STANDARD OPERATING PROCEDURES

ETHICS REVIEW COMMITTEE

POSTGRADUATE INSTITUTE OF MEDICINE

UNIVERSITY OF COLOMBO

Date: 31.10.2018.

Version 3.0

Standard Operating Procedures
Ethics Review Committee
Postgraduate Institute of Medicine
University of Colombo

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Document History		
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Version 1	2012	Original guidelines adopted at the time of establishing the ERC
Version 2	23-04-2018	SOPs updated incorporating change in practice and approved by the ERC
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PGIM Ethics Review Committee

Standard Operating Procedures dated October 31, 2018, Version 3

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Abbreviations

BOM - Board of Management

CIOMS - Council for International Organizations of Medical Sciences

DoH - Declaration of Helsinki

ERC - Ethics Review Committee

ICF - Informed Consent Form

ICHGCP - International Conference on Harmonization, Guidance on Good Clinical Practice

IRB - Institutional Review Board

IS - Information Sheet

MOU - Memorandum of Understanding

PGIM - Postgraduate Institute of Medicine

PI - Principal Investigator

SOP - Standard Operating Procedures

TOR - Terms of Reference

UOC - University of Colombo

WHO - World Health Organization

WMA - World Medical Association

Glossary

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.

Adverse Drug Reaction: In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase “responses to a medicinal product” means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

Agenda: A list of things to be done; a program of business for the meeting

FERCSL: Forum of Ethics Review Committees, Sri Lanka

Meeting: Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.

Minutes: An official record of proceedings at a meeting

SAEs: Serious Adverse Events

SUSARs: Suspected Unexpected Serious Adverse Events

SOP: Standard Operating Procedures

TOR: Terms of Reference Quorum: Number of

ERC members required to act on any proposal presented to the committee for action.

Workshop: A group of people engaged in study or work on a creative project or subject

References

Declaration of Helsinki (DoH) of the World Medical Association (WMA), 2013.

Ethics review committee guidelines, Forum of Ethics Review Committees, Sri Lanka 2007.

Ethical review committee Guidelines. Sri Lanka Medical Association. Colombo 1999.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) E6 (R1) 1996.

International Ethical Guidelines for Epidemiological Studies - Prepared by the Council for International Organizations of Medical Sciences(CIOMS) 2008.

National Ethical Guidelines for Health Research in Nepal. Nepal Health Research Council, Nepal 2001.

Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization 2011.

Standards Operating Procedures, Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura 2012.

Standard Operating Procedures, Ethics Review Committee, Faculty of Medicine, University of Colombo 2016.

Standards Operating Procedures, Ethics Review Committee, Faculty of Medicine, University of Kelaniya 2018.

WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. Available at: http://www.wma.net/en/30publications/10policies/d1/index.html [Accessed 12 November 2016]

The Nuremberg Code. Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2. Washington, D.C., U.S. Government Printing Office, 1949. Available at

WHO Operational Guidelines for Ethical Review Committee that review biomedical research, Geneva 2000. Available at www.who.int/tdr/publications/ [Accessed on 25th August 2015)

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 001 Review of Standard Operating Procedures	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for the process for reviewing and amending SOPs within the ERC, PGIM/UOC.**

   It is the responsibility of the Chairperson of the ERC to appoint the SOP subcommittee to amend the SOPs by following the same procedures, format and coding system when drafting or editing any SOP of the ERC.

2. **Scope:**

   This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ERC, PGIM/UOC.

3. **Detailed Instruction:**

   3.1. The Terms of reference and Standard Operating Procedures shall be reviewed at least every three years and amended as necessary.

   3.2. SOPs may be emended at any time if a need arises for such amendments

   3.3. The SOPs may be amended by following the procedure below

   1. Any member of the ERC can propose an amendment to the SOPs in writing.
   2. The proposed amendment shall be submitted in writing to the Secretary to be placed in the agenda of the next available Ethics Review Committee meeting for consideration and possible adoption by at least two-thirds of the committee members present and voting. Any member unable to attend such a meeting may register their views in writing
   3. The Chairperson shall send the amendment to the Director, PGIM/UOC for review and approval, if appropriate.
   4. The amendment shall come into effect once approved by the Director and Board of Management, PGIM/UOC.

1. Purpose: To describe the overall functions and scope of ERC

The Ethics Review Committee (ERC), Postgraduate Institute of Medicine, University of Colombo (PGIM/UOC) is established to safeguard the mental, physical and social well-being, dignity, rights and safety of all human subjects participating in biomedical research; and to promote standards of human research through ethical, efficient and effective review and monitoring processes in accordance with the guidelines of the Forum of Ethics Review Committees in Sri Lanka (FERCSL Guidelines) and other relevant national and international legislations and guidelines.

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of ERC of PGIM/UOC.

2. Scope

The SOP applies to all activities under the ERC of PGIM/UOC.

3. Detailed instructions:

Scope of Responsibilities:

3.1. ERC, PGIM/UOC shall

a. provide oversight on all matters relating to ethics of research projects involving human subjects.

b. ensure that the fundamental principles of research viz. autonomy, beneficence, non-maleficence and justice are adhered to in research involving human subjects.

c. provide independent, competent, timely ethics review and monitoring of research projects involving human subjects.

3.2. The ERC shall review only research proposals submitted by trainees, trainers, extended faculty and staff of Postgraduate Institute of Medicine, University of Colombo except as provided hereunder:

a. The ERC may review research proposals from researchers outside the

PGIM/UOC provided a valid and current Memorandum of Understanding (MOU) between the PGIM/UOC and the institution to which the researcher is accredited exists. Such MOU shall define:

i. the role of the ERC in providing ethics approval and monitoring of the research;
ii. the role of the institution to which the researcher is accredited in giving approval for the research to be conducted within its premises;
iii. a statement indemnifying the PGIM/UOC from responsibility for liabilities that may arise from the ethics review conducted by the ERC; and
iv. a statement that the institution to which the researcher is accredited bears responsibility for liabilities arising from the conduct of research.

3.3. All applications will be subject to a handling fee as decided by the Board of Management, PGIM/UOC on recommendation of the Finance Committee, PGIM/UOC (Table 01).

3.4. The ERC will review research protocols in accordance with the guidelines of the Forum of Ethics review committees in Sri Lanka (FERCSL), relevant national and international guidelines and national and international legal requirements in order to determine their acceptability. This shall include an examination of the scientific and technical aspects of the proposal.

3.5. ERC, PGIM/UOC shall seek advice from an external reviewer if the committee lacks the expertise among its members to review specific subject or technical areas.

3.6. The terms 'human research projects' include, but are not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records and clinical databases, as well as epidemiological, social and psychological investigations using human subjects.

3.7. The ERC may review projects involving quality assurance including audits and student feedback.

3.8. ERC, PGIM/UOC shall not function as a committee funding research and approving research grants.

3.9. ERC, PGIM/UOC shall not advise clinicians regarding ethical issues which may arise in their routine clinical/medical practice.

	Ethics Review Committee Postgraduate Institute of Medicine University of Colombo	
	SOP – 003 Membership Composition	
	Version 3 - 31/10/2018	

1. Purpose: To describe the membership composition of the ERC

The Ethics Review Committee, Postgraduate Institute of Medicine, University of Colombo (ERC, PGIM/UOC) includes scientists and non-scientists as well as institutional and noninstitutional personnel. It is independent in its reflection, advice and decision. This SOP describes the Terms of Reference (TOR) which provide the framework for the constitution of ERC, PGIM/UOC.

2. Scope

The ERC, PGIM/UOC is composed representing and not representing scientific/ medical/ dental professions. It is independent in its reflection, advice, and decision. These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for constitution of ERC, PGIM/UOC.

3. Detailed instructions:

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

3.2. Membership comprises of at least eleven (11) and not more than nineteen (19) members.

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

3.3.1. Membership shall include the following categories:

a. members from PGIM
b. members of scientific/medical/dental institutions other than PGIM
c. members not representing scientific/ medical/ dental professions
d. a lawyer (legal expert)

3.4. Members shall be appointed to the ERC to ensure diversity including in gender and language.

3.5. Administrative staff of the PGIM/UOC shall not be members.

3.6. Where required, the ERC may seek advice and assistance from appropriate external experts to assist with the review of a protocol as detailed in SOP 011.

	Ethics Review Committee Postgraduate Institute of Medicine University of Colombo	
	SOP – 004 Appointment of ERC members	
	Version 3 - 31/10/2018	

1. Purpose: To describe the procedure for appointment of members to ERC, PGIM/UOC

This SOP describes the procedure for appointment of members to the ERC. Members are appointed by the Director, PGIM/UOC on recommendation of Board of Management of the PGIM as individuals for their knowledge, qualities and experience and not as representatives.

2. Scope:

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for appointment of members of ERC, PGIM/UOC.

3. Detailed instructions

3.1. Members of ERC, PGIM/UOC are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organization, group or opinion.

3.2. Prospective members of ERC, PGIM/UOC shall be appointed by nominations or advertisement.

3.3. Recruitment by nomination: When the expertise of a specific individual is required the ERC will request the Director, PGIM/UOC to take steps to appoint the said individual to the ERC.

3.4. Recruitment by advertisement: Applications for membership shall be called from members of the Boards of Study, PGIM/UOC by the Director, PGIM/UOC.

3.5. Prospective members are invited to sign a Confidentiality Agreement and Conflict of Interest Declaration (as per Annexure 1b) and attend a meeting of the ERC as observers.

3.6. Prospective members shall provide a copy of their curriculum vitae (as per Annexure 2) to the Board of Management, PGIM/UOC through Director, PGIM/UOC.

3.7. A selection committee, consisting of the Chairperson, the Secretary and a member of the ERC shall interview the prospective applicants and make recommendations to the Director, PGIM/UOC.

3.8. Letters of appointment (as per Annexure 3) will be issued by the Director, PGIM/UOC. The letter of appointment shall include the date of appointment, length of tenure, conditions of appointment, terms of reference, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as a member of the ERC, PGIM/UOC and the circumstances whereby membership may be terminated according to the relevant SOPs.

