



STANDARD OPERATING PROCEDURES

ETHICS REVIEW COMMITTEE

Health Informatics Society of Sri Lanka

Version 0.2

APRIL 2016

STANDARD OPERATING PROCEDURES
ETHICS REVIEW COMMITTEE
HEALTH INFORMATICS SOCIETY OF SRI LANKA

TABLE OF CONTENTS

Table of Contents

Mandate 1

Objectives 1

Scope 2

Standard Operating Procedures..... 4

Annexures 39



Mandate

The primary objective of the Ethics Review Committee (ERC), of Health Informatics Society of Sri Lanka (HISSL) is to promote the rights, dignity, safety and wellbeing of persons; of whom the information is entered, stored, processed, transmitted or archived in a health and related information systems through an efficient and effective review and monitoring process.

Objectives

The objectives of the ERC are:

- i. To promote adopting ethical standards in health and related information systems.
- ii. To provide independent and competent review and auditing of health information systems in respect of their ethical acceptability.
- ii. To provide ethical oversight, monitoring and advice for health related information systems.
- iii. To prescribe the principles and procedures to govern information systems with personally identifiable information.
- iv. To provide guidance on enhancing the privacy, security and confidentiality of the information in health and related information systems.

Scope

1. Health related information systems may include, but are not limited to, information systems, databases, repositories and archives involving Personal Health Records, Clinical Information, Pharmacy / prescription, human genomics, medical laboratory, public health , medical imaging, and biological samples.
2. The ERC will assess projects submitted to it for review or auditing.
3. The ERC will review proposals for information systems referred by other ERCs. In such circumstances, an agreement shall exist between the ERC and the external ERC that seeks expert opinion. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review.
4. Those who commission any particular health and related information system shall ensure standard information system security measures are adhered to. The ERC or HISSL shall not be liable to any damage caused by non-adherence to such security measures, or due to mechanical malfunctions, software errors (bugs), human errors or acts of will.

Standard Operating Procedures

Reference Number:	SOP 001
Date:	April 2016
Subject:	Membership Composition
Purpose:	To describe the membership and the composition of the ERC

1. There shall be at least one representatives from following categories in the membership:
 - i. Community Representative
 - ii. Legal professional
 - iii. Clinical Specialists
 - iv. Public Health Specialists
 - v. Statistician
 - vi. IT specialist
 - vii. Health Informaticians

2. To ensure the membership will equip the ERC to address all the relevant considerations arising from the types of information systems, and that a quorum is present at all meetings, some or all of the categories may be represented by more than one person.

3. Where required, the ERC may seek advice and assistance from appropriate experts to assist with the review of a proposal. However, the ERC must be satisfied that such experts have no conflicts of interest in relation to the proposal under consideration arising from any personal involvement or participation in the proposal, any financial interest in the outcome or any involvement in competing information systems. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

4. Additional members may be appointed to ensure the ERC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the ERC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members.

5. The person currently holding the position of the President shall not be eligible to become a member of the Ethics Review Committee while holding that position.

Reference Number:	SOP 002
Date:	April 2016
Subject:	Appointment of members
Purpose:	To describe the procedure for the appointment of members to the ERC

1. Members may be appointed as individuals or in a representative capacity.
2. Prospective members of the ERC may be recruited by direct approach, nomination or by advertisement or in official capacity. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the ERC website.
3. A selection committee, consisting of the Chairperson and at least one other ERC member shall interview the prospective applicant, consult with the ERC members and make a recommendation to the Council of HISSL. Prospective members may be invited to attend a meeting of the ERC as an observer.
4. Members are appointed by the council of the HISSL in consultation with the ERC and will receive a formal notice of appointment.
5. The Chairperson and the Secretary will be appointed by the HISSL council from the ERC members. In the absence of the Chairperson, a member selected by members of the ERC from among its membership will perform the role and duties of the Chairperson.
6. The letter of appointment shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of duties as a ERC member, the circumstances whereby membership may be terminated and the conditions of appointment.
7. Members will be required to sign a confidentiality undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the ERC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the ERC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a ERC member.
8. Upon appointment, members shall be provided with the following documentation:
 - Terms of Reference of the ERC;
 - Standard Operating Procedures of the ERC;

- up-to-date list of members' names and contact information;
 - Current FERCSL Guidelines;
 - any previous reports on the ERC's activities; and
 - any other relevant information about the ERC's processes, procedures and protocols.
9. Members are appointed for a period of three years, renewable at the discretion of the council of HISSL.
 10. Appointments shall allow for continuity, the development of expertise within the ERC, and the regular input of fresh ideas and approaches.
 11. All members are encouraged to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the ERC.
 12. Members shall not be remunerated. Members will be reimbursed for legitimate expenses incurred in attending ERC meetings, such as travelling and parking expenses.
 13. Members may seek a leave of absence from the ERC for extended periods. Steps shall be taken to fill the vacancy.
 14. Membership will lapse if a member fails to attend three consecutive meetings of the ERC without reasonable excuse/apology, unless exceptional circumstances exist. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy.
 15. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled ERC meetings in each year, barring exceptional circumstances.
 16. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will be expected to be available between meetings to participate in Executive meetings where required.
 17. A member may resign from the ERC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy.

