

Instructions to Applicants

PLEASE NOTE THAT SLMA ERC WILL NOT ACCEPT APPLICATIONS FOR RESEARCH CONDUCTED IN INSTITUTIONS WHERE THERE IS AN ERC RECOGNISED BY CTEC, NMRA, SRI LANKA.

The ERC's recognized by the Ministry of Health, Sri Lanka can be found at

<http://www.nmra.gov.lk/images/PDF/guideline/Guideline-for-the-conduct-of-Clinical-Trials-in-Sri-Lanka.pdf>

Please read this carefully to ensure that your application is properly filled, the relevant documents are correctly prepared as this would minimize delays in evaluating your application.

1. Badly planned and poorly designed research that causes inconvenience to participants with possible risks will not produce useful or valid results and is considered to be unethical. It is the responsibility of the principal researcher to ensure that his / her research is of good scientific quality before making an application for ethics review.
2. The ERC may return the application if it is flawed in research methodology and fails to demonstrate adequate scientific rigor.
3. Applicants must prepare the information sheets and consent forms to include all relevant information.

Guidance can be obtained from

https://www.who.int/ethics/review-committee/informed_consent/en/

Please download a soft copy (e-copy) of the application form from <https://slma.lk/erc/> or request SLMA office to email it to you.

4. Please ensure that ALL documents have a version number/date and a page number in the footer/header. This is applicable for submission of revisions.
5. Please note that all communications by the ERC, SLMA will be exclusively with the Principal Investigator.

6. Please allow a minimum of 2 months for initial processing.

In the event that the application is sent to External Experts, the processing time may be longer.

7. Filling an application form

- a. The current version of the application form (**ERC/SLMA Application Form – Human studies (Version 4.0 January 2021)**) is available at the SLMA office or is downloadable from <https://slma.lk/erc/>
- b. Please obtain an electronic copy of it and type in all relevant information.
- c. All research proposals must be submitted on the prescribed application form.
- d. The application form must be typed with word processing software such as MS Word. The cages are expandable as you type.
- e. The application form should be completely filled, giving pertinent information according to instructions given.
- f. Ensure that contact details of applicant, co-investigators and supervisors are current and accurate to avoid delays.
- g. Please do not leave any sections blank and indicate as 'not applicable' any questions that are not relevant.
- h. The relevant section/s and page numbers on the proposal must be clearly indicated in the application form as required
- i. Applications and all other relevant documents including translations must be typed and handwritten applications/forms will not be accepted.
- j. Once filled, the applicant and all other co-investigators must sign the hard copy of the application form.
- k. If the principal investigator is from overseas, e-signatures may be used on the application. However, one hard copy must be sent via post with the original signature.

8 Documents to be submitted

- Duly filled **application form, checklist, and all relevant documents.**
- One copy of each of the following
- Covering letter signed by the applicant

Letter from supervisor (if relevant)

Curriculum Vitae of Principal Investigator

Permission letter from the institution/hospital to conduct the study
(Example: Permission from the Hospital Director/ Medical Superintendent if the study is conducted at a hospital)

- **One (1) copy of the application form** duly filled and signed
- **One (1) copy** of the following documents **must be stapled and bound together**
 - i. The proposal - Postgraduate students must submit a copy identical to that approved by the board of study
 - ii. Please note that all postgraduate student projects must have approval from their respective Boards of Study BEFORE submitting the application.
 - iii. Study instruments in English and Sinhala and Tamil translations where relevant e.g. questionnaires, focus group guides etc
 - iv. Information sheet in English and Sinhala and Tamil translations where relevant Consent forms in English and Sinhala and Tamil translations where relevant
 - v. Assent forms in English and Sinhala and Tamil translations where relevant Advertisement for recruitment and Sinhala and Tamil translations where relevant.
 - vi. All points in documents should be numbered and bullets should be avoided.
 - vii. Email a complete set of all documents submitted (include one copy of your application, protocol, instruments and forms in all languages) **as individual PDF files** to **erc.slma@gmail.com** at the time of submission.
- Large files which cannot be attached to an email may be compressed using ZIP or RAR formats only.

- The documents should be named in the following manner. Please indicate the total number of files in the body of the email as per the serial numbers.

Name of the serial number_document_version_language_date

Example:

1_Proposal_version_3_03.03.2020

2_Information_sheet_tamil_version_3_03.03.2020

3_Questionnaire_english_version_2_03.03.2020

4_CV_PI_Perera_U

5_CV_CoI_Ganage_N

6_Payment

9. Collaborative international research

- There should be at least one co-investigator who is a citizen of Sri Lanka in research where the principal investigator is not a citizen to ensure co-ordination and adherence to procedures in Sri Lanka.
- The applicant representing Sri Lanka should obtain ethical clearance from a recognized ethical review committee in Sri Lanka.
- The applicants should follow the routine application procedure as described in this document.
- The applicant should attach copies of the relevant documents if ethical clearance has been obtained in another country.

10. Submission process

- Principal Investigator/Applicant should pay the appropriate processing fee as stipulated in the Application Form to Sri Lanka Medical Association office.
- Alternatively, Principal Investigator/Applicant can make an online payment as mentioned below and send the payment slip along with the application form

Account name: Sri Lanka Medical Association Bank: Hatton National Bank

Account Number: 076010001669

Branch: Cinnamon Gardens Branch

Bank Address: HNB PLC, Cinnamon Gardens Branch, No 85 & 87, Barnes Place, Colombo 7

SWIFT code: HBLILKLX001

Please state ERC PAYMENT as details

The processing fees are as follows:

For evaluation of an initial submission of a protocol

Category	Fees
Self-funded	3000.00
Local funding agencies such as NSF, UGC	LKR 10,000
Foreign funding agencies such as WHO, ADB, JICA, World Bank	LKR 25,000
Industry sponsored trials – (excluding Phase 2 & 3 clinical trials)	LKR 25,000
Phase 2-4 multi centre clinical trials	USD 1,000

For evaluation of major amendments to protocols already approved which needs a full board review

- For research that is self-funded – Rs 1500.00
- For research funded by local funding agencies such as NSF, UGC etc. – Rs 5,000.00
- For research funded by foreign funding agencies such as WHO, ADB, JICA, world bank - Rs 12,500.00
- Industry sponsored trials (excluding Phase 2 & 3 clinical trials) – Rs 12,500.00
- Phase 2-4 multi centre clinical trials – USD 500

Opening hours for submission

- ERC Office is located at the Sri Lanka Medical Association, No 6, Wijerama Mawatha, Colombo 7
- Opening hours: Monday to Friday - 8.30 am to 3.30 pm.

11. Submission deadline and meeting dates

- The ERC, SLMA meets **every third Friday of the month.**
- Duly completed applications should be submitted on the **last working date of the current month (before 3 pm)**, to be taken up at the next scheduled meeting.