**Full proposal protocol**

The researcher should submit an application in a prescribed format along with the **study protocol** that should include the following:

1. the protocol must have content page with corresponding page number
2. clear objective and rationale for the study
3. detail stepwise procedure of the study
4. precise description of the methodology including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any
5. inclusion and exclusion criteria for entry of subjects in the study
6. a description of the process used to obtain and document informed consent
7. a statement describing any compensation for study participants (including expenses and access to medical care) to be given to research participants.
8. a description of the ethical consideration such as any effect on physical, mental, social, environmental and program management in the research.
9. a description of the ethical consideration in subject recruitment procedure
10. expected outcomes
11. plans for publication of results while maintaining the privacy and confidentiality of the study subjects.
12. safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research
13. procedure for maintaining confidentiality.