Reference Number:	SOP 003
Date:	April 2016
Subject:	Orientation of new members
Purpose:	To describe the procedure for the orientation of new members

1. New ERC members will be provided with adequate orientation.

2. Orientation may involve all or some of the following:
 - Introduction to other ERC members prior to the ERC meeting.
 - Informal meeting with the Chairperson, Secretary and Officials of the ERC to explain their responsibilities as an ERC member, the ERC processes and procedures.
 - An opportunity to sit in on ERC meetings before their appointment takes effect.
 - 'Partnering' with another ERC member in the same category.
 - Priority given to participate in training sessions.

Reference Number:	SOP 04
Date:	April 2016
Subject:	Submission procedure for new applications
Purpose:	To describe the procedure for the submission of new applications

1. Applications must be submitted in the appropriate format as determined by the ERC, and shall include all documentation as required by the ERC. Information about the procedures for application to the ERC and the application format shall be readily available to applicants.
2. Guidelines shall be issued by the ERC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the ERC is necessary.
3. A fee will be charged for applications submitted for assessment by the ERC, but may be waived at the discretion of the ERC (e.g. for student proposals).
4. All applications for ethical review must be submitted to the office of the ERC by 1600 hrs on the relevant closing date.
5. Information about the closing date for receipt of new applications onto the next ERC agenda shall be readily available to prospective applicants. The closing dates for general applications shall normally be the working day of the month which should be no less than 14 days prior to the monthly ERC meeting.

Reference Number:	SOP 05
Date:	April 2016
Subject:	Processing of applications for review
Purpose:	To describe the procedure for the processing of new applications

1. Applications will be checked for their completeness by an official of the ERC prior to their acceptance onto the agenda. Incomplete applications may be returned to the applicant.
2. Once a completed application has been accepted for ethics review, the ERC shall assign a unique identification number
3. The office of the ERC will acknowledge acceptance of an application for ethical review by issuing an acknowledgement letter to the applicant within five (5) working days of receipt of the application. The acknowledgement letter shall include the date of the meeting at which the application will be reviewed, as well as the unique identification number.
5. An application will be included on the agenda for the next available ERC meeting, provided it is received by the relevant closing date and is complete.

Reference Number:	SOP 06
Date:	April 2016
Subject:	Preparation of agenda
Purpose:	To describe the process and format of agenda for an ERC meeting

1. The Secretary of the ERC will prepare an agenda for each ERC meeting.
2. All complete applications and relevant documents received by the Secretary of the ERC will be included on the agenda for ERC consideration at its next meeting.
3. The meeting agenda and associated documents will be prepared by the Secretary of the ERC and circulated to all ERC members at least seven (7) calendar days prior to the next meeting.
4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chairperson.
5. Agenda items will include at least the following items:
 - i. apologies;
 - ii. minutes of the previous meeting;
 - iii. business arising from the previous minutes;
 - iv. conflicts of interest;
 - iv. new applications;
 - v. applications awaiting clarification;
 - vi. amendments to approved protocols;
 - vii. correspondence;
 - viii. other business;
 - ix. close and next meeting.

Reference Number:	SOP 07
Date:	April 2016
Subject:	Conduct of meetings
Purpose:	To describe the format of meetings of the ERC

1. The ERC shall meet on a regular basis, which will normally be at monthly intervals. Information about meeting dates and agenda closing dates shall be publicly available.
2. Members may attend ERC meetings in person or via teleconference or video link. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Secretary of the ERC or direct communication with the Chairperson. The minutes should record the submission of written comments and direct communications.
3. A quorum must be present in order for the ERC to reach a final decision on any agenda item. A quorum shall exist when at least five (5) members of which at least one member is a non-medical member is present.

In circumstances where members cannot be present, they may provide written comments in lieu of attendance. However, in these circumstances, there must be at least five (5) members physically/ via teleconference present to achieve quorum, including one non-medical member.

4. If the meeting does not achieve quorum, the Chairperson shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the ERC must be ratified by at least one lay representative.
5. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved (refer to paragraph 2). Should this occur, the ERC will convene within ten (10) working days of the cancelled meeting to ensure all agenda items are considered.
6. Meetings will not be scheduled for an allocated time. Meetings will continue until all agenda items have been considered.
7. 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.
8. Notwithstanding paragraph 7, the ERC may agree to the presence of visitors or observers at a meeting.

9. 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 interest beforehand. This will be dealt with in accordance with SOP 022.