3.9. Members of ERC, PGIM/UOC shall agree to their names and professions being made available to the public and being published on the PGIM/UOC website.

3.10. Upon appointment, members shall be provided with the following documents:

a. Letter of appointment (Annexure 3)

b. Copy of the Confidentiality Agreement and Conflict of Interest Declaration (Annexure 1a) Standard Operating Procedures

c. An updated list of ERC members including their names and contact information.

d. Any other relevant information about the ERC's processes, procedures, and proposals

3.11. Duration of membership will be for a period of three (03) calendar years.

3.12. Members are eligible for re-appointment. The committee shall be reconstituted at the end of three (03) years. The new committee should comprise of at least seven (07) members who have a minimum of two years' experience as members of the preceding ERC, PGIM/UOC in order to maintain the expertise and to facilitate the efficient functioning and continuity of the ERC.

3.13. New members are expected to attend training sessions.

3.14. Non-affiliated members will receive an allowance and travel expenses in accordance with the PGIM regulations.

3.15. Members may seek leave of absence from the ERC for extended periods and steps shall be taken to fill the temporary vacancy if the period exceeds three months.

3.16. Membership shall lapse if a member fails to attend three consecutive meetings of the ERC without a reasonable excuse/ apology unless exceptional circumstances exist. Such circumstances should be notified to the ERC in writing.

a. A valid excuse is defined as being involved in designated academic or clinical work. This should be informed to the ERC in writing prior to commencement of the ERC meeting for which the member is going to be absent.

b. The Director, PGIM/UOC will notify the members of such lapse of membership in writing. Steps shall be taken to fill the vacancy.

3.17. The Director, PGIM/UOC may take steps to dissolve the ERC and appoint a new committee if the ERC fails to carry out its functions to the satisfaction of the Board of Management, PGIM/UOC. The Director may take this action only if requested to do so by the majority of the members of the Board of Management, PGIM/UOC.

3.18. A member may resign from the ERC at any time upon giving notice in writing to the Chairperson/ERC and the Director, PGIM/UOC. The effective date of resignation will be the date on which the resignation is formally accepted by the Director, PGIM/UOC and BOM, PGIM/UOC.

3.19. Vacancies in the ERC will be filled as per SOP 003 and SOP 004.

3.20. The ERC shall elect the Chairperson and Secretary from amongst its members and inform Director, PGIM/UOC who will issue formal notice of appointment. (An individual should have relevant training and at least three (03) years' experience in ethics review to be eligible for the posts of Chairperson and Secretary).

3.21. Subcommittees of Ethics Review Committee: The term subcommittee refers to a group of at least three ERC members appointed by the Chairperson, to manage a specific task or make a particular decision or recommendation relating to the functioning or standard operating procedures of ERC, PGIM/UOC.

a. Expedited review Subcommittee:

1. A proposal is considered for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case, the proposal is reviewed by the subcommittee.

2. The subcommittee will comprise of the Chairperson, the Secretary, and at least one assigned member.

b. SOP subcommittee:

1. It is the responsibility of the SOP subcommittee to amend the SOPs by following the same procedures, format and coding system when drafting or editing any SOP of the ERC.

2. The subcommittee will comprise of the Chairperson, the Secretary, and at least one assigned member.

c. SAE sub- committee:

1. The sub-committee shall review Adverse events and determine the appropriate course of action and inform ERC, PGIM/UOC of its recommendations as per the SOP.

2. The subcommittee will comprise of

- Chairperson,
- Secretary ERC
- A Clinical Pharmacologist
- A clinician with special training/interest in the clinical discipline/field

d. Site monitoring sub-committee

1. It is the responsibility of the subcommittee to perform site monitoring.

2. The subcommittee will comprise of the Chairperson, the Secretary, or a nominee, one of the primary reviewers of the study and one other ERC member.

e. If any of the subcommittee members has conflict of interest related to any proposal, another member from the ERC should be appointed for the subcommittee to review such proposals.

3.22. Members are expected to participate in relevant specialized subcommittees as and when required.

SOP – 005 Responsibilities of ERC Members

1. Purpose: To describe the functions of members of the ERC.

This SOP describes the responsibilities of the members of ERC, PGIM/UOC.

2. Scope:

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for responsibilities of members of ERC, PGIM/UOC.

3. Detailed instructions:

3.1. Responsibilities of ERC members:

3.1.1. Attend meetings regularly and remain until meetings are adjourned. Those who are unable to participate meetings in person, can join the meetings through videoconferencing or teleconferencing with prior notice. However, the absence will be noted in minutes.

3.1.2. Remain independent, impartial, and objective.

3.1.3. Maintain confidentiality with regard to all matters pertaining to the ERC.

3.1.4. Disclose conflicts of interests and where a conflict exists, refrain from reviewing, and leave the room during deliberations and voting.

3.1.5. When assigned as primary reviewers;

a) Complete and handover assessment forms to the Secretary two (02) working days prior to the scheduled ERC meeting. If unable to attend, the forms should be sent to the Secretary ERC two (02) working days before the scheduled ERC meeting.

b) To describe and present the review findings of the assigned protocol.

3.1.6. Decide on studies following deliberation at full board meetings as per SOP 015 - 2.5

3.1.7. Keep up-to-date with national and international research ethics and regulatory guidance.

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

3.1.9. Perform any other duties assigned by the Chairperson/Secretary.

3.2. Responsibilities of Chairperson:

3.2.1. Conduct all meetings of the ERC according to the SOPs. Provide guidance to ERC members and staff.

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

3.2.3. Periodically review existing and formulate new ERC policies and guidelines in consultation with the members of ERC.

3.2.4. Appointment of subcommittee members for subcommittees.

3.2.5. Revision & approval of SOPs.

3.2.6. Ratifies minutes of previous meetings in consultation with ERC members.

3.2.7. Seeks COI declarations.

3.2.8. Ensure quorum & fair decision making.

3.2.9. Encourage active participation of all ERC members.

3.2.10. Handle complaints against researchers, COI issues.

3.2.11. Decide on any requests for ERC data by non-ERC members.

3.3. Responsibilities of Secretary:

3.3.1. Organize meetings, maintain records, and communicate with all concerned parties.

3.3.2. Supervise, guide and monitor office staff.

3.3.3. Prepare minutes of the meetings and general correspondence in concurrence with the Chairperson.

3.3.4. Prepare the agenda for the ERC meeting.

3.3.5. Ensure that membership files are current and up to date.

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

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

3.3.8. Responsible for categorization of protocols

3.3.9. Ensure training of ERC members & staff

3.3.10. Prepare for & respond to audits & inspections

3.3.11. Ensure that the quorum/ COI is maintained throughout the meeting

3.3.12. Perform any other duties assigned by the Chairperson.

3.4. Responsibilities of Lawyer (Legal Expert):

3.4.1. Review regulatory related matters along with the other ethical issues related to the study & interpret it to ERC members.

3.5. Responsibilities of Support Staff

3.5.1. Coordinate and process all initial, continuing review and study modification submissions.

3.5.2. Prepare letters to applicants, relaying specific ERC requests and follow-up.

3.5.3. Assist the Secretary in preparation of official minutes of the meetings.

3.5.4. Coordinate electronic (or other) distribution of applications and related documents received for review.

3.5.5. Maintain communications with members of the ERC.

3.5.6. Circulate relevant information, records etc. to the members of the ERC.

3.5.7. Maintain the electronic database of the ERC and updating on regular basis.

3.5.8. Filing and archiving of study related documents systematically in the ERC office

3.5.9. Perform any other duties pertaining to the ERC assigned by the Chairperson and the Secretary.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 006 Orientation of New Members and Training	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for the orientation of new members and training.** Upon being appointed to the ERC, PGIM/UOC as a new member, such members are expected to follow the instructions given in this SOP.

2. **Scope:**

These standard operating procedures describe the Terms of Reference (TOR) which describe the procedure of orientation of new members of ERC, PGIM/UOC and training of all the members in the ERC.

3. **Detailed instructions:**

3.1. New members shall receive an electronic copy of SOPs and TORs as per SOP 004 - 2.8. It is the responsibility of the members to read and understand their functions as members of the ERC, PGIM/UOC.

3.2. Chairperson and Secretary shall hold an informal meeting with new members to discuss responsibilities of members, ERC processes and procedures.

3.3. The members should attend training/workshops pertaining to the functions of the ERC regularly and maintain a training record in the member file.

3.4. Training for New members

3.4.1. Shall be given the priority in the trainings

3.4.2. Training should include training in Standard Operating Procedures, Research Ethics and human subject protection in compliance with FERCSL and other national and international guidelines.

3.4.3. Mandatory GCP training to be provided with in one year.

3.5. It is the responsibility of members to obtain information and attend training courses, workshops and conferences that are announced periodically on websites, bulletin boards and the media.

3.6. Keeping the training records – fill in the Training Record as per Annexure 4 to record the training/workshop/conference activities in chronological order. A copy of the certificates of such training must be retained in the ERC office.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 007 Initial Review Process	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for submission of new protocols**

New protocol submission includes initial submission of new protocols, resubmission of corrections/amendments and continuing review of approved protocols. It is the responsibility of the Secretary to receive, record, and distribute the protocols among the reviewers.

2. **Scope:**

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

3. **Detailed Instruction:**

3.1 Applications must be submitted to the Secretary/ERC in the format prescribed by the ERC (Annex 05) and shall include all necessary documents. ERC application is available in the PGIM/UOC website.

