

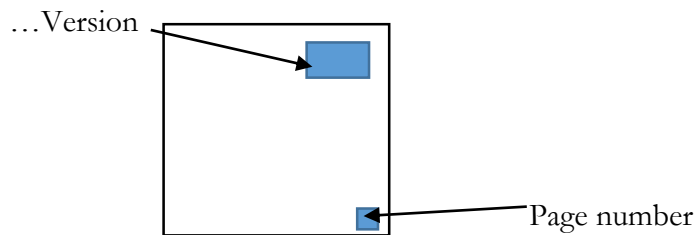
**UNIVERSITY OF KELANIYA- GUIDELINES FOR WRITING PROTOCOLS**

**GUIDELINES FOR WRITING PROTOCOLS TO ETHICS REVIEW COMMITTEE**

**UNIVERSITY OF KELANIYA**

The protocol should have following documents/information. Three copies must be submitted with the application. **If you are filling Annexure 1 for research involving animals or Annexure II involving humans, don't include this document.**

1. The "Introduction" and the "Justification" should be limited to one page of the protocol.
2. Following documents
  - I. Questionnaire (if applicable) in Sinhala/English/Tamil<sup>1</sup>
  - II. Informed Consent Form in Sinhala/English/Tamil<sup>2</sup>
  - III. Participant Information sheet in Sinhala/English/Tamil<sup>3</sup>
3. Summary of the proposal (3 copies) of no more than one page (300 words). Your project summary must include the following and provide with the given sequence;
  - I Title
  - II Objective
  - III Study Design
  - IV Study setting
  - V Study population
  - VI Sample size
  - VII Method of data collection
  - VIII Proposed data analysis
  - IX Main ethical issues
5. Version of the protocol, questionnaire, Participant information sheet, and the Consent form (i.e. if you are submitting for the first time, it is identified as the 1<sup>st</sup> version, whereas the current submission is you revised version and submitted for the second time, it is named as the 2<sup>nd</sup> version) must be indicated on the top right hand corner of all your documents.



6. Protocol must be typed, single-spaced, in "Times New Roman" with 12 point, All margins must be of 1", and the page number must be indicated at the bottom right corner of each page.
7. Name of the investigator will be deleted from all documents to ensure the transparency of the review process.

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<sup>1</sup> Justifications should be provided if the Questionnaire is submitted only in one language

<sup>2</sup> Justifications should be provided if the Questionnaire is submitted only in one language

<sup>3</sup> Justifications should be provided if the Questionnaire is submitted only in one language