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

Reference Number:	SOP 08
Date:	April 2016
Subject:	Consideration of applications for ethical review by the ERC
Purpose:	To describe the process of the ERC's consideration of applications for ethical assessment

1. The ERC will consider a new application at its next meeting provided that the completed application is received by the relevant closing date.
2. Each application will be assigned to a principal reviewer who will:
 - review the application in detail prior to the meeting.
 - communicate with the applicant prior to the meeting on behalf of the ERC to clarify and issues; request further details/documentation; or request and receive revisions to the proposal.
 - lead the discussion on the application at the committee meeting.
3. The application will be reviewed by all members of the ERC present at the meeting or providing written comments in lieu of attendance.
4. The ERC will assess each application in accordance with the FERCSL Guidelines and other relevant national and international guidelines. The ERC must ensure that it is sufficiently informed on all aspects of the health related information system including handling of personally identifiable information and scientific validity, to make an ethical assessment.
6. The ERC may consider whether an advocate for any participant or group of participants should be invited to the ERC meeting to ensure informed decision-making.
7. The ERC will ensure that all information sheets, GUIs or other relevant formats, intended for general public are in all official languages of Sri Lanka proposal
8. The ERC, after consideration of an application at a meeting, will make one of the following decisions:
 - It may approve the proposal as being ethically acceptable, with or without conditions / minor amendments.
 - It may defer making a decision on the proposal until an issue is clarified or further information is provided or the proposal is modified.
 - It may decide the proposal as ethically unacceptable, and suggest re-submission with major changes.

9. The ERC will endeavour to reach a decision concerning the ethical acceptability of a proposal 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 two-thirds of members present and examined the proposal and making submissions in writing in lieu of attendance, who provided that the majority includes at least one non-medical member.

10. In order to facilitate consideration of an application, the ERC may invite the applicant to attend the relevant meeting to discuss the application and answer questions. The applicant will be asked to leave the meeting prior to ERC deliberation and decision-making concerning the application.

11. For proposal which the ERC considers ethically acceptable with conditions / minor amendments, the ERC may choose to delegate the authority to review the applicant's response and give final approval for the proposal to proceed to one of the following:
 - chairperson alone; or
 - chairperson, in oral or written consultation with one or more named members who were present at the meeting or who submitted written comments on the application; or
 - an executive committeeIn such circumstances, the ERC shall be informed at the next meeting of the final decision taken on its behalf.

12. For proposals which the ERC has deferred making a decision until an issue is clarified or further information is provided or the proposal is modified, the principle applicant's response will be considered at a subsequent meeting of the ERC.

13. The ERC may conduct expedited review of proposals in accordance with SOP 10.

Reference Number:	SOP 09
Date:	April 2016
Subject:	Preparation of minutes
Purpose:	To describe the process and format for minutes of a meeting of the ERC

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

2. The format of the minutes will include at least the following items:
 - i. apologies;
 - ii. attendance;
 - iii. minutes of the previous meeting;
 - iv. business arising from the previous minutes;
 - v. conflicts of interest;
 - vi. new applications;
 - vii. applications awaiting clarification;
 - viii. amendments to approved proposals;
 - ix. correspondence;
 - x. other business;
 - xi. close and next meeting.

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

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

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

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

7. Declarations of conflicts of interest by any member of the ERC and the absence of the member concerned during the ERC consideration of the relevant application will be minuted (refer to SOP 023 regarding a member's declaration of a conflict of interest).

8. The minutes will be produced as soon as practicable following the relevant meeting and, when appropriate, should be checked by the Chairperson for accuracy.
9. The minutes will be circulated to 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.
10. The original copy of each meeting's minutes will be retained in a 'Minutes' file.
11. The minutes of each Committee meeting shall be forwarded to HISSL Council.

Reference Number:	SOP 10
Date:	April 2016
Subject:	Expedited review
Purpose:	To describe the procedure for the expedited review of information system by the ERC

1. The ERC will establish an Executive Committee consisting of at least the Chairperson or the Secretary and a member of the ERC. The Executive may undertake expedited review of health related information systems in the following circumstances:
 - i) health related information systems which does not collect, process, archive or transmit personally identifiable data/ information.
 - ii) continuing review of information system previously approved by the convened ERC as follows:

where

 - a. the information system remains active only for long-term follow-up of participants; or where no participants have been enrolled and no additional risks have been identified; or where the remaining information system activities are limited to data analysis.
 - v) Continuing review of information system, which was determined and documented at a convened meeting that the information system involves no greater than minimal risk and no additional risks have been identified.

Expedited review of proposals may be undertaken between scheduled committee meetings, at the discretion of the Chairperson, by an executive committee. Either may seek advice from other ERC members or suitably qualified experts, as appropriate, before reaching a decision. The decision of this review must be tabled at the next ERC meeting.

The Executive Committee may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, proposal reports, minor amendments and the like.

