



Guidelines for submitting proposals to ERC of Faculty of Health-Care Science, Eastern University Sri Lanka

1. List of items to be submitted

- 1.1. Two (2) hard copies of project proposal in separate files (This should include protocol, Participant information sheet, Informed consent form and Questionnaires)
- 1.2. One (1) hardcopy of application form
- 1.3. 08 hard copies of single paged summary with title of the proposal
- 1.4. Payment receipt [if none of the investigators are from Eastern University Sri Lanka (EUSL) or an extended faculty]
- 1.5. Approval letter from the relevant institution where research will be conducted (If any)
- 1.6. Approval letter from the relevant postgraduate institution (for Postgraduate degrees)
- 1.7. Supervisor's letter (for Postgraduate degrees)

2. For clinical trials

- 2.1 Investigator brochure
- 2.2 Clinical record forms
- 2.3 In case of multi centered studies, listing of overseas centre(s) and ERC/IRB approval status if relevant and copies of ERC/IB approval letters from other centers
- 2.4 Principle investigators' / coordinating PI's curriculum vitae
- 2.5 Product liability letter or insurance certificate
- 2.6 Patient recruitment procedures
- 2.7 Patient's diary cards (if required in non-clinical trial proposals as well)
- 2.8 Justification for use of placebo (if any)
- 2.9 Required processing fee

3. Proposal from undergraduate of FHCS

- 3.1. Two (2) hard copies of project proposal in separate files
- 3.2. One (1) hard copy of application form including supervisors' signature
- 3.3. 08 hard copies of single paged summary with title of the proposal

4. Resubmissions and amendments

- 4.1. Resubmissions
 - Period of resubmission is **one month from the date of notification.**
 - One hard copy of corrected proposal (highlight changes) with a covering letter and the letter issued by ERC should be submitted.
 - It will be directed to the same reviewers.



4.2. Amendments

- Approval for any changes in the proposals which already approved should be submitted with 2 hard copies (highlight amendments) with a covering letter and the letter of approval issued by ERC. Please mention the proposal and version number and date in each page.

5. The fees levied as processing charges of individual research applications

1. The fees levied for non-institutional members for processing of non-industry sponsored research is Rs. 3000/=.
2. The fees levied for undergraduate (Non EU SL) or post graduate degree research is Rs. 2500/=
3. The fees levied for non Sri Lankan or industry sponsored intervention studies irrespective of affiliation of the investigators is Rs 10000/=.
4. The fees levied for reviewing amendments for industry sponsored intervention studies irrespective of affiliation of the investigators is Rs 2500/=.

6. Submission of documents

Project proposals are accepted on working days of Faculty of Health-Care Science, Eastern University Sri Lanka at Dept. of Medical Education and Research.

7. The approval

Ethic Review Committee meet will be held on every 2nd or 3rd Tuesday of each month. Proposals which are submitted before the 30th of each month 3.00 pm will be directed to reviewers and approved on meeting in subsequent month, proposals which are submitted after 30th of a month will be discussed in next ERC meeting.

If there are any deficiencies in the submitting documents those proposals will be directed to the authors at the end of the month and submitted to the reviewers only after completion of the documents in following month.

If proposal is approved the committee will inform the investigators through post (If self-addressed envelope with stamps for registered post is attached with the application form). Otherwise response letter can be collected from the Department of Medical Education and Research one week after the meeting.

If there is any inquiry contact Secretary, ERC, Department of Medical Education and Research, Faculty of Health-Care Sciences, Eastern University, Sri Lanka, 50, New Road, Batticaloa. Telephone 0652227026