

## **Guidelines for the format of research protocol to be submitted to ERC, NIMH**

The researcher should follow key elements listed below in submitting research protocol:

1. Title
2. Investigators/ Collaborators /supervisors - with qualifications, designation, place of work/institute
3. Introduction/Background and Justification
4. Literature survey
5. Aims (objectives)
6. Methodology
  - 6.1 Study design
  - 6.2 Study setting
  - 6.3 Selection of subjects
    - 6.3.1 Study population & study unit (Inclusion and/or Exclusion criteria)
    - 6.3.2 Sample size -basis of calculation
    - 6.3.3 Sampling method - how to identify the sampling frame, method of selecting eligible subjects, clearly describe stratifications if relevant
  - 6.4 Variables
  - 6.5 Data collection methods and tools
    - 6.5.1 Adaptation and validation of tools if relevant
    - 6.5.2 Consent Forms and Information Sheet
  - 6.6 Data collectors/investigators
    - 6.6.1 Training & certification
  - 6.7 Data collection procedures
    - 6.7.1 Recruitment methods
    - 6.7.2 Logistics
  - 6.8 Data collection
  - 6.9 Data processing and analysis
7. Ethical issues
  - 7.1 Procedure for obtaining consent from subjects
    - 7.1.1 Procedure for obtaining the consent of minors /mental ill, if relevant
    - 7.1.2 Information sheet
    - 7.1.3 Consent forms
  - 7.2 Procedures for, administrative concurrence, where relevant
  - 7.3 Justify potential harm, risk, burden to subjects vs benefits of the study to the subject and the society at large
    - 7.3.1 Indicate if any incentives given,
    - 7.3.2 Whether investigators are at any risk,
  - 7.4 If an intervention study justify the safety /relevance
  - 7.5 Confidentiality/Privacy / dignity concerns, plans for data sheet storage

- 7.6 Arrangement to address problems identified in data collection
- 7.7 If limited to one ethnic group, justify
- 7.8 Conflict of interests, funding sources
- 8. Expected outcome of the study
- 9. Dissemination plans
- 10. Timeline and budget if applicable
- 11. References
  - Either BMJ Vancouver, Harvard Referencing or any other accepted style of referencing should be used with consistency throughout the protocol
    - BMJ Vancouver Style:  
<https://www.southampton.ac.uk/library/resources/documents/vancouverreferencing.pdf>
    - Harvard Referencing Style:  
[https://www.staffs.ac.uk/assets/harvard\\_quick\\_guide\\_tcm44-47797.pdf](https://www.staffs.ac.uk/assets/harvard_quick_guide_tcm44-47797.pdf)