2. A summary of the matters dealt with at Executive Committee meetings will be included in the agenda for the next ERC meeting.
3. Proposals with the potential for physical or psychological harm will generally not be considered for expedited review. This includes clinical trials, proposals involving invasive physical procedures, Sensitive personally identifiable information (e.g. information about HIV status of a client) and information system dealing with vulnerable groups.

4. Where the Chairperson considers that the proposal may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full ERC and cannot be dealt with by expedited review.

Reference Number:	SOP 11
Date:	April 2016
Subject:	Notification of decisions of the ERC for new applications
Purpose:	To describe the procedure for the notification of decisions of the ERC concerning the review of new applications

1. The ERC will report in writing to the applicant, advising whether the application has received ethical approval (including any conditions of approval), within 5 working days of the meeting, unless otherwise notified.
2. If the ERC determines that further information, clarification or modification is required for the consideration of a proposal, the correspondence to the applicant 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 FERCSL Guidelines or other relevant documents including legislation.
3. The ERC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of proposals relating to ethical issues. The ERC may nominate one of its members to communicate directly with the applicant or invite the applicant to attend the relevant ERC meeting.
4. The ERC will notify the applicant of the ethical approval of a proposal only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:
 - the title of the proposal;
 - the name of the applicant(s);
 - the unique ERC proposal identification number;
 - the version number and date of all documentation reviewed and approved by the ERC including protocols, GUIs, databases, patient information sheets, consent forms, advertisements, questionnaires etc;
 - the date of the ERC meeting at which the proposal was first considered;
 - the date of the ERC's approval;
 - the duration of the ERC's approval; and
 - the conditions of the ERC's approval, if any.A standard approval letter will be issued, in the format set out in ANNEXURE B. Implementation of the information system may not commence until written notification which confirms this has been received.

5. If the ERC determines that a proposal is ethically unacceptable, the notification of the ERC's decision will include the grounds for rejecting the proposal with reference to the FERCSL Guidelines or other relevant pieces of legislation.

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

Reference Number:	SOP 012
Date:	April 2016
Subject:	Submission of amendments and extensions to approved proposals
Purpose:	To describe the procedure for the submission and ERC review of requests for amendments and extensions to approved protocols

1. Approval for proposed changes to approved health related information systems including extensions to the length of ERC approval, must be sought by the applicant in writing.
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 said information system. All amended documents must have the changes highlighted and contain revised version numbers and dates.
3. Expedited review of requests for minor amendments and extensions may be undertaken by the ERC Executive Committee between scheduled meetings at the discretion of the Chairperson and in accordance with SOP 011, on the condition that it is ratified at the next ERC meeting. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the ERC will review the decision at its next meeting.
4. 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.
5. The ERC will report in writing to the applicant, advising of the ethical approval of the proposed amendment and/or request for extension and that the amended information system may commence, within five (5) working days of the meeting at which the request was considered (this may be the full ERC meeting or the Executive Committee meeting).
6. A standard response letter will be issued in the format set out in ANNEXURE B.
7. 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 applicant 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 FERCSL Guidelines or relevant pieces of legislation.
8. All reviewed and approved requests for amendments and extensions shall be recorded in the relevant proposal file and, where appropriate, in the ERC's register of received and reviewed applications.

Reference Number:	SOP 13
Date:	April 2016
Subject:	Handling of adverse events
Purpose:	To describe the procedure for the reporting and handling of adverse events

1. This is applicable only to Category one (research proposals involving health information systems) proposals. The ERC shall require, as a condition of approval of each health related information system proposal, that principle proponent immediately report serious or unexpected adverse events to the ERC, including those that have occurred at other institutions where the system is implemented/piloted.

2. Notifications of adverse events must be submitted in the appropriate format (ANNEXURE G), and shall include all documentation as required by the ERC. This documentation shall include as a minimum:
 - Advice from the applicant as to whether, in his/her opinion, the adverse event was related to the information system.
 - Advice from the applicant as to whether, in his/her opinion, the adverse event necessitates an amendment to any of the components of the information system.

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

4. Adverse events may be reviewed by the Executive Committee or Sub-committee of the ERC, which shall determine the appropriate course of action. This may include:
 - a notation on the proposal file of the occurrence;
 - increased monitoring of the proposal;
 - a request for an amendment to the information system and/or patient information sheet/consent form;
 - suspension of ethical approval; or
 - termination of ethical approval.Any such adverse events shall be reported to the ERC at the next available meeting.

5. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:
 - Immediate request for additional information;
 - Immediate suspension of ethical approval;
 - Immediate termination of ethical approval.

6. The ERC shall provide notice to the applicant that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.
7. The Chairperson shall immediately notify the HISSL Council if a proposal is suspended or terminated because of a serious adverse event.