3.2 Guidelines to fill the ERC applications are available in the PGIM/UOC website

3.3 A fee will be charged for applications as per Table 01.

3.4 Applications should be accompanied by the following documents:

a. Covering letter: covering letter should be signed by the applicant. If the applicant is a postgraduate trainee of the PGIM, covering letter should be submitted through the supervisor who is officially assigned to the applicant.

b. Declaration of Applicant (Annexure 06)

c. Submission Check List. (Annexure 07)

d. Research Protocol (03 copies).

e. Information Sheet (Annexure 08) and Consent Form (Annexure 09) in English, and in Sinhala and Tamil where appropriate (03 copies).

f. Other relevant documents (i.e. questionnaires) in English, and in Sinhala and Tamil where appropriate (03 copies).

g. Approval letter from the relevant Board of Study for postgraduate study protocols.

h. Updated Curriculum Vitae of principal investigator and all the coinvestigators as per Annexure 10. In general, each CV should not be more than 2-3 pages, unless a complete CV is specifically requested for.

i. Online payment receipt

3.5 Supporting staff of the ERC office ensures that all required forms and documents are submitted along with the application using the Document Receipt Form (Annexure 11) under the supervision of the Secretary.

3.6 Upon receipt of complete protocol, supporting staff of the ERC office should issue a ERC registration number and enter the protocol in to the electronic database. Format of the number should be ERC/PGIM/current year/serial number.

3.7 Document Receipt Form will be issued upon receipt of complete application along with all the necessary documents as per Annexure 11.

3.8 A compressed/zipped folder containing soft copies of all the documents relevant to the application should be emailed to the ERC at erc@pgim.cmb.ac.lk within 24 hours of receipt of Document Receipt Form. Subject of the email should be ERC Registration Number followed by the last name of the applicant (eg. ERC/PGIM/2018/XXX – Perera).

3.9 Upon receipt of an email from the principal investigator, initial review will be performed by the Chairperson and the secretary.

3.10 Initial review process

a. The Chairperson and the secretary meets weekly on every Monday and screen all the new proposals received within the previous week and assesses the degree of risk involved and decides the review type.

b. Types of review:

Based on the degree of risk, a proposal will be subjected to one of the following review types

1. Exemption from review

No risk is associated, and proposals are exempted from ethics review when there is no possibility of harm arising as a result of the conduct of the research project or when the information being collected is available from the public domain. Refer SOP 008.

2. Expedited review

   A proposal is considered for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case, the proposal is reviewed by the subcommittee. Refer SOP 009.

3. Full committee review

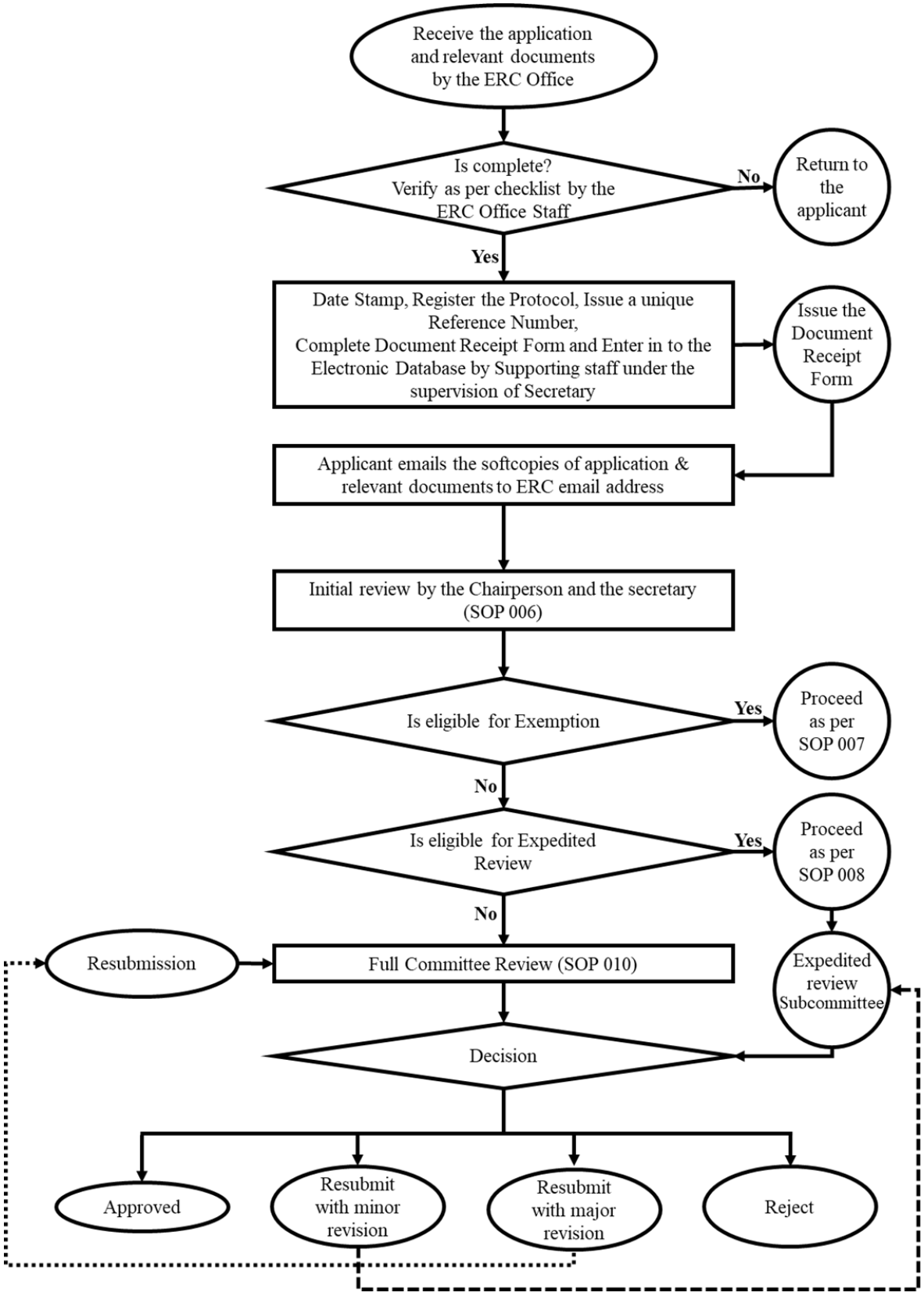
   All research protocols with more than minimal risk to human subjects are reviewed by four ERC members as per SOP 11, using the prescribed format (Annexure 05 Part B), who present the protocol to the ERC followed by a general discussion and a consensus decision. All the member of the ERC are expected to go through such proposal and provide their comments at the discussion.

3.11 Duly completed applications are accepted by the ERC office from Monday through Friday (except on public holidays) during office hours (9.00am to 4.00pm).

3.12 Deadline of applications for the regular monthly meeting shall be the close of business of the last working day of the previous month.

In the event of a public health emergency, such as the investigation of a disease outbreak or a disaster relief operation, the investigators may request a proposal to be reviewed expeditiously. In such instances, the Chairperson/Secretary may call an emergency meeting of the subcommittee/ full committee to discuss such protocols.

Submission Procedure Flow Chart



	Ethics Review Committee Postgraduate Institute of Medicine University of Colombo	
	SOP – 008 Exempted from Review	
	Version 3 - 31/10/2018	

1. Purpose: To describe the procedure for new protocols exempted from review

Protocols which carry less than minimal risk fall under this category. It is the responsibility of the subcommittee comprised of the Chairperson, the Secretary, and an assigned member of the ERC to grant approval for exemption.

2. Scope:

This SOP applies to protocols that may be exempt from review at a full ERC meeting and to be considered at an Executive Committee.

3. Detailed Instruction:

3.1. At the weekly meeting, new proposals received within the previous week will be reviewed by the chairperson and secretary and the proposals with less than minimal risk will be exempted from review.

3.2. Proposals that fulfil any of the following conditions are exempted from review

a. Does not involve collection or use of individual level data or community level data on sensitive topics.

b. All data to be used are freely available in the public domain.

c. Audits

d. Educational research proposals are exempt provided all of the following conditions are met:

1. All of the research is conducted in a commonly accepted educational setting (e.g. public school).

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

3. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
4. The study procedures involve no increase in the level of risk or discomfort associated with normal, routine educational practices.
5. The study procedures do not involve sensitive subjects (e.g. sex education).
6. Provisions have been made to ensure the existence of a non-coercive environment for those students who choose not to participate.
7. The school or other institution grants written approval for the research to be conducted.

3.3. Applications which are eligible for exemption from review will be submitted to the next ERC meeting for ratification of the decision of the subcommittee.

3.4. Formal letter of exemption will be issued only after confirmation of the subcommittee's decision by the ERC (Annexure 12).

1. Purpose: To describe the procedure for expedited review of new protocols

Protocols that carry a minimal risk to the participants, or the community fall under this category. It is the responsibility of the expedited review subcommittee comprised of the Chairperson, the Secretary, and an assigned member of the ERC to review and grant approval if appropriate.

2. Scope:

This SOP applies for the following instances.

2.1 To review protocols identified for expedited reviews, such as those with minimal risk.

2.2 To review life threatening issues, additional investigators, continuing review, protocol amendments and other study activities of previously approved protocols that do not require Full Board Review.

3. Detailed Instruction:

3.1 Subcommittee meets weekly on Monday and screen all the new proposals received within the previous week. Subcommittee assesses the degree of risk involved and decides the review type.

3.2 The Subcommittee may undertake expedited review of proposals with minimal risk and those on non-sensitive topics under following circumstances

a. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

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

c. 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 subjects behaviour and the research will not involve stress to the subject.

3.3 Applications which are eligible for expedited review will be submitted to the next ERC meeting for ratification of the decision of the subcommittee.

3.4 Formal letter of approval will be issued only after the confirmation of the subcommittee's decision by the ERC (Annexure 16).

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 010 Full Committee Review	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for full board review of new protocols**

   Protocols which carry more than minimal risk fall under this category. Proposals which were not considered for exemption nor expedited review as needing full board review also will be reviewed.

2. **Scope**

   This SOP applies to the review of protocols with more than minimal risk and were not considered for exemption nor expedited review.

3. **Detailed Instruction:**

   3.1. If proposal is not exempted nor undergone expedited review, then the secretary will assign primary reviewers based on their expertise. Two scientific reviewers and two non-scientific reviewers will be assigned to each protocol coming under this category.

   3.2. The scientific reviewers are tasked to review technical soundness and related ethical issues while the non-scientific reviewers are mainly tasked to review the informed consent process and forms.

   3.3. The Secretary prepares the proposals for primary review and circulate among the assigned reviewers. Primary reviewers will review the protocols using Protocol Check List (Annexure 5 part B). Based on their preference hard copies will be circulated. Soft copies of all the proposals that undergo full board review shall be emailed to all the ERC members.

   3.4. Decision making: Decision is arrived at by consensus or voting as per SOP 012 - 2.5

   3.5. Opinions of absent members that are transmitted by mail or telephone or fax should be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.

3.6. External reviewer/s who are experts in the subject may be invited where necessary to offer their views, but external reviewer/s should not participate in the decision-making process. However, his/her comments must be recorded.

3.7. The full board review of a research proposal will result in one of the following actions.

3.7.1. Approved: The research proposal is approved as submitted. This does not preclude the Committee from sending comments for the consideration of the research team or requesting proof of approval by the local ERC/ERB/ IRB or proof of clinical trial registration in the Sri Lanka Clinical Trial Registry when appropriate.

3.7.2. Resubmit with minor revisions: If the full board approves a research proposal in principle subject to minor modifications, the revised project proposal submitted by the proponent will be reviewed and approved by the expedited review subcommittee. When the requirements are met, a letter of approval will be issued. Such revised proposals will not be taken up for the full board review. If required, submitted responses will be sent to primary reviewers by the subcommittee. If the primary reviewers are not satisfied with the response, the Secretary will request the applicant to provide further clarifications.

3.7.3. Resubmit with major revisions: The research proposal is not approved as submitted either because there is insufficient information to make a decision, or the proposal is not ethically sound. However, the proposal should be resubmitted for full board review after addressing all the comments of the first review. The revised documents will be discussed in a full board meeting.

3.7.4. Reject: The research proposal is ethically or scientifically unacceptable.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 011 External/ Independent Reviewers	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for assigning external/independent reviewers**

   ERC will seek advice of an external reviewer when the committee lacks the expertise among its members to review specific subject/technical areas. It is the responsibility of the Chairperson and the Secretary to assign external/independent reviewers.

2. **Scope:**

   These standard operating procedures describe the procedure to seek advice external/independent reviewers by the Chairperson and the Secretary when the committee lacks the expertise among its members to review specific subject/technical areas.

3. **Detailed Instruction:**

   3.1. ERC maintains a list of external/independent reviewers who are experts in different subject areas.

   3.2. The chairperson and the secretary may invite external/independent reviewers when they think the expertise within the ERC is not sufficient to evaluate a particular proposal.

   3.3. ERC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to sign a Confidentiality Agreement and Conflict of Interest Declaration (Annexure 1a) and shall not be entitled to vote on any matter.

   3.4. Secretary shall send the relevant documents for review with the Confidentiality Agreement and Conflict of Interest Declaration (Annexure 1a) and Protocol Check List (Annexure 5 part B).

   3.5. The external/independent reviewer must complete and send a report to the Secretary ERC to 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.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 012 Preparation of Agenda	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure and format of agenda for a meeting of the ERC**

   This SOP describes the process and format of the agenda. It is the responsibility of the Secretary to prepare and share the agenda.

2. **Scope:**

   The Secretary, ERC will prepare the agenda for the next meeting considering the previous minutes, new protocols submitted and other documents pertaining to the protocols under consideration.

3. **Detailed Instructions:**

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

   3.2. All completed applications and relevant documents received by the ERC office by the close of business of the last working day of the previous month will be included in the agenda.

   3.3. The Secretary will circulate the agenda and associated documents among members of the ERC at least seven (07) calendar days prior to the respective meeting.

   3.4. Agenda will include the following items

   1. Announcements/ Welcome/ Excuses
   2. Declaration of conflicts of interest by ERC members
   3. Confirmation of minutes of the previous meeting
   4. Matters arising from the previous minutes
   5. New protocols
      - 5.1. Exempted New Protocols for Ratification
      - 5.2. New Protocols Subjected to Expedited Review for Ratification

5.3. New Protocols for Full Board Review

6. Amendments/extensions to approved protocols
7. Progress/final reports of the approved protocols
8. Reports of subcommittees
9. Amendments to SOPs
10. Correspondence
11. Any other matters
12. Training
13. Date, time and venue for the next meeting

SOP – 013 Conduct of Meetings

1. Purpose: To describe the procedure for conduct of ERC meetings

This SOP describes the procedure for conduct of the ERC meeting. It is the responsibility of the Chairperson and the Secretary to inform members and facilitate the conduct of regular and special meetings of the ERC.

2. Scope:

These standard operating procedures describe the procedure for conduct of the ERC meeting.

3. Detailed Instruction:

3.1. The ERC shall meet on monthly basis.

3.2. Members may attend ERC meetings in person or via teleconference or videoconference. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Secretary of the ERC. The minutes should record the submission of written comments.

3.3. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when more than one half of the members are present including the Chairperson or Secretary and at least one member falling under category 3.3.1.c or 3.3.1.d described in SOP 003.

3.4. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the ERC will convene another meeting within fourteen (14) working days of the cancelled meeting to ensure all agenda items are taken up for discussion.

3.5. Conflicts of Interest:

a. An ERC member shall inform the Chairperson/Secretary 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 in writing with Annexure 1c: Conflict of Interest Declaration Form for ERC members/ External Reviewers

b. 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.

c. All declarations of conflicts of interest and the resolutions of the same shall be minuted.

3.6. Deliberations: All deliberations will be conducted in a manner that is nonoffensive, unbiased, sensitive and inclusive and will be focused on relevant aspects including,

a. Scientific Validity

b. Social Value

c. Participants rights and consent

d. Confidentiality and Privacy

e. Fair Participation Selection and vulnerability

f. Responsibilities of the researcher

g. Foreign Funded Studies

h. Information sheet/ Consent Form.

3.7. The discussion should be summarised by the member secretary at the end of the deliberations.

3.8. Decision making process: The ERC will endeavour to reach a decision concerning the ethical acceptability of a protocol by consensus. Any significant dissenting view or concern shall be noted in the minutes. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of votes of members present provided that the majority includes at least one member not representing scientific/ medical/ dental professions. However, members who are joining the meeting through videoconferencing and teleconferencing are also eligible to vote. Decision reached should be stated by the chairperson following decision making process.

3.9. Meetings will not be restricted for an allocated time. Meetings will continue until all agenda items have been considered.

3.10. The ERC meeting will be conducted in private to ensure confidentiality and open discussion. Members will be advised of the venue in the meeting agenda.

3.11. Notwithstanding paragraph 2.7 above, the ERC may agree to the presence of visitors or observers at a meeting.

3.12. Any member of the ERC who has any interest, financial or otherwise in a proposal or other related matter(s) considered by the ERC, must declare such interests beforehand.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 014 Preparation of Minutes	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure and format of minutes of the ERC meeting** This SOP describes the administrative procedure for preparation, review, approval and distribution of ERC meeting minutes. It is the responsibility of the Secretary to prepare the minutes and to ensure the quality and validity of the minutes after the meeting is over. It is the responsibility of the Chairperson to review and approve the minutes sent to him by the Secretary.

2. **Scope:**

   This SOP applies to administrative processes concerning the preparation of minutes for all ERC meetings.

3. **Detailed Instruction:**

   3.1. The Secretary of the ERC will prepare the minutes of each meeting of the ERC as per the template given in Annexure 13.

   3.2. All completed applications and relevant documents received by the ERC office by the agenda closing date will be included in the agenda.

   3.3. The format of the minutes will include the following items:

   1. Attendance
   2. Announcements/Welcome/Excuses
   3. Declaration of Conflicts of interest
   4. Proceedings of the previous meeting
   5. Matters arising from the previous minutes
   6. New protocols

      6.1. Exempted New Protocols for Ratification

      6.2. New Protocols Subjected to Expedited Review for Ratification

6.3. New Protocols For Full Board Review

7. Amendments/extensions of approved proposals
8. Progress/Final reports of the approved proposals
9. Reports from subcommittees
10. Amendments to SOPs
11. Correspondence
12. Any other matters
13. Training
14. Date, time and venue for the next meeting and Close

3.4. The minutes should include the recording of decisions taken by the ERC as well as a summary of relevant discussions. This includes reference to views expressed in writing by absent members.

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

3.6. In recording a decision made by the ERC, any significant dissenting view or concern will be noted in the minutes.

3.7. To encourage free and open discussion and to emphasize 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.

3.8. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC deliberation of the relevant application will be minuted (Refer to SOP 01 3.5 regarding Conflicts of Interest).

3.9. The minutes will be produced within two weeks following the relevant meeting and will be checked by the Chairperson for accuracy.

3.10. The minutes will be circulated among all members of the ERC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be formally ratified at the next ERC meeting.

3.11. The confirmed and amended minutes of each meeting (with the inclusion of revisions if any) signed by the member secretary will be filed in the 'Minutes File'.

3.12. The extracts of minutes shall be sent to the Director, PGIM/UOC and Board of Management, PGIM/UOC. The extracts will consist of the titles of the approved proposals and the decision of the ERC that would need Board of Management ratification.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 015 Notification of Decisions of ERC	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for the notification of ERC decisions concerning review of new applications**

The purpose of this SOP is to ensure proper completion, distribution and filing of communications with investigators. It is the responsibility of all ERC members, including the Secretary and the Chairperson, 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.

2. **Scope:**

This SOP applies to all communicating activities related to the studies under the approval of the ERC, PGIM/UOC.

3. **Detailed Instruction:**

3.1. The Secretary of the ERC will prepare the ERC Decision letter within two weeks of the monthly ERC meeting.

3.2. Decision letters can be collected from the ERC office two weeks after the monthly meeting

3.3. If the ERC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required (Annexure 14). Where possible, requests for additional information/ clarification/ modification should refer to the FERCSL Guidelines or other relevant documents including legislation.

