

## 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://nmra.gov.lk/images/PDF/guideline/clinical\\_trial\\_guidelines\\_Jan2019.pdf](http://nmra.gov.lk/images/PDF/guideline/clinical_trial_guidelines_Jan2019.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 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 [http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/)
4. **Please download a soft copy (e-copy) of the application form from <http://slmaerc.info/index.php> or request SLMA office to email it to you.**
5. **Please ensure that ALL documents have a version number/date and a page number in the footer/header.**
6. **Please note that all communications by the ERC, SLMA will be exclusively with the Principal Investigator.**
7. Please allow a minimum of 2 months for processing.
8. **Filling an application form**
  - a. The current version of the application form (Version 5 of March 2015) is available at the SLMA office or is downloadable from <http://slmaerc.info/index.php>  
**Please obtain an electronic copy of it and type in all relevant information.**
  - b. All research proposals must be submitted on the prescribed application form.
  - c. The application form must be typed with word processing software such as MS Word. The cages are expandable as you type.
  - d. The application form should be completely filled, giving pertinent information according to instructions given.
  - e. Ensure that contact details of applicant, co-investigators and supervisors are current and accurate to avoid delays.
  - f. Please **do not leave any sections blank** and indicate as 'not applicable' any questions that are not relevant.
  - g. The relevant section/s and page numbers on the proposal must be clearly indicated in the application form as required.

- h. Applications and all other relevant documents including translations **must** be typed and **hand written applications/forms will not be accepted.**
- i. Once filled, **the applicant and all other co-investigators must sign the hard copy of the application form.**
- j. 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.

**Documents to be submitted**

- o Duly filled **application form, checklist and all relevant documents.**
- o One copy of each of the following
  1. Covering letter signed by the applicant
  2. Letter from supervisor (if relevant)
  3. Curriculum Vitae of Principal Investigator
- o **Four (4) copies of the application form** duly filled and signed
- o **Four (4) copies** of the following documents **must be stapled and bound together**
  - The proposal - Postgraduate students must submit a copy identical to that approved by the board of study  
Please note that all postgraduate student projects must have approval from their respective Boards of Study **BEFORE** submitting the application.
  - Study instruments in English and Sinhala and Tamil translations where relevant e.g. questionnaires, focus group guides etc
  - Information sheet in English and Sinhala and Tamil translations where relevant
  - Consent forms in English and Sinhala and Tamil translations where relevant
  - Assent forms in English and Sinhala and Tamil translations where relevant
  - Advertisement for recruitment and Sinhala and Tamil translations where relevant.
- o Email a complete set of all documents submitted (include one copy of your application, protocol, instruments and forms in all languages) **as .pdf files** to <erc.slma@gmail.com> at the time of submission.
- **Submission process**
  - o Principal Investigator/Applicant should pay the appropriate processing fee as stipulated in the Application Form to Sri Lanka Medical Association office.
  - o The processing fees are as follows:

**For evaluation of an initial submission of a protocol**

- For research that is self-funded – Rs 3000/-
- For research funded by funding agencies such as NSF, JICA, UGC, WHO etc. – Rs 10,000/-
- Industry sponsored trials (excluding Phase 2 & 3 clinical trials) – Rs 25,000/-
- Phase 2-4 multi centre clinical trials – USD 1000

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

- For research that is self-funded – Rs 1500/-
- For research funded by funding agencies such as NSF, JICA, UGC, WHO etc. – Rs 5,000/-

- Industry sponsored trials (excluding Phase 2 & 3 clinical trials ) – Rs 12,500/-
- 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.

## **5. Submission dead line and meeting dates**

- o The ERC, SLMA meets **every third Friday of the month**.
- o 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.