.6 The Dean will determine whether there is to be a further investigation of the complaint.

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

4.8 The panel will 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 will ask 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 will notify the complainant and the ERC of the outcome of the investigation. The outcomes 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 such actions 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 - 2016 **Version 1.1, April 2016**

1. **Purpose:**
   The purpose of this SOP is to identify the administrative process and provide instructions for the 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 will 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 will 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, will be kept as confidential files.

   4.5. To ensure confidentiality, all documents provided to ERC members, which are no longer required, are to be 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 will be five (5) years from the date of approval. Files which are longer required for retention shall be electronically archived. Retention periods shall be ten (10) years of 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 - 2016 **Version 1.1, April 2016**

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 outcome
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 will be available upon request to the general public, and will 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 : Multi site research studies
	SOP – 027 - 2016 **Version 1.1, April 2016**

1. Purpose :

To describe the procedure for the handling by the ERC of multi-centre research

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 will 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 - 2016 **Version 1.1, April 2016**

2. Purpose :

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

3. Scope:

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

4. 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.

5. Detailed instructions:

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

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

5.3. For those proposals made by a ERC member:

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

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

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

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

5.4. For those proposals made by the Faculty Board:

5.4.1. The Dean shall send the proposal in writing to the ERC

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

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

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

5.4.5. The decision of the ERC will be conveyed to the Faculty Board.

5.5. Process of maintaining history of SOP revisions

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

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.

Annexure

Annexur: **(AF/01- 003/Version 1.0, April 2016)**

The letter of appointment

Date:

Name:

Address

Dear ……..,

Appointment to the Ethics Review Committee

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

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 1.0, April 2016)**

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 1.0, April 2016)**

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

Name of training session	Date	Conducted by

Annexur: **(AF/04- 007/Version 1.0, April 2016)**

ETHICS REVIEW COMMITTEE
FACULTY OF DENTAL SCIENCES
UNIVERSITY OF PERADENIYA

For office use

Application No: ……../……

Date received: ……./……../…….

Reviewed by :……..

ERC meeting date:

Version: …….

Name of Applicant: (Prof/Dr/Mr/Ms) ……..

PART I- Basic Information

1. **Title of Research Project:**

2. Details of principal investigator

Title(Prof./Dr./Mr/Ms):	Name:
Current designation and name and address of institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address: *please notify any change of address	
Phone:	e-mail:

3. Co-Investigators. Details of supervisors if any;

Title, Name and Designation of Investigators

4. Location(s) where the research will be conducted:

4.1 Is this a multi-center study? Yes ☐ No ☐

4.2 Specify all study centers

**If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a hospital/school), it is the responsibility of the researcher to obtain approval prior to starting the project.

Type of site (hospital/clinic/school/community,etc.)	Details

5. Other research ethics board approval(s)

5.1 Has any other ERC approved this project? Yes ☐ No ☐

If Yes, please attach a copy of the approval letter.

6. Funding for project

Intended source of funding

*It is the responsibility of the researcher to inform the ERC if the funding source is changed.

7. For Clinical Trials only

7.1 What is the phase of the clinical trial that is being conducted?

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV (post marketing) ☐

Other ☐

If other specify:

7.2 Is it a multicenter trial?

Yes ☐ No ☐

If yes, list the other trial sites

*Please attach ethical board approval from the sponsoring country or country of the overseas principal investigator (if any)

7.3 Is the clinical trial registered with clinical trials registry in Sri Lanka?

Yes ☐ No ☐ Pending ☐

If yes, indicate the registration number

If No, give reasons

7.4 Has this study been approved by the SCOCT (Subcommittee on Clinical Trials) of the Ministry of Health

Yes ☐ No ☐ Pending ☐

If yes, give details of Approval Number

If No, give reasons

7.5 Data Safety Monitoring Board (only if available)

Name and Designation of Members	Role

7.6 Details of Indemnity and insurance coverage for participants, investigators and ethics committee

PART II - Research Proposal

8. Duration of the project:

Date of commencement:

Date of completion:

9. Protocol check list:

Please include the following information as given in your project proposal indicating the page number(s) relevant to each section in the box which will help the reviewers.