3.4. Notification of ethical approval will be in writing, and will contain the following information. A standard letter will be issued, in the format set out in Annexure

15.

a. Title of the project
b. Name of the principal investigator(s)
c. ERC registration number, Version number and date of all documentation reviewed and approved by the ERC including protocols, information sheets, consent forms questionnaires etc.
d. Date of the ERC's approval
e. Conditions of the ERC's approval, if any
f. Duration of the ERC's approval

3.5. Research project may not commence until written notification of ethical approval is received and non-adherence to this requirement amounts to ethical misconduct.

3.6. Any extensions for ethics approval for conducting the research project should be requested before the expiry of the validity indicated in the previous ethics clearance approval.

3.7. If the ERC determines that a project is ethically unacceptable, the notification of the ERC‟s decision will include the grounds for rejecting the project with reference to the FERCSL Guidelines or other relevant pieces of legislation. A standard rejection letter will be issued, in the format set out in Annexure 16.

3.8. The status of the project shall be updated on the ERC's register of received and reviewed applications.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 016 Amendments and Extensions to Approved Protocols	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for the submission and ERC review of requests for amendments and extensions to approved protocols.**

   This SOP applies to proposals submitted to the ERC, PGIM/UOC undergoing amendments or subsequent extensions after initial approval. It is the responsibility of the Secretary to forward such requests to the ERC considering the need for expedited review or full committee review in consultation with the Chairperson.

2. **Scope:**

   This SOP applies to proposals submitted to the ERC, PGIM/UOC undergoing amendments or subsequent extensions after initial approval.

3. **Detailed Instruction:**

   3.1. Approval for proposed changes to approved research protocols or to the conduct of the research, including extensions to the length of ERC approval, must be sought by the principal investigator in writing.

   3.2. Requests shall outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must have the changes highlighted. The request for extension must be accompanied by a current progress report of the study.

   3.3. Expedited review of requests for minor amendments and extensions may be undertaken as per SOP 009.

   3.4. Where an urgent protocol amendment is required for safety reasons, it should be reviewed by the full board. The chairman should convene an unscheduled meeting to review and approve the request.

3.5. All other 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.

3.6. If the ERC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the relevant pieces of legislation.

3.7. All reviewed and approved requests for amendments and extensions shall be recorded in the relevant protocol specific file and, where appropriate, in the ERC‟s register of received and reviewed applications.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 017 Appeals and Complaints of Review Process and Decisions of ERC	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for receiving and handling appeals or complaints regarding the ERC's review process and decisions**

   This SOP applies to complaints/appeals submitted to the ERC, PGIM/UOC by applicants who are not satisfied with the ERC review/decision. It is the responsibility of the Chairperson to investigate such complaints/appeals.

2. **Scope:**

   This SOP applies to the conduct and actions of the ERC, PGIM/UOC with regards to the review process of applications made.

3. **Detailed Instruction:**

   3.1. An applicant who is not satisfied with the outcome of the ERC's decision may complain to the Chairperson and/or the Director, PGIM/UOC detailing in writing the grounds of the concern or complaint.

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

   3.3. Appeal/complaint will be tabled at the next ERC meeting and the Chairperson will appoint a panel of three members, excluding the members who originally reviewed the protocol, to investigate the appeal/complaint.

   3.4. The decision of the panel will be discussed at the subsequent ERC meeting. The decision of the ERC will be informed to the applicant within three months of the complaint.

3.5. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Director, PGIM/UOC or request that the Chairperson do so.

3.6. The ERC will provide the Director, PGIM/UOC with all relevant information about the complaint/concern, including:

1. The appeal.
2. Material reviewed .
3. The decision of the review panel.
4. Any other relevant documentation.

3.7. Further action if necessary, will be at the discretion of the Director, PGIM/UOC, and may include one or more of the following:

1. Agree with the ERC decision.
2. Appoint a three member panel comprising the Director, PGIM/UOC or his/her nominee and two senior academics nominated by the Board of Management of the PGIM/UOC to review and give recommendations.
3. Any action deemed suitable considering the recommendations of the panel.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 018 Monitoring of Approved Research Projects	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for monitoring research projects approved by the ERC to ensure compliance with ethical approval.**

   The ERC will monitor approved protocols to ensure compliance with its ethical approval. The purpose of this SOP is to describe the procedure for monitoring research protocols approved by the ERC to ensure compliance with ethics approval.

2. **Scope:**

   This SOP applies to all studies under the approval of the ERC, PGIM/UOC.

3. **Detailed Instruction:**

   3.1. The ERC shall monitor approved projects to ensure compliance with the conditions for ethical approval. In doing so, it may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the ERC shall require the investigators to provide progress reports (Annexure 17) and a final report (Annexure 18) at the completion of the study.

   3.2. The ERC shall require the following information in the progress reports

   1. Progress to date or outcome in the case of completed research
   2. Maintenance and security of records
   3. Compliance with the approved protocol
   4. Compliance with conditions of approval
   5. Changes related to study investigators and sources of funding

   3.3. The ERC may undertake random site visits as part of monitoring.

3.4. The ERC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of the ethical approval of the proposal, including, but not limited to:

1. any unforeseen events that might affect continued ethical acceptability of the project
2. new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the project, or which may indicate the need for amendments to the protocol.

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

3.6. Where the ERC is of the opinion that the research project is not 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 as well as any Regulatory Authority of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 019 Complaints About the Conduct of a Research Study	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for receiving, handling and responding to complaints concerning the conduct of a project approved by the ERC.**

   The ERC shall receive complaints from research participants, researchers, or other interested individuals regarding the conduct of approved research projects. The contact details of the ERC must be included in the Patient/ Participant Information Sheet for each project.

2. **Scope:**

   This SOP applies to all studies under the approval of the ERC, PGIM/UOC.

3. **Detailed Instruction:**

   3.1. Any concern or complaint received will be forwarded to the Chairperson of the ERC. The Chairperson is responsible for obtaining a written complaint stating the grounds of the concern. Upon receiving this, the ERC will be notified as soon as possible.

   3.2. The ERC shall send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator outlining the complaint and the mechanism for investigating (described below) the complaint.

   3.3. Where the complaint concerns a serious matter within the jurisdiction of the Ministry of Health or other institution, the Chairperson shall consider referral of the complaint to the Ministry of Health or the relevant governing body.

   3.4. A panel consisting of a minimum of three (03) members will be appointed by the ERC to conduct an investigation of the complaint. This panel upon completion of the investigation shall make recommendations to the ERC on the appropriate course of action. Based on the seriousness of the violation one or more of the following action will be recommended.

   1. Amendments to the protocol
   2. Warning and increased monitoring by the ERC

3. Suspension of the project
4. Termination of the project
5. Other appropriate action to resolve the complaint

3.5. Such action will be taken within three months of receiving a written complaint.

3.6. The complainant shall be informed of the action taken. He/she will also be informed of his /her right to refer the complaint to the Director, PGIM/UOC if he/she is not satisfied with the decision of the ERC.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 020 Dealing with Protocol Deviations/ Violations/ Non-compliance	
	Version 3 - 31/10/2018	

1. **Purpose: To describe the procedure for the process for reporting and handling of protocol deviations and violations**

The purpose of this SOP is to describe how the ERC, PGIM/UOC provides instructions for acting and maintaining records, when investigators fail to follow the procedures written in the approved protocol or fail to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the ERC, PGIM/UOC requests.

2. **Scope:**

This SOP applies to all studies under the approval of the ERC, PGIM/UOC.

3. **Detailed Instruction:**

3.1. The ERC shall require, as a condition of approval of each proposal, that researchers report to the ERC of any protocol deviation or violation as soon as possible but no later than one (01) calendar month of its first knowledge.

3.2. The report should include,

1. ERC reference number
2. Details of the site
3. Details of protocol deviation/violation
4. Reason(s) for deviation – patient related/investigator related/other (specify)
5. Details of reporter – Name, address, telephone number, other administrative information
6. Measures taken by the investigators to deal with the violation and to avoid future occurrences

3.3. All reported deviations and violations will be dealt with by a subcommittee consisting of Chairperson, Secretary and an assigned ERC member and will be informed to the ERC, at the next meeting.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 021 Handling of serious adverse events	
	Version 3 - 31/10/2018	

1. Purpose: The purpose of this SOP is to describe the procedure for the reporting and handling of serious adverse events (SAEs)

The purpose of this SOP is to describe how the ERC, PGIM/UOC communicate and act in related to a serious adverse event defined as undesirable clinical responses to an intervention, including a treatment or diagnostic procedure of studies under the approval of the ERC, PGIM/UOC, that have resulted in harm/death of participants.

2. Scope:

This SOP applies to all communications and actions related to a serious adverse event defined as undesirable clinical responses to an intervention, including a treatment or diagnostic procedure of studies under the approval of the ERC, PGIM/UOC, that have resulted in harm/death of participants.

3. Detailed Instruction:

3.1. The ERC shall require, as a condition of approval of each project that researchers immediately report Suspected Unexpected Serious Adverse Events (SUSAR) or Serious Adverse Events (SAE) to the ERC, including those that have occurred at other institutions participating in the study.

3.2. As per the current guidelines of the Sri Lankan Drug Regulatory Authority the following timelines apply for reporting of such events occurring at local trial site to ERC, PGIM/UOC:

a. 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.

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

3.3. Notifications of Serious Adverse Events (SAEs) must be submitted in the appropriate format (Annexure 19), and shall include all documentation as required by the ERC. This documentation shall include as a minimum:

a. Advice 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.

b. Advice 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.

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

3.5. Adverse events may be reviewed by a sub-committee of the ERC appointed as per SOP 004 3.21 c

3.6. The review shall take place within (one) 1 week of notification of the event. The subcommittee shall determine the appropriate course of action and inform ERC of its recommendations. This may include:

a. a notation on the project file of the occurrence

b. increased monitoring of the project

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

d. suspension of ethical approval or

e. termination of ethical approval.

3.7. Any such adverse events and the recommendations of the committee/subcommittee shall be reported to the ERC at the next available meeting.

