

## Instructions to Applicants

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

**The REC's recognised 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 completed and that the relevant documents are correctly prepared. This will minimise delays in evaluating your application.**

1. Poorly planned and designed research that causes inconvenience and possible risks to participants will not yield useful or valid results and is deemed unethical. The principal researcher is responsible for ensuring that their research meets high scientific standards before applying for an ethics review.
2. The REC may return the application if it is flawed in its research methodology and fails to demonstrate sufficient 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/](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 that the SLMA office email it to you.

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

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

If the application is sent to External Experts, the processing time may be longer.

## **7. Filling out an application form**

- a. The current version of the application form (**REC/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 using the prescribed application form.
- d. The application form must be typed using word processing software such as MS Word. The cages are expandable as you type.
- e. The application form should be filled out, giving pertinent information according to the instructions provided.
- f. Ensure that the contact details of the 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 located overseas, e-signatures may be utilised on the application. However, a hard copy with the original signature must be sent via post.

## 8. Documents to be submitted

- Duly filled **application form, checklist, and all relevant documents.**
- One copy of each of the following
- A 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

Documents that do not adhere to the above format will be returned to the PI, resulting in delays.

## **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 coordination and adherence to procedures in Sri Lanka.
- The applicant representing Sri Lanka should obtain ethical clearance from a recognised 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**

- The Principal Investigator/Applicant should pay the appropriate processing fee as stipulated in the Application Form to the Sri Lanka Medical Association office.
- Alternatively, the 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 the evaluation of an initial submission of a protocol**

Category	Fees
Self-funded	5000.00
Local funding agencies such as NSF, UGC	LKR 15,000
Foreign funding agencies such as WHO, ADB, JICA, World Bank	LKR 50,000
Industry sponsored trials – (excluding Phase 2 & 3 clinical trials)	LKR 100,000
Phase 2-4 multi centre clinical trials	USD 1,000

**For evaluation of major amendments to protocols already approved which need 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**

- REC 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 REC, SLMA meets **every third Friday of the month.**
- Duly completed applications should be submitted on the **last working day of the current month (before 3 p.m.)**. They will be discussed at the next scheduled meeting.