	9. 1 Collaborative partnership	**Yes**	**No**	**N/A**	**Section in protocol & page**	**Reviewer checked**
1.	Collaborations established with institutions where the study is to be conducted					
2.	Collaborations established with the community where the study is to be conducted					
3.	Benefits to institutions, communities, and participants in your research					

Reviewer's comments

	9.2 Social Value	**Yes**	**No**	**N/A**	**Section in Protocol & page**	**Reviewer checked**
1.	Beneficiaries of the research and the benefits to the participants and others					
2.	Plan for dissemination of study findings					

Reviewer's comments

Reviewer's comments

9.3. Scientific Validity		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Scientific importance of the study in relation to improving health care and/or knowledge on the subject.	☐	☐			
2.	Justification if the study is a replication study.	☐	☐			
3.	How the sample size was calculated	☐	☐			

9.4 Confidentiality		Yes	No	N/A	Section in Protocol & page	Reviewer checked
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 personal data of the research participants	☐	☐			
5.	How confidentiality of participants will be ensured	☐	☐			
6.	Procedure for data and sample storage	☐	☐			
7.	Procedure for data and sample disposal	☐	☐			

Reviewer's comments

9.5 Rights of the participants		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Procedure for subjects to withdraw from the research at any time					
2.	Procedure for subjects to ask questions and register complaints					
3.	Procedure for register complaints					
4.	Contact person for research subjects					
5.	Provisions for participants to be informed of results					
6.	Provision to make the study product available to the study participants after research					

9.6 Fair participant selection		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Justification for the selection of the study population					
2.	Inclusion and exclusion criteria					

Reviewer's comments

Reviewer's comments

9.7 Responsibilities of the researcher		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Provision of medical care to research participants					
2.	Provisions for continuation of care after the research is completed					
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts					
4.	Ethical/legal/social and financial issues relevant to the study.					

* For further information on conflict of interest please refer (this should be get from Dr. Gunawardena)

9.8 Vulnerable populations		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Justification for conducting the study in this population					

Reviewer's comments

9.9 Research funded by industry		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Justification for conducting the study in Sri Lanka	☐	☐			
2.	Relevance of the study to Sri Lanka	☐	☐			
3.	Post research benefits to Sri Lanka	☐	☐			
4.	Steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐			
5.	Sharing of rights to intellectual property	☐	☐			
6.	Fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study	☐	☐			
7.	Agreement between the sponsor/funding agency and the investigator	☐	☐		Please Attach	
8.	Materials transfer agreement, if biological material is to be transferred abroad	☐	☐		Please Attach	

Reviewer's comment

9.10 Community based research		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Impact and relevance of the research on the community in which it is to be carried out					
2.	Procedure used to obtain consent from the community leader					
4.	Contribution to capacity building of the community					
5.	Procedure for making available results of research to the community					

Reviewer's comment

9.11 Clinical trials		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Justification for withdrawing any therapy from participants to prepare them for the trial					
2.	Justification for withholding standard therapy from trial participants (e.g. control group)					
3.	Justification for deviating from the accepted standard procedure					
4.	Procedure for dealing with adverse events					
5.	Procedure for reporting adverse events					
6.	Provisions for safety monitoring					
7.	Provisions/criteria for termination of the trial					
8.	Provisions for making the trial drug available to participants after the trial if found to be effective					

Reviewer's comment

9.12 Information Sheet (IFS)/Informed Consent Form (ICF) Check List (List the sections in IFS/ICF where you have dealt with the following)		Section IFS/ICF	Reviewer checked
1.	Purpose of the study		
2.	Voluntary participation		
3.	Duration of the study		
4.	Procedures of the study		
5.	Participant's responsibilities		
6.	Potential benefits		
7.	Risks, hazards and discomforts		
8.	Reimbursements		
9.	Confidentiality		
10.	Termination of study participation		