3.8. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:

a. Referral to the Clinical Trials Sub-committee of the Ministry of Health

b. Immediate request for additional information

c. Immediate suspension of ethical approval

d. Immediate termination of ethical approval.

3.9. The ERC shall provide notice to the investigator that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.

3.10. The Chairperson shall immediately notify the Dean (or delegate) if a project is suspended or terminated because of a serious adverse event.

	Ethics Review Committee **Postgraduate Institute of Medicine University of Colombo**	
	SOP – 022 Record Keeping	
	Version 3 - 31/10/2018	

1. Purpose: To describe the procedure for the preparation and maintenance of records of the ERC activities

It is the responsibility of the Secretary ERC to prepare and maintain written/electronic records of all the ERC activities. The supporting staff of the ERC will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed.

2. Scope:

This SOP applies to administrative processes concerning the preparation and maintenance of written/ electronic records of all the ERC activities.

3. Detailed Instruction:

3.1. Supporting staff 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 under the supervision of the Secretary:

1. ERC registration number
2. Title of the project
3. Principal investigator(s) with contact details
4. Name of the responsible institution or organization
5. Date of Submission
6. Date of review at an ERC meeting and the decision(s) taken at this meeting
7. Decision/s of the ERC - approval or non-approval - with date/s
8. Approval or non-approval of any changes to the project
9. Terms and conditions, if any, of approval of the project and

10. Type of approval, whether approval was by expedited review.

3.2. The protocol 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.

3.3. All relevant records of the ERC, including applications, membership, minutes, correspondence, and progress/final reports will be kept as confidential files.

3.4. To ensure confidentiality, all documents provided to ERC members, which are no longer required, are to be disposed of in a secure manner, such as shredding.

3.5. All records pertaining to research protocols shall be held for sufficient time to allow for future reference The minimum period for retention will be five (5) years after termination/ completion of study or as long as required by the sponsor. Files which are no longer required for retention shall be deleted or shredded.

3.6. A register of all the applications received and reviewed shall be maintained in accordance with the FERCSL and other national/international guidelines.

3.7. Backup of the database will be created locally every day at the close of business. The backup will be copied to an encrypted external hard drive every other week on the last working day of the week after creating the daily backup and will be stored at the safe at the deputy registrar's office, PGIM/UOC.

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Table 1 - Applicable Fees	
	Version 3 - 31/10/2018	

Category	**Current Fee**	**New Fee**
1. Trainers and Staff of the PGIM of UOC	Free	
2. Trainees of the PGIM of UOC	Rs. 2000	
3. Extended Faculty of the PGIM of UOC	Rs. 5000	
4. Industry sponsored projects	Rs. 7500	
5. Foreign Funded Research projects		

- Where the application falls under two or more of these categories, whichever the highest fee will apply.
- All the payments should be made through PGIM online payment system prior to the submission and a hard copy of the receipt should be submitted along with the application.
- Fees once paid will not be refunded.

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 1 - Confidentiality Agreement and Conflict of Interest Declaration	
	Version 3 - 31/10/2018	

Annexure 1a: Agreement on Confidentiality and Conflict of Interest Declaration for ERC members/ external reviewers

As a member of the Ethics Review Committee of the PGIM/ UOC, I hereby undertake to maintain confidentiality regarding all matters of which I become aware during the course of my work on the ERC and to declare any conflicts of interest which exist or may arise during my tenure on the ERC.

I hereby also declare that I have not been subjected to any criminal conviction or disciplinary action which may prejudice my standing as a member of the ERC.

Signature _____ Date _____

Name & Designation _____

Chairperson's Signature _____ Date _____

Annexure 1b: Agreement on Confidentiality and Conflict of Interest Declaration for office staff/ visitors

By signing this statement, I undertake to respect and maintain confidentiality regarding all matters of which I become aware during the course of my work on the ERC.

I undertake to handle responsibility the information gathered during ERC work and to hand over the documents to the ERC committee following my work.

Signature_____ Date _____

Name & Designation _____

Chairperson's Signature _____ Date _____

Annexure 1c: Conflict of Interest Declaration Form for ERC members/ External Reviewers

I am aware of the policy of the ERC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which she/he has actual/potential conflict of interest except to provide information as requested by the IEC.

I declare _____ (actual or potential COI) in relation to the proposal entitled "_____ _____" submitted for review to the IEC. The reason for COI is _____ _____. I will refrain from the review process and /or discussion at the IEC meeting/ and also will not take part in ongoing and periodic review and monitoring of this study.

Signature _____ Date _____

Name & Designation _____

Chairperson's Signature _____ Date _____

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 2 - Curriculum Vitae of ERC Members	
	Version 3 - 31/10/2018	

Personal Information			
Name	Rev/Prof/Dr/Mr/Ms		
Current Designation			
Home Address			
Contact Number			
Email address			
Educational Qualifications			
Bachelor's degree			
Postgraduate degrees			
Work Experience			
Employment	**Designation**	**Work place**	**Period**
Present			
Previous 1			
Previous 2			
Training in Ethics			
Training 1			
Training 2			
Publications			

Date

Signature of the ERC Member

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 3 - Letter of Appointment	
	Version 3 - 31/10/2018	

<Reference No.>

<Date>

<Name of the member>
<Address of the member>

Dear <Name of the member>,

Appointment as a Member of the Ethics Review Committee, Postgraduate Institute of Medicine, University of Colombo

I am pleased to inform you that you have been appointed as a member of the Ethics Review Committee of the Postgraduate Institute of Medicine, by the Board of Management for a period of three years effective from <Date of appointment>.

The Secretary, ERC, PGIM/UOC will provide you with the Standard Operating Procedures (SOPs) of the ERC, PGIM/UOC with which you are expected to be familiar. These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for functions of members of ERC, PGIM/UOC. You are required to sign a Confidentiality Agreement and Conflict of Interest Declaration and on the assumption of duties.

The PGIM will indemnify you in respect of liabilities that may arise in the course of bona fide conduct of duties as an ERC member.

Your contributions as a member of the ethics review committee will be greatly appreciated.

Yours sincerely,

<Signature of the Director>
<Name of the Director> Director, PGIM

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 4 - Training Record	
	Version 3 - 31/10/2018	

Name of the ERC Member: Rev/Prof/Dr/Ms/Mr

Name of the Training	**Training Provider**	**Venue**	**Date**

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 5 - Application Form for Scientific and Ethical Review	
	Version 3 - 31/10/2018	

For Office Use Only:

Application Number: PGIM/ERC/20___/_____ Date Received: ___/___/20___

Name of the Applicant:
Rev/Prof/Dr/Mr/Ms_____

This application should be forwarded by the principal investigator who requests ethical approval for a research project. All the co-investigators should provide signed consent to submit the application to ERC, PGIM/UOC. Application guidelines are available at PGIM website. Only the trainees, trainers, extended faculty and staff of the PGIM/UOC are eligible to apply for ERC approval from PGIM/UOC.

Part A – Administrative Details

1. **Title of the Research Project:** Enter title of the research project here

2. **Details of the Investigators:**

Title, Name, Designation and Affiliation	Role	Signature
	Principal Investigator	

3. **Contact Details of the Principal Investigator:**

3.1 Postal Address	Enter the name of Principal Investigator
3.2 Email Address	Enter the name of Principal Investigator
3.3 Telephone	Enter the name of Principal Investigator

4. Nature of the study:

Observational/non-interventional ☐ Clinical trial ☐ (investigator initiated) ☐

Research database/information system ☐ Sponsored clinical trial ☐

Other ☐

5. Proposed starting (initial date of enrolment of participants) and ending (completion of data collection) dates (retrospective approval will not be given to the projects already started)

Start Date: End Date:

6. Has the relevant Board of Study/Specialty Board approved the research project (if applicable)?

Yes : ☐ No: ☐

If Yes, Board of Study/Specialty Board: Details:

7. Has ethics approval for this study been requested earlier from ERC, PGIM/UOC or another ERC? (if you have received ethics approval already, please attach a copy of the approval)

Yes : ☐ No: ☐

Details:

8. Funding (if any)

Name and Address of the funding source: Amount:

9. Do you believe the proposed project has conflicts of interest?

Yes : ☐ No: ☐

If Yes, Details:

Part B – Protocol Check List

Under each category, indicate the protocol section of the research proposal. If a particular category in not relevant to your study, indicate it as 'NA'

	Scientific validity	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Title					
2	Research problem					
3	Research questions/ hypothesis					
4	Objectives					
5	Study setting					
6	Study design					
7	Study population (giving inclusion exclusion criteria)					
8	Sample size					
9	Sampling method					
10	Measurements / variables					
11	Study instruments					
12	Procedures to ensure quality of data					
13	Plan for analysis					
14	Ethical considerations					
15	Budget (if relevant)					
16	Work plan and time frame					
17	Justification for a replication study, if your study is a repl..					

