MNTRH-IREC GUIDELINES FOR WRITING PROJECT PROPOSALS

Research proposals submitted by investigators should contain sufficient information to allow MNTRH-IREC reviewers to determine whether the proposed research is scientifically justified and that it adheres to local and international guidelines on ethical conduct of research prior to approval.

1. **TITLE OF THE PROJECT:** This should be concise and not longer than 30 words
2. **INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS:** The investigator should include their Curriculum Vitae
3. **ABSTRACT:** It should provide a concise summary of the background, justification, objective, work planned, nature of results expected and their significance. This should be structured as one paragraph
4. **INTRODUCTION/BACKGROUND:** This section should provide historical and /or scientific background to the project proposal with literature citations. The literature cited should be listed at the end of the proposal document with the full names of the authors, title of the publication, the journal/book, the year and volume.
5. **JUSTIFICATION FOR THE STUDY:** This section should provide a short justification of the significance of the proposed research, emphasizing how the results will build into new knowledge in the proposed field, and why it will be important for National or International development.
6. **STATE THE NULL HYPOTHESIS:** Where applicable state the null hypothesis
7. **OBJECTIVES:**
    I. GENERAL OBJECTIVES: The main aim should be stated clearly.
    II. SPECIFIC OBJECTIVES: This section must clearly state achievable objectives. The objectives should be written in short concise statements each not consisting of more than two sentences. Specific objectives should not be more than 4.
8. **DESIGNS AND METHODOLOGY:**
    I. Geographical study site
    II. Study populations
        a. Criteria for inclusion of subjects
        b. Criteria for exclusion of subjects
        c. Rationale for animal use and justification for animal species chosen
    III. Sampling
        a. Sample size determination
        b. Sampling procedure
    IV. Procedures
        a. Description of the type of data to be collected and collection procedures to be followed

b. Provision for data verification and validation in the field and laboratory (where applicable)

The structure of this section depends on the specific nature of the study. In a clinical study, it should specify the study site, patient selection, inclusion and exclusion criteria, summary of procedures to be used etc. In a laboratory or field study, it should specify the study site, materials, procedures to be used etc. Instruments to be used in surveys, clinical studies, questionnaires, should be appropriately mentioned and copies of the instruments attached in the appendices. The Informed Consent Forms and Explanations should be attached in the appendices.

9. DATA MANAGEMENT

I. Data Storage
   a. Provision for database management incorporating how data will be stored before and after analysis
   b. Description of devices to be used for data storage e.g. type of computer, software to be used in data entry, checking and management

II. Data Management

III. Data Analysis: This section outlines the statistical techniques to be applied in the analysis to meet requirements of each of the specific objectives and hypothesis to be tested. This section should clearly describe how the data obtained will be processed, calculated or computed Software used should be specified.

10. TIME FRAME/DURATION OF THE PROJECT

I. Pilot study (where applicable)
II. Definitive study
III. Data analysis
IV. Report preparation

The total period planned for the project should be stated in months/ years, followed by a breakdown of each stage implementation.

11. ETHICAL CONSIDERATIONS

I. Human Subjects

The goals of human research often include understanding real-life phenomena, studying effective treatments, investigating behaviors, and improving lives in other ways. Key ethical considerations must guide human research.

These considerations work to

- protect the rights of research participants
- enhance research validity

- maintain scientific integrity

The following guidelines should be observed

a. First, do no Harm
b. Direct benefit to study subjects or community should exist.
c. Informed consent by subjects and/or community leaders including possible benefits, risks and inconveniences.
d. Indicate the method of maintaining confidentiality of information obtained during the study.
e. In case of new drug and/or procedures to be used on human subjects, any possible side effects, untoward reactions and results of previous use even in animals must be stated.

II. Animal Subjects

The guidelines below should be followed in all investigations involving animals:

a. Methods to minimize pain and distress must be specified
b. If applicable, a strong justification must be mad for not using proper drