



Ethics Review Committee

Faculty of Medicine, Wayamba University of Sri Lanka

Guidelines for writing protocols to ERC of Faculty of Medicine, Wayamba University of Sri Lanka.

1. The “Introduction” and “Justification” should be limited to one page of the protocol.
2. Four hard copies of project proposal in separate bundles. Each bundle should include following:
 - Questionnaire (in English, if relevant-Sinhalese/Tamil)
 - Consent form (in English, if relevant-Sinhalese/Tamil)
 - Patient Information Sheet (in English, if relevant-Sinhalese/Tamil)
3. One hard copy of the application form signed by all investigator and supervisors (when relevant)
4. Summary of a proposal (15 copies) of no more than one page (300 words) is required.

The summary must be arranged in the following sequence:

Title

Objective

Study design

Study setting

Study population

Definition of intervention/main exposure variable

Definition of primary outcome

Sample size

Data collection method

Proposed data analysis

Main ethical issues

5. The version of the Protocol, Questionnaires, Patient Information Sheet and Consent Form should be stated separately and clearly, with the relevant date in all submissions at the left upper corner each page. (e.g., Prevalence of diabetes in Gampaha District, Version 01 Dated 15 Jan 2013; Patient Information Sheet, Version 01 Dated 15 Jan 2013)
6. All proposals should be typed, single-spaced, with ‘Times New Roman’ font - size 12. The top, bottom and side margins should be 25 mm. All pages should be numbered consecutively at the bottom right-hand corner.
7. Apart from one hard copy, all other documents should not contain names of the investigator/s.