	Social Value	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Benefits of the study to the community/society					
2	Plan for dissemination of study findings					

3	Scientific importance of the study					

	Risk Benefit Assessment	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Potential risks to the participants					
2	Potential benefits to the participants					
3	Justification for risks against benefits					
4	Steps taken to minimize risks					
5	Support provided to participants (medical, educational, other)					

	Participants rights and consent	Protocol pages	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Procedure for recruiting the participants					
2	Information provided to the participants					
3	Procedure for requesting informed consent					
4	Procedure for requesting proxy consent					
5	Procedure for requesting assent (subjects between 12y to 18y)					
6	Procedure for withdrawing consent					
7	Incentives provided to participants					
8	Procedure for participants to ask questions / register complaints					

9	Participants right to decline consent without losing entitled benefits					

	Confidentiality and Privacy	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Steps to ensure confidentiality of data					
2	Justification for collecting personal identification data					
3	Steps taken to ensure privacy during data collection					
4	How long data and samples will be kept					
5	Who will have access to the data					
6	Procedure for storage of data and samples					
7	Procedure for disposal of data					

			Reviewer Evaluation			
	Fair participant selection and vulnerability	Protocol page/s	Acceptable			Comments
			Yes	No	N/A	
1	Justification for selection of study population					
2	Justification for conducting the study in a vulnerable population					

	Responsibilities of the researcher	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	

1	Ethical, legal, financial issues related to the study					
2	Any conflicts of interest and how the researcher plans to manage them					
3	Permissions from relevant institutions / authorities					
4	Collaborations with the relevant stakeholder					
5	Provision of medical / psychological care to the participants					
6	Qualifications of the research team to handle the research study					

	Foreign funded studies	Protocol page/s	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	
1	Justification for conducting the study in SL					
2	Relevance of the study to SL					
3	Post research benefits to SL					
4	The sharing of intellectual property rights					
5	How the results will be conveyed to authorities in SL					

	Information Sheet / Consent Form	Section in Info. sheet consent form	**Reviewer Evaluation**			
			Acceptable			Comments
			Yes	No	N/A	

1	Purpose of the study					
2	Voluntary participation					
3	Duration of the study and responsibilities of the participants					
4	Potential benefits					
5	Risks, Hazards, Discomforts					
6	Incentives / Reimbursements					
7	Confidentiality					
8	Contact person for the participants					
9	Understanding of information provided by the researcher					
10	Agreement of the participant to provide information / samples					
11	Consent for dissemination of research findings					
12	Appropriate translation of the information sheet					
13	Appropriate translation of the consent form					

Decision of the reviewer:

Approved ☐

Resubmit with minor revision ☐

Resubmit with major revision ☐

Reject ☐

Comments of the Reviewer:

Name of the Reviewer:

Signature of the Reviewer: ,,, Date: ………………………..

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 6 – Applicant Declaration	
	Version 3 - 31/10/2018	

Declaration

As the principal investigator of 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 humans and cadavers. I understand that if there is any significant 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 to the proposed study. I declare that I am not seeking approval for a study that has already been commenced or has already been completed.

……. Date:……..

Signature of principal investigator

Full name of principal investigator:

……

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 7 - Submission Check List	
	Version 3 - 31/10/2018	

For Office Use Only:

Application Number: PGIM/ERC/20___/_____ Date Received: ___/___/20___

To be Filled by the Applicant:

Title:

Name of the Applicant: Rev/Prof/Dr/Mr/Ms

Document	Version	Date
1. Application form (3 copies)		
2. Detailed research proposal (3 copies)		
3. All study instruments (questionnaires/interview guides/checklist/data extraction forms) English (3 copies)		
4. Study instruments - Sinhala (if applicable) (3 copies)		
5. Study instruments - Tamil (if applicable) (3 copies)		
6. Information sheet - English (3 copies)		
7. Information sheet - Sinhala (if applicable) (3 copies)		
8. Information sheet - Tamil (if applicable) (3 copies)		
9. Consent forms - English (3 copies)		
10. Consent forms - Sinhala (if applicable) (3 copies)		
11. Consent forms - Tamil (if applicable) (3 copies)		
12. Any other relevant documents - English (3 copies)		
13. Any other relevant documents - Sinhala (3 copies)		
14. Any other relevant documents - Tamil (3 copies)		
15. Curriculum vitae of all investigators (1 copy)		

16. Approval letter from relevant Board of Study/Specialty Board for postgraduate studies (1 copy)		
17. Online payment receipt (1 copy)		

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 8 - Sample Information Sheet	
	Version 3 - 31/10/2018	

<Title of the project>

I/We <name of principal investigator/s>, a <Designation> attached to <institute/s of affiliation> would like to invite you to take part in a research project titled <Nontechnical Title> conducted by <Names of Investigators> at <Study Site>

1. **Purpose**

   The objective/s of the study in non-technical terms

2. **Voluntary participation**

   Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. **Duration, procedures of the study and participant's responsibilities**

   This study will be conducted over a period of < anticipated duration of study>. If you volunteer to participate in this study, we will ask you to do the following:

   a. We will ask you to <take part /visit the clinic> for < duration of each visit and number of visits> over the course of a total of about < expected duration of participation>.

   b. You will need to <the procedure/s of the research including what happens at each visit in simple terms and how the participant has to take part in the study> **4. Potential benefits**

   Participation in this study may benefit you/others by < all the actual and potential benefits>

5. **Risks, hazards and discomforts**

<Any potential or actual risks, hazards and discomforts should be clearly defined>

6. **Reimbursements**

You would be paid a sum of Rs. < if any payment to the participant indicating the amount, when it would be paid and any conditions attached to it> OR you will not be paid any sum of money for participating in this study

7. **Termination of study participation**

You may stop participating in this study at any time (with no penalty or effect on medical care or loss of benefits). Please notify the investigator as soon as you decide to withdraw your consent.

8. **Confidentiality**

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.

9. **Clarifications**

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.

<The names and contact information of investigator/s>

<postal address, email address, telephone numbers>

If you have any clarification, concerns, or complaints related to this research project, you may contact the Ethics Review Committee, Postgraduate Institute of Medicine, University of Colombo.

ERC Office Address: Ethics Review Committee, Postgraduate Institute of Medicine, University of Colombo, 160, Prof. Nandadasa Kodagoda Mawatha, Colombo 07.

Telephone: 0112-689266 (between 9am and 4pm on working days)

Email: erc@pgim.cmb.ac.lk

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 9 - Sample Consent Form	
	Version 3 - 31/10/2018	

<Title of the Research Project>

To be completed by the participant (Please tick the appropriate box)

	Yes	No
1. Have you read the information sheet? (Please keep a copy for yourself)	☐	☐
2. Have you had an opportunity to discuss this study and ask any questions?	☐	☐
3. Have you had satisfactory answers to all your questions? 4. Have you received enough information about the study?	☐	☐
5. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☐	☐
6. Sections of your medical notes, including those held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as strictly Confidential. Do you give your permission for these individuals to have access to your records?	☐	☐
7. Have you had sufficient time to come to your decision? 8. Do you agree to take part in this study?	☐	☐

Who explained you about the study:……

Signature of the participant:…… Date:……..

Full name:……..

Signature of the Legally Acceptable Representative or impartial witness for illiterate participant:

…… Date:……..

Full name:……..

To be completed by the investigator/ person obtaining consent

I have explained the study to the above participant and he/ she has indicated her willingness to take part in this study.

Signature of Investigator:…… Date:……..

Full name:……..

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 10 - Curriculum Vitae of the Applicants	
	Version 3 - 31/10/2018	

Personal Information			
Name	Rev/Prof/Dr/Ms/Mr		
Current Designation			
Home Address			
Contact Number			
Email address			
Educational/Professional Qualifications			
Bachelor's degree			
Postgraduate degrees			
Work Experience			
Employment	**Designation**	**Work place**	**Period**
Present			
Previous 1			
Previous 2			
Publications (list up to 5 most relevant to the proposed study)			
Ongoing Research Projects (other than this project)			

Date

Signature of the Applicant

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 11 - Document Receipt Form	
	Version 3 - 31/10/2018	

Please insert the **Title** and the **Name of the Applicant**

Title:
Name of the Applicant: Rev/Prof/Dr/Mr/Ms

For Office Use Only: This check list will be filled and signed by the person who receives the application at ERC, PGIM/UOC office.

Application Number: PGIM/ERC/20___/_____ Date Received: ___/___/20___

1. Covering Letter	
2. Submission Check List	
3. Declaration of Applicant	
4. Application form (3 copies)	
5. Detailed research proposal (3 copies)	
6. All study instruments in English (questionnaires/interview guides/checklist/data extraction forms) with Sinhala and Tamil translations where relevant (3 copies)	
7. Information sheet in English with Sinhala and Tamil translations where relevant (3 copies)	
8. Consent forms in English with Sinhala and Tamil translations where relevant (3 copies)	
9. Any other relevant documents in English with Sinhala and Tamil translations where relevant (3 copies)	
10. Curriculum vitae of all investigators	
11. Approval letter from the relevant Board of Study (if applicable)	

12. Online payment receipt	

Instructions for the applicants:

Please **email all the documents within 24 hours of receipt of this checklist** to erc@pgim.cmb.ac.lk as a compressed/zipped folder. Subject line should be the Application Number followed by the last name/surname of the applicant (Eg **PGIM/ERC/2017/xxx Perera**).

Received by:

……	……..	……..
Name of the Staff Member	Signature	Date

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 12 - Exemption Letter	
	Version 3 - 31/10/2018	

<ERC Reference Number>
<Date>

<Name of the Principal Investigator>
<Address of the Principal Investigator>

Dear < Name of the Principal Investigator >,

<Title of the Proposal>

Investigators:<Names of the investigators>

Thank you for submitting the above research proposal to the ERC of the Postgraduate Institute of Medicine. I am pleased to inform you that the study was exempted from the ethics review by the ERC at its meeting held on <meeting date> after reviewing the following documents submitted by you.

Document	Version No	Submission Date
Protocol	<Version>	<Date>
Information Sheet	<Version>	<Date>
Consent form	<Version>	<Date>
Study Instrument	<Version>	<Date>

Thank you.
Yours sincerely,

<Signature of the Secretary>
<Name of the Secretary>
Secretary-ERC/PGIM

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 13 – Expedited Approval Letter	
	Version 3 - 31/10/2018	

<ERC Reference Number>
<Date>

<Name of the Principal Investigator>
<Address of the Principal Investigator>

Dear < Name of the Principal Investigator>,

<Title of the Proposal>

Investigators:<Names of the investigators>

Thank you for submitting the above research proposal to the ERC of the Postgraduate Institute of Medicine. I am pleased to inform you that the study was approved by the ERC at its meeting held on <meeting date> after an expedited review of the following documents submitted by you.

Document	Version No	Submission Date
Protocol	<Version>	<Date>
Information Sheet	<Version>	<Date>
Consent form	<Version>	<Date>
Study Instrument	<Version>	<Date>

The approval is valid until one year from <approval date>. You may submit a written request for renewal/extension of the approval, along with a progress report.
Please note that you are required to inform the ERC about the following:

- Any unanticipated events involving potential risks to study subjects
- Any deviations in protocol
- Any changes to the documents listed above

You are required to submit the final report to the ERC/PGIM with the following declaration: "*the research was conducted in accordance with the proposal for which approval was granted by the ERC of PGIM*" within three (03) months upon the completion of the study.

Thank you.
Yours sincerely,
<Signature of the Secretary>
<Name of the Secretary> Secretary-ERC/PGIM

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 14 – Template for Minutes of the ERC Meetings	
	Version 3 - 31/10/2018	

Minutes of the <Meeting No> Meeting of the PGIM Ethics Review Committee <Date> at <Time> at <Venue>

-CONFIDENTIAL- Attendance

Name	**Position**	**<Year>**								
		Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon	Date Mon
<Name of the Chairperson>	Chairperson									
<Name of the Secretary>	Secretary									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									
<Name of the Member>	Member									

P – Present **E** – Excused **V-** Virtually Participated **A** – Absent **L** – on Leave

The <Meeting No.>th ERC meeting was called to order at <time>. <Name of the person who chaired the meeting> chaired the meeting.

<Meeting No.> .1 **Announcements/Welcome/Excuses**
<announcements, welcome and excuses if any>

<Meeting No.> .2 **Declaration of Conflict of Interest**
<Member> – <ERC Ref No of the protocol>

<Meeting No.> .3 Confirmation of the Minutes

Minutes of the <last Meeting No>th ERC meeting held on <last meeting date> were confirmed. Proposed by <name of the member who proposed > and seconded by <name of the member who seconded>

<Meeting No.> .4

Matters arising from the Minutes

<matters arising from the minutes of the last meeting>

<Meeting No.> .5 Training

<Meeting No.>.5.1 In-house Training

<inhouse training topic, name of the member who conducted the training>

<Meeting No.>.5.2 Other trainings

<details if any>

<Meeting No.> .6 New Protocols

<Meeting No.>.6.1 Exempted New Protocols for Ratification

<Meeting No.>.6.1.1 <ERC Ref No.><Title><Name of the Principal Investigator>

<Meeting No.>.6.1.2 New Protocols Subjected to Expedited Review for Ratification

<Meeting No.>.6.1.3 <ERC Ref No.><Title><Name of the Principal Investigator>

<Meeting No.>.6.2 New Protocols For Full Board Review

<Meeting No.>.6.2.1 <ERC Ref No.><Title><Name of the Principal Investigator>

ERC No:	<ERC Ref No.>	Date Submitted:	<submission date>
Applicant	<Name of the applicant>		
Study Design	<Type of study>		

Documents	Application	Protocol	Instrument			IS/ICF		
			E	S	T	E	S	T
Version	<version No>	<version No>	<version No>			<version No>		
Internal reviewers	<Name of the 1st Primary Reviewer>	<Name of the 2nd Primary Reviewer>	<Name of the person who Reviews Sinhala version> <Name of the person who Reviews Tamil version>					
ERC Discussion	<discussion points>							
Recommendation	<ERC recommendation. i.e. type of approval>							
Remarks	<details if any>							

<Meeting No.> .7 Previously Considered Protocols

ERC No:	<ERC Ref No.>	Date Submitted:	<submission date>

Applicant	<Name of the applicant>							
Study Design	<Type of study>							
Documents	Application	Protocol	Instrument			IS/ICF		
			E	S	T	E	S	T
Version	<version No>	<version No>	<version No>			<version No>		
Internal reviewers	<Name of the 1st Primary Reviewer>	<Name of the 2nd Primary Reviewer>	<Name of the person who Reviews Sinhala version> <Name of the person who Reviews Tamil version>					
ERC Discussion	<discussion points>							
Recommendation	<ERC recommendation. i.e. type of approval>							
Remarks	<details if any>							

<Meeting No.> .8 Amendments/Extensions to Approved Protocols

<Meeting No.>.8.1 <ERC Ref No.> - <Title>

<Meeting No.> .9 Progress/Final Reports of approved proposals <Meeting No.>.9.1

<ERC Ref No.> - <Title>

<Meeting No.> .10 Reports of the Subcommittees

<Details, if any>

<Meeting No.> .11 Amendments to SOPs

<Details, if any>

<Meeting No.> .12 Correspondence

<Details, if any>

<Meeting No.> .13 Any Other Business

<Details, if any>

<Meeting No.> .14 Date, Time and Venue for the next meeting

<Date> <Time><Venue> for the next meeting

Meeting adjourned at <adjourned time>

<Signature of the Secretary>
<Name of the Secretary>
Secretary, ERC, PGIM/UOC

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 15 - Resubmission Letter	
	Version 3 - 31/10/2018	

<ERC Reference Number>
<Date>

<Name of the Principal Investigator>
<Address of the Principal Investigator>

Dear < Name of the Principal Investigator >,

<Title of the Proposal>

Investigators:<Names of the investigators>

Thank you for submitting the above research proposal. ERC at its meeting held on <meeting date> reviewed the following documents submitted by you.

Document	Version No	Submission Date
Protocol	<version>	<date>
Information sheet	<version>	<date>
Consent form-	<version>	<date>
Study Instrument	<version>	<date>

The ERC has suggested following modifications prior to the consideration for approval.

<suggested modifications>

Please resubmit the revised proposal with a covering letter, within three (03) months of this letter. Please underline all the changes in the proposal and indicate the changes in the covering letter in a table with four columns indicating reviewers comments, original wording, the responses/revisions and page numbers.

Thank you.
Yours sincerely,

<Signature of the Secretary>
<Name of the Secretary>
Secretary-ERC/PGIM

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 16 - Approval Letter	
	Version 3 - 31/10/2018	

<ERC Reference Number>
<Date>
<Name of the Principal Investigator>
<Address of the Principal Investigator>

Dear < Name of the Principal Investigator >,
<Title of the Proposal>

Investigators:<Names of the investigators>

Thank you for submitting the above research proposal. I am pleased to inform you that the study was approved by the ERC at its meeting held on <meeting date> after reviewing following documents submitted by you.

Document	Version No	Submission Date
Protocol	<version>	<date>
Information sheet	<version>	<date>
Consent form-	<version>	<date>
Study Instrument	<version>	<date>

The approval is valid until one year from the meeting date stated above. You may make a written request for renewal/extension of the validity, along with the submission of a progress report.

Please note that you are required to inform the ERC about the following:

- Any unanticipated events involving potential risks to study subjects
- Any deviations in protocol, protocol violation and SAE
- Any changes to the documents listed above

You are required to submit the final report to the ERC/PGIM with the following declaration: "*the research was conducted in accordance with the proposal for which approval was granted by the ERC of PGIM*" within three (03) months upon the completion of the study. Thank you.
Yours sincerely,
<Signature of the Secretary>
<Name of the Secretary>
Secretary-ERC/PGIM

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 17 - Rejection Letter	
	Version 3 - 31/10/2018	

<ERC Reference Number>
<Date>

<Name of the Principal Investigator>
<Address of the Principal Investigator>

Dear < Name of the Principal Investigator >,

<Title of the Proposal>

Investigators:<Names of the investigators>

Thank you for submitting the above research proposal. I regret to inform you that your study was NOT approved by the ERC at its meeting held on <meeting date> based on following documents submitted by you.

Document	Version No	Submission Date
Protocol	<version>	<date>
Information sheet	<version>	<date>
Consent form-	<version>	<date>
Study Instrument	<version>	<date>

Main reason/s for this decision is/are
<reasons for rejection>

You may submit a new application after addressing all above comments.

Thank you.
Yours sincerely,

<Signature of the Secretary>
<Name of the Secretary>
Secretary-ERC/PGIM

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 18 - Progress Report	
	Version 3 - 31/10/2018	

ERC Ref No.	
Title	

Details of Principal Investigator

Name of the Principal Investigator	
Address of the Principal Investigator	
Phone Number	

Details of the Study

Date of Approval	
Study Start Date	
Progress report Date	
Progress	
Progress to the date	
Number of participants enrolled so far	
Maintenance and security of records	
Compliance with approved protocol	
Amendments/ Changes	
Protocol deviations/violations	
Adverse events/SAE if any	
Presentations/publications related to data gathered in this study	
Any other	

Date

Signature of the PI

This report should be submitted every six (06) months

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 19 - Final Report	
	Version 3 - 31/10/2018	

ERC Ref No.	
Title	

Details of Principal Investigator

Name of the Principal Investigator	
Address of the Principal Investigator	
Phone Number	

Details of the Study

Date of Approval	
Study Start Date	
Study End Date	
Total number of participants,	
% recruited	
Main Findings/ Outcome	
Adverse events/SAE if any	
Protocol Deviations/ Violations	
Presentations/ Publications	
Any other	
outcome data, publication plan	

Date

Signature of the PI

	Ethics Review Committee **Postgraduate Institute of Medicine, University of Colombo**	
	Annexure 20 - Serious Adverse Events (SAE) Reporting Form	
	Version 3 - 31/10/2018	

Principal Investigator: Study Title: Name of the studying medicine/herbal/device: Sponsor:	Application Number: Protocol Number: Report Date: Initial Follow up Onset Date: Date of first use:
Subject's initial / number:	Age: / Gender: Male ☐ Female ☐
Subject's history:	Laboratory findings:
State the SAE:	Treatment: Outcome: ☐ resolved ☐ on- going

Seriousness		**Relation to Drug/Device/Study**
☐	Death	Not related/Possibly related/Definitely related
☐	Life Threatening	Not related/Possibly related/Definitely related
☐	Hospitalization	Not related/Possibly related/Definitely related
☐	Disability/ Incapability	Not related/Possibly related/Definitely related
☐	Congenital Anomaly	Not related/Possibly related/Definitely related
☐	Unknown	Not related/Possibly related/Definitely related
☐	Other	Not related/Possibly related/Definitely related

Changes to the protocol recommended? ☐ No ☐ Yes, attach proposal Changes to the informed consent form recommended? ☐ No ☐ Yes, attach proposal
Reviewed by: Comment: Action: Date: