



**Ethics review committee**  
**Faculty of medicine, Wayamba University of Sri Lanka**

**Guidelines for submitting protocols.**

**1. List of items to be submitted.**

- 1.1. Four (4) hard copies of project proposal in separate files
- 1.2. One (1) hard copy of application form
- 1.3. Fifteen hard copies of single paged summary of your protocol
- 1.4. Payment receipt – unless exempted from the administrative fee
- 1.5. Approval letter from the relevant postgraduate institution (for Postgraduate degrees)
- 1.6. Supervisor's letter (for Postgraduate degrees)
- 1.7. A CD with PDF formats of,
  - Application form
  - Protocol and other documents

**2. For clinical trials**

- 2.1 Investigator brochure
- 2.2 Clinical record forms
- 2.3 In case of multi centre studies, list of overseas centre (s) and ERC/IRB approval status and copies of ERC/IB approval letters from other centers
- 2.4 Principal 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
- 2.9 Payment receipt of the administrative fee

**3. Undergraduate proposals**

- 3.1. Three (3) hard copies of project proposal in separate bundles
- 3.2. One (1) hard copy of application form including supervisor's signature

## **4. Resubmissions and amendments**

### **4.1. Resubmissions**

- Four hard copies of corrected protocol, highlight changes should be submitted along with a covering letter. The letter issued by ERC informing the previous ERC decision should be submitted. A soft copy should be submitted in a CD (in PDF format).

### **4.2. Amendments**

- Approval for proposal changes for already approved proposals should be submitted with 4 hard copies (highlight amendments) with a covering letter and the letter of approval issued by ERC. Please mention the protocol and version number and date in each page.
- A soft copy should be submitted in a CD (in PDF format)

## **5. The fees levied as administrative charges for research applications,**

The following fee structure will be applicable to proposals submitted for review. The Payment has to be made to the accounts branch of Faculty of medicine, Wayamba University of Sri Lanka. The receipt should be attached to the application form.

1. The fees levied for non-institutional members for processing of non-industry sponsored research is Rs. 1000/=.
2. The fees levied for post graduate degree research is Rs. 2500/=.
3. The fees levied for industry sponsored intervention studies irrespective of affiliation of the investigators is US\$ 1000/=.
4. The fees levied for reviewing amendments for industry sponsored intervention studies irrespective of affiliation of the investigators is US\$ 250/

## **6. Submission of documents**

All types of project proposals are accepted on working days at the ERC office of Faculty of Medicine, Wayamba University of Sri Lanka. Proposals submitted before 12 noon on 30<sup>th</sup> of each month, will be forwarded to the reviewers to be considered at the next ERC meeting.

## **7. The approval**

Ethic reviewing meeting will be held on every 2nd or 3rd Tuesday of each month. Decisions on proposals will be informed to the investigators. Incomplete proposals will be returned back to the authors.