Reference Number:	SOP 14
Date:	April 2016
Subject:	Monitoring of approved health related information systems
Purpose:	To describe the procedure for monitoring of health related information systems approved by the ERC to ensure compliance with ethical approval

1. The ERC will monitor approved proposals to ensure compliance with its ethical approval. In doing so, it may request and discuss information on any relevant aspects of the proposal with the applicant at any time. In particular, the ERC will require applicants to provide a report at least annually. Continuing approval of the information system will be subject to the applicant's submitting an annual report.
2. The ERC shall require the following information in the annual report:
 - progress to date or outcome of the information system;
 - maintenance, confidentiality and security of records;
 - compliance with the approved protocol; and
 - compliance with any conditions of approval.
3. The ERC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
 - written reports;
 - random inspections of information systems;
 - interview, with their prior consent, of information system stakeholders.
4. The ERC shall require, as a condition of approval of each proposal, that applicant immediately report anything which might warrant review of the ethical approval of the protocol, including:
 - proposed changes in the protocol;
 - any unforeseen events that might affect continued ethical acceptability of the proposal; and
5. The ERC shall require, as a condition of approval of each proposal, that applicant inform the ERC, giving reasons, if the health related information system is discontinued.
6. Where the ERC is satisfied that circumstances have arisen which prevent a health related information system from being operated in accordance with the approved protocol, the ERC may withdraw approval. In such circumstances, the ERC shall inform the applicant the institution of such withdrawal of approval in writing, and recommend to the institution that the health related information system be discontinued, suspended, or that other necessary steps be taken.

7. In determining the frequency and type of monitoring required for approved proposals, the ERC will give consideration to the degree of risk to stakeholders of the health related information system.

Reference Number:	SOP 15
Date:	April 2016
Subject:	Complaints about a health related information system
Purpose:	To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a proposal approved by the ERC

1. The ERC shall nominate a person to whom complaints about approved health related information systems may be made in the first instance. The name and/or position and contact details of the person nominated by the ERC to receive complaints must be included in the patient information sheet and/or consent form for each proposal.
2. Any concern or complaint received about a health related information system approved by the ERC should be directed to the attention of the person nominated by the ERC. That nominated person is responsible for obtaining in writing the grounds of the concern or complaint and shall notify the Chairperson as soon as possible after a complaint is received.
3. If the Chairperson considers the complaint to be of a sufficiently serious nature, he/she will bring it to the attention of the HISSL council as soon as possible.
4. Where the complaint concerns a serious matter within the jurisdiction of the Ministry of Health or other institution HISSL shall consider referral of the complaint to that body.
5. The Chairperson or Secretary will send a letter of acknowledgement to the complainant and a letter of notification to the applicant, outlining the complaint and the mechanism for investigating the complaint, as set out below.
6. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the ERC on the appropriate course of action at its next meeting. If the complaint is substantiated, action may include:
 - the requirement for amendments to the proposal, including increased monitoring by the ERC;
 - suspension of the proposal;
 - termination of the proposal; or
 - other action to resolve the complaint.The complainant shall be informed of the outcome of the Chairperson's investigation.
7. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the President of HISSL , or request that the Chairperson do so.

8. The Chairperson of the ERC will provide the HISSL Council with all relevant information about the complaint/concern, including:
 - the complaint;
 - material reviewed in the Chairperson's investigation;
 - the results of the Chairperson's investigation; and
 - any other relevant documentation.

9. The President HISSL will determine whether there is to be a further investigation of the complaint. Where there is to be no further investigation, the President HISSL will inform the complainant and the Chairperson of this.

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

11. The panel will include, at least, the following members:
 - the President HISSL or his/her nominee, as convenor of the panel;
 - two Council members of HISSL (not members of the ERC); and
 - the ERC chairperson or his/her nominee.

12. The panel will afford the ERC and the complainant the opportunity to make submissions. Where the complaint concerns the conduct of a proposal team member or any staff member, the panel shall also provide that person with an opportunity to make submissions.

13. The panel may access any documents relating to the proposal. The panel may interview other parties, and seek internal and external expert advice, as it sees fit.

14. The President - HISSL will notify the complainant, the Chairperson and the applicant (if an allegation has been made against them) of the outcome of the investigation. The outcomes may include:
 - The complaint/concern is dismissed;
 - The President-HISSL directs appropriate action to be taken to resolve the complaint.