Reviewer's comment

9.13 Consent (List the sections in consent form where you have dealt with the following)		Yes	No	N/A	Section in Protocol & page	Reviewer checked
1.	Procedure for initial contact of participants*					
2.	Procedure for obtaining informed consent Verbal					
	Written					
3.	Information (written/oral) provided to participants					
4.	Has the understanding of the subjects verbally verified					
3.	Procedure for obtaining proxy consent.					
4.	Procedure for withdrawing consent.					
5.	Incentives/rewards/compensation provided to participants.					
6.	The procedure for re-consenting if the research protocol changes during the course of research.					
7.	The procedure for consenting if vulnerable groups / children under 18 years of age being recruited.					
8	The procedure for consenting if children aged 12 - 18 years of age being recruited. (for children aged 12-18 years in addition to parental consent, children's assent must be sought)**					

* **Attach a copy of all posters, advertisements, flyers, and letters to be used for recruitment.**

**** Attach an assent form for children aged 12-18 years**

10. Data Collection

What is the procedure to be carried out on these subjects (give **details of all study instruments** to be used, collection of samples/blood/application of tests/administration of drugs etc, in detail).

Page Number/s	
Section/s	

11. Experience of Investigators with this type of research

11.1 Do you have previous experience in data collection?
11.2 Are the investigators competent in carry out this type of study?
11.3 If not how do you expect to acquire it?

(Please provide a brief description of previous experience with this type of research by either the principal investigator or the research team or the people who will have direct contact with the participants. If there has not been previous experience, please describe how the principal investigator/research team will be trained/prepared.)

PART III –Description of the risks and benefits

12. Possible Risks

12.1 Please indicate all potential risks to participants that may arise from this research:

(i) Physical risks (e.g., any bodily contact or administration of any substance): Yes ☐ No ☐

(ii) Psychological/emotional risks (feeling uncomfortable, embarrassed, upset): Yes ☐ No ☐

(iii) Social risks (e.g., loss of status, privacy and/or reputation): Yes ☐ No ☐

(iv) Legal risks (e.g., apprehension or arrest, subpoena): Yes ☐ No ☐

12.2 If Yes to any of the above, please describe.

12.3 State measures employed during the procedure/study to remove or minimize these risks

13. Possible Benefits

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential direct benefits to the community (e.g., capacity building)
- Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

14.Compensation

14.1 Will participants receive compensation for participation?

Financial Yes ☐ No ☐

Other Yes ☐ No ☐

14.2 If **Yes**, please provide details and justification for the amount or the value of the compensation offered.

14.3 If **No**, please explain why compensation is not possible or inappropriate.

14.4 if participants choose to withdraw, how will compensation be affected?

15.Feedback/debriefing/referral/after care

Please describe what information/feedback/services will be provided to participants and/or communities after their participation in the project is complete (e.g., health education, referral to clinic/hospital, etc.)

16. Do you think that the project has a conflict of interest?

16.1 Commercially

16.2 Financially

16.3 Intellectually

16.4 Other (Explain)

17. Does any member of the research team have any affiliation with the provider(s) of funding/ support, or a financial interest in the outcome of the research?

Yes ☐ No ☐

If yes, please explain:

18. If there is a duality of interest identified above describe the interest and state whether it constitutes a potential conflict of interest.

19. Declaration of applicant

- 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.
- 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.
- I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
- I declare that I am not seeking approval for a study that has already commenced or has already been completed.
- I understand that at least two months are required for ethics review and granting of ethics clearance.

- I will submit progress reports/reports of adverse events and side effects as requested by the ERC FDS/UOP.
- I will submit the final reports at the completion of the study.

……..

Signature of Principal Investigator Date :___ /____/_____

Full name of Principal Investigator :

20. Consent from all Investigators

We, the undersigned hereby confirm that we have consented to be co investigators of the project titled

Name	Qualifications	Institutional Affiliations	Signature

Official:

1. Are the investigator's qualifications and experience appropriate to conduct the study?

Yes NO

2. Recommendation: Approve Reject Conditional Approval (Pl state the conditions)

Reviewer:..... Signature:……
Date:……..

Application for Ethics Review- Document check list

	One copy each of the following	**To be marked by the applicant**	**To be marked by ERC office**
1.	Covering letter signed by the applicant	☐	☐
2.	Letter from supervisor (if relevant)	☐	☐
3.	Bank receipt	☐	☐
4.	Copy of approval letter from Board of Study (*for postgraduate students only*)	☐	☐
5.	Curriculum Vitae of principal Investigator	☐	☐
6.	Consent from all investigators confirming their participation	☐	☐
7.	**Three copies** of the application form	☐	☐
8.	**Three copies** of complete research proposal (*postgraduate students must submit a copy identical to that approved by the board of study*)	☐	☐
9.	Study instruments **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
10.	Information Sheet **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
11.	Consent forms **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
12.	Assent forms		

	English	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
13.	Data collection forms/questionnaires **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
14.	Ethics approval from sponsoring country or the country of overseas investigator (if any)	☐	☐

PLEASE NOTE:

Your application will not be processed until all required documents are received by the ERC office.

……..

Signature of Principal Investigator Date :___ /____/_____

Annexur: **(AF/05- 007/Version 1.0, April 2016)**

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 1.0, April 2016)**

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 exempt 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 exemption is pertaining to the submitted protocol and any alteration or deviation should be notified to the ERC.

Chairperson Secretary

Annexure: **(AF/07-015/ Version 1.0, April 2016)**

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 1.0, April 2016)**

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 – 015/ Version 1.1, April 2016)**

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 …….. entitled .....

.....

...."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 IERC, Faculty of Dental Sciences, Peradeniya using the **Amendment Submission Form.**
- This certificate is valid until....., when an extension is required; a properly filled **Protocol Extension Submission Form** should be submitted to the IERC, 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 patient/guardian.
- Submission of progress report on ethical issues to the ERC, Peradeniya at the completion of one year period.
- Submission of a final report to the ERC, Peradeniya at the end of the study.
- The study has to be conducted in compliance with the approved protocol; failing to oblige may terminate the approval.

....

Secretary ERC Chairperson ERC

Annexure **:(AF/10 - 015/ Version 1.0, April 2016)**

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 may not commence this study until final approval has been granted. Please highlight the changes made to documents to assist the Committee's checking of the amended documents. (delete if not applicable).

In order for your response to be presented at the next Ethics Review Committee meeting, this information should be forwarded to the ERC Office by ……./……../……..

Yours sincerely,

Secretary

Ethics Review Committee

Annexure : **(AF/11 -016/ Version 1.0, April 2016)**

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 the Forum of Ethics Review Committees in Sri Lanka (FERCSL) and the International Conference on Harmonisation Good Clinical Practice (ICH GCP), has decided not to approve your project for the following reasons:

You may discuss the ERC's review of your proposal with the chairperson or with me on an appointment.

Yours sincerely,

Secretary

Ethics Review Committee

Annexure**: (AF/12– 017/ Version 1.0, April 2016)**

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

Notification of Serious Adverse Event (SAE)

I herewith send you the filled three monthly/ six monthly serious adverse event reporting form to the attention of the Ethics Review Committee.

Chief Investigator's Comments -

Yours sincerely,

.....

Chief Investigator

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/13– 018/ Version 1.0, April 2016)**

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/14 -018/ Version 1.0, April 2016)**

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/15 – 019/ Version 1.0, April 2016)**

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:
Found by. Date .	Reported by. Date.

Annexure: **(AF/16 – 020/ Version 1.0, April 2016)**

CHECKLIST OF A 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:
Are informed consent up to date? ☐ yes ☐ No	Comments:
Any adverse event found? ☐ yes ☐ No	Comments:
Ant protocol non-compliance/violence? ☐ yes ☐ No	Comments:
Are all case records forms up to date? ☐ yes ☐ No	Comments:
Are 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:	

Annexure: **(AF/17 – 021/ Version 1.0, April 2016)**

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/18 – 008/ Version 1.0, April 2016)**

Template for ERC Agenda

1. Apologies
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/19 – 009/ Version 1.0, April 2016)**

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 asked for declaration of COI from members on the protocols under review / discussion by identifying the protocol before start of 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,