

Full proposal

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

- a) the protocol must have content page with corresponding page number
- b) clear objective and rationale for the study
- c) detail stepwise procedure of the study
- d) precise description of the methodology including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any
- e) inclusion and exclusion criteria for entry of subjects in the study
- f) a description of the process used to obtain and document informed consent
- g) a statement describing any compensation for study participants (including expenses and access to medical care) to be given to research participants.
- h) a description of the ethical consideration such as any effect on physical, mental, social, environmental and program management in the research.
- i) a description of the ethical consideration in subject recruitment procedure
- j) plans for publication of results while maintaining the privacy and confidentiality of the study subjects.
- k) safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research
- l) procedure for maintaining confidentiality.