Reference Number:	SOP 016
Date:	April 2016
Subject:	Complaints concerning the ERC's review process
Purpose:	To describe the procedure for receiving and handling concerns or complaints from applicant about the ERC's review process

1. Any concern or complaint about the ERC's review process should be directed to the attention of the Chairperson of the ERC, detailing in writing the grounds of the concern or complaint. Complaints may also be made to the President-HISSL.
2. The Chairperson will inform the President - HISSL as soon as possible of any complaints received by him/her. The President will inform the Chairperson as soon as possible of any complaints received by him/her. The President will send a letter of acknowledgement to the complainant, outlining the following mechanism.
3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the ERC on the appropriate course of action at its next meeting.
4. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the President –HISSL or his/her nominee, or request that the Chairperson do so.
5. The Chairperson of the ERC will provide the President -with all relevant information about the complaint/concern, including:
 - the complaint;
 - material reviewed in the Chairperson's investigation;
 - the results of the Chairperson's investigation; and
 - any other relevant documentation.
6. The President-HISSL will determine whether there is to be a further investigation of the complaint.
7. If the President determines there is to be a further investigation, then he/she will establish a panel to consider the complaint/concern. Where there is to be no further investigation, the President will inform the application and the Chairperson of this.
8. The panel will include, at least, the following members:
 - The President-HISSL or his/her nominee, as convenor of the panel.
 - Two nominees of the HISSL President (not members of the ERC).

9. The panel will afford the ERC and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the proposal. The panel may interview other parties, including internal and external expert advice. In conducting its review, the panel shall be concerned with ascertaining whether the ERC acted in accordance with the FERCSL Guidelines, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or biased manner.
11. The President –HISSL -will notify the complainant and the ERC of the outcome of the investigation. The outcomes of this process may include:
 - The complaint/concern is dismissed.
 - The complaint/concern is referred back to the ERC for consideration, bearing in mind the findings of the panel.
12. The panel may also make recommendations about the operation of the ERC including such actions as:
 - a review of the Terms of Reference and Standard Operating Procedures;
 - a review of the ERC’s membership;
 - other such action, as appropriate.

Reference Number:	SOP 017
Date:	April 2016
Subject:	Complaints concerning the ERC's rejection of an application
Purpose:	To describe the procedure for receiving and handling complaints from applicant about the ERC's rejection of an application

1. An applicant with a concern or complaint about the ERC's rejection of his/her application should detail the grounds of the concern or complaint in writing and bring it to the attention of the Chairperson of the ERC. Complaints may also be made to the President-HISSL.
2. The Chairperson will bring to the attention of the President-HISSL as soon as possible any complaints received by him/her. The President-HISSL will inform the Chairperson as soon as possible of any complaints received by him/her. The President-HISSL will send a letter of acknowledgement to the complainant, outlining the following mechanism.
3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the ERC on the appropriate course of action. This investigation shall take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
4. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the President-HISSL or his/her nominee, or request that the Chairperson do so.
5. The Chairperson of the ERC will provide the President-HISSL with all relevant information about the complaint, including:
 - the complaint;
 - material reviewed in the Chairperson's investigation;
 - the results of the Chairperson's investigation; and
 - any other relevant documentation.
6. The President-HISSL will determine whether there is to be a further investigation of the complaint.
7. If the President-HISSL determines there is a case to be investigated, then he/she will establish a panel to consider the complaint.
8. The panel will include, at least, the following members:
 - The President-HISSL or his/her nominee, as convenor of the panel;

- Two nominees of the President-HISSL (not members of the ERC);
 - An expert or experts in the discipline of information system of the proposal under consideration.
9. The panel will afford the ERC and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the proposal. The panel may interview other parties, and seek any other internal and/or external expert advice.
11. The President-HISSL will notify the complainant and the ERC of the outcome of the investigation. The outcomes of this process may include:
- The complaint/concern is dismissed.
 - The complaint/concern is referred back to the ERC for consideration, bearing in mind the findings of the panel.
 - The application may be referred for external review by an independent ERC if the President-HISSL concludes that due process has not been followed by the ERC in reaching its decision.
12. Should the ERC be requested to review its decision, then the outcome of this review by the ERC will be final.
13. The panel or President-HISSL cannot substitute its approval for the approval of the ERC.

Reference Number:	SOP 018
Date:	April 2016
Subject:	Record keeping
Purpose:	To describe the procedure for the preparation and maintenance of records of the ERC's activities

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

2. The designated official 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:
 - the unique proposal identification number;
 - the applicant(s);
 - the name of the responsible institution or organisation;
 - the title of the proposal;
 - the ethical approval or non-approval with date;
 - the approval or non-approval of any changes to the proposal;
 - the terms and conditions, if any, of approval of the proposal;
 - whether approval was by expedited review; and
 - action taken by the ERC to monitor the conduct of the information system.

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

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

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 or via confidential disposal bins. Members who do not have access to secure disposal should leave their documents in the ERC Office for disposal.

5. Data pertaining to health related information systems shall be held for sufficient time to allow for future reference. Files which are no longer required for retention shall be electronically archived. Retention periods shall comply with relevant national guidelines and the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).

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

Reference Number:	SOP 19
Date:	April 2016
Subject:	Handling of conflicts of interest of members
Purpose:	To describe the procedure for the handling of conflicts of interest of ERC members

1. A ERC member shall, as soon as practicable during the ERC meeting, inform the Chairperson if he/she has a conflict of interest, financial or otherwise, in a proposal or other related matter(s) to be considered by the ERC.
2. The ERC will determine if this results in a conflict of interest for the member and, if so, the member will withdraw from the meeting until the ERC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on proposal.
3. All declarations of conflict of interest and the absence of the member concerned will be minuted.

Reference Number:	SOP 20
Date:	April 2016
Subject:	ERC reporting requirements
Purpose:	To describe the reporting requirements of the ERC

1. The minutes of each ERC meeting will be forwarded to the HISSL Council via the President-HISSL.

2. The ERC shall provide an annual report to the HISSL Council via the President-HISSL at the end of each calendar year on its progress, including:
 - membership/membership changes;
 - number of meetings;
 - number of proposals reviewed, approved and rejected;
 - monitoring procedures for ethical aspects of information systems in progress and any problems encountered by the ERC in undertaking its monitoring role;
 - description of any complaints received and their outcome;
 - description of any information system where ethical approval has been withdrawn and the reasons for withdrawal of approval; and
 - general issues raised.

3. The ERC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the website.

Reference Number:	SOP 21
Date:	April 2016
Subject:	Review of Standard Operating Procedures and Terms of Reference
Purpose:	To describe the procedure for the approval of amendments to the ERC Standard Operating Procedures and Terms of Reference

1. The Terms of Reference and Standard Operating Procedures shall be reviewed at least every two years and amended as necessary.
2. The Terms of Reference and Standard Operating Procedures may be amended by following the procedure below:

For those proposals made by a ERC member:

- The proposal must be in writing and circulated to all ERC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the ERC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his/her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the President-HISSL for review and approval, if appropriate.

For those proposals made by the President-HISSL and HISSL Council:

- The President-HISSL will send the proposal to the ERC and seek the views of any relevant person.

Annexures

ANNEXURE A: STANDARD LETTER FOR ERC OF ACKNOWLEDGEMENT OF NEW APPLICATION

[ERC LETTERHEAD]

REFERENCE: «Protocol_No»

«Date»

«Name_and_Address»

«Salutation»,

Re: Protocol No «Protocol_No» - “«Protocol_Title”

Thank you for submitting the above proposal. The proposal has been assigned the protocol number stated above.

It will be considered by the Ethics Review Committee at its meeting on «Date_of_Meeting». The principal reviewer to whom this proposal has been assigned may contact you in due course if any clarifications; additional documentation; or revision are required.

Yours sincerely,

«name»

Secretary

Ethics Review Committee

ANNEXURE B - STANDARD LETTERS FOR ERC APPROVAL OF NEW APPLICATION

This should include at least the following pieces of information:

- title of proposal;
- name of the applicant(s);
- unique ERC proposal identification number;
- the version number and date of all documentation reviewed and approved by the ERC including Clinical Protocols, Patient Information Sheets, Consent Forms, Advertisements, Questionnaires, etc;
- date of ERC meeting at which the proposal was first considered;
- date of ERC approval;
- duration of ERC approval;
- conditions of ERC approval, if any; and
- if the information system is being designed developed and/or implemented by an external organisation (if it is in the ERC's TOR to provide ethical review for that external organisation) a statement that approval of this proposal does not have the effect of conferring any insurance or indemnity coverage on the external organisation by the Health Informatics Society of Sri Lanka in relation to the proposal, and responsibility for any liabilities arising from the conduct of the proposal remains entirely with the external organisation.

[ERC LETTERHEAD]

REFERENCE: «Protocol_No»

«Date»

«Name_and_Address»

«Salutation»,

Re: Protocol No «Protocol_No» - “«Protocol_Title”

Thank you for submitting the above proposal, which was considered by the Ethics Review Committee, at its meeting of «Date_of_Meeting». Approval is granted to proceed.

This approval relates to the following:

- «insert details of approved documents»

The following members of the ERC were present at the meeting

«insert list of names with designations»

You are asked to note the following:

- This approval is valid for << >> years, and the Committee requires that you furnish it with «period» monthly reports on the progress beginning in «Report_Due».
- This approval relates only -to the ethical content of the information system, and you are responsible for the following:
 - negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved,
 - if appropriate, informing the sponsor that the membership and procedures of the Health Informatics Society of Sri Lanka Ethics Review Committee comply with appropriate guidelines of the Forum of Ethics Review Committees in Sri Lanka.

Yours sincerely,

«name»

Chairperson

Ethics Review Committee

ANNEXURE C - STANDARD LETTERS FOR ERC APPROVAL OF AMENDMENT

This should include at least the following pieces of information:

- title of proposal;
- name of the applicant(s);
- unique ERC proposal identification number;
- the version number and date of all documentation reviewed and approved by the ERC including Clinical Protocols, Patient Information Sheets, Consent Forms, Advertisements, Questionnaires, etc;
- date of ERC meeting (or Executive Meeting) at which the amendment and/or request for extension was first considered;
- date of ERC approval; and
- conditions of ERC approval, if any.

[ERC LETTERHEAD]

REFERENCE: «Protocol_No»

«Date»

«Name_and_Address»

«Salutation»,

Re: Protocol No «Protocol_No» - “«Protocol_Title”

The Ethics Review Committee, at its meeting of «Date_of_Meeting», considered «Correspondence_From» correspondence of «Date_of_Correspondence» and gave its approval for the project to proceed.

This approval is subject to the following: *...delete.if.not.applicable*

- [insert details of amendment]

In order for your response to be presented at the next Ethics Review Committee meeting, your acceptance of these conditions should be forwarded to the ERC Office by «Date» *...delete.if.not.applicable*

This approval relates to the following:

- [insert details of amendment]
- [insert details of other approved documents]

Yours sincerely,

«name»

Chairperson

Ethics Review Committee

ANNEXURE D - STANDARD LETTER FOR ERC REQUEST FOR ADDITIONAL INFORMATION

[ERC LETTERHEAD]

REFERENCE: «Protocol_No»

«Date»

«Name_and_Address»

«Salutation»

Re: Protocol No «Protocol_No» - “«Protocol_Title”

Thank you for submitting the above proposal, which was considered by the Ethics Review Committee, at its meeting of «Date_of_Meeting». The following additional information is requested: «insert text from minutes».

You are reminded that you may not commence this study until final approval has been granted.

You are asked to highlight the changes made to documents to assist the Committee’s checking of the amended documents. ...*delete.if.not.applicable*

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

Yours sincerely,

«name»

Chairperson

Ethics Review Committee

ANNEXURE E - STANDARD LETTER FOR ERC REJECTION OF NEW APPLICATION

[ERC LETTERHEAD]

REFERENCE: «Protocol_No»

«date»

«Name_and_Address»

«Salutation»

Re: Protocol No «Protocol_No» - “«Protocol_Title”

Thank you for submitting the above proposal which was first considered by the Ethics Review Committee at its meeting on «date». The Committee is a duly constituted ethics review committee on health related information system which operates in accordance with the relevant guidelines of the Forum of Ethics Review Committees in Sri Lanka.

The Committee has decided not to approve your proposal for the following reasons:

1. [List each reason separately. Each reason must refer to the relevant paragraph/s of the FERCSL Guidelines, relevant legislation or other applicable guidelines].

Should you wish to discuss the ERC’s review of your proposal, please contact me (on the telephone number or email address listed above) or the Chairman, «name», on «details».

Yours sincerely,

«name»

Chairperson

Ethics Review Committee

ANNEXURE F - STANDARD LETTER FOR EXPEDITED ERC APPROVAL OF NEW APPLICATION

[ERC LETTERHEAD]

REFERENCE: «Protocol_No»

«date»

«Name_and_Address»

«Salutation»

Re: Protocol No «Protocol_No» - “«Protocol_Title”

Thank you for submitting the above proposal, which was considered by the Executive of the Ethics Review Committee, at its meeting of «Date_of_Meeting».

Approval is granted to proceed. It is anticipated that this approval will be ratified by the Ethics Review Committee at its meeting on «Date_of_Meeting».

This approval relates to the following:

- [insert details of approved documents]

You are asked to note the following:

- This approval is valid for one year, and the Committee requires that you furnish it with «period» reports on the progress beginning in «Report_Due».
- This approval relates only to the ethical content of the information system, and you are responsible for the following:
 - negotiating individual arrangements with the Heads of service departments in those situations where the use of their resources is involved,
 - if appropriate, informing the sponsor that the membership and procedures of the Health Informatics Society of Sri Lanka Ethics Review Committee comply with appropriate guidelines of the Forum of Ethics Review Committees in Sri Lanka.

Yours sincerely,

«name»

Chairperson

Ethics Review Committee

ANNEXURE G - STANDARD REQUIREMENTS FOR REPORTING OF SERIOUS AND UNEXPECTED ADVERSE EVENTS

[LETTERHEAD]

[Date]

«name»

Secretary

Ethics Review Committee,

Faculty of Medicine,

University of Colombo,

Kynsey Road,

Colombo 00800,

Re: Notification of Serious Adverse Event

Please bring the enclosed serious adverse event report to the attention of the Ethics Review Committee.

ERC Protocol No:

Sponsor Protocol No:

SAE Identification Number:

Patient: No Yes

Description of SAE:

Study Drug/Device:

Relationship to Study Drug: Unlikely Possible Probable Definite

Requires alteration to:

- Information for Participants: No Yes (if yes, revised copy attached)
- Participant Consent Form: No Yes (if yes, revised copy attached)
- Protocol: No Yes if yes, revised copy attached)

Chief Investigator's Comments:

Yours sincerely

«name»

Chief Investigator

REVISION HISTORY

Verson 0.1 –

Version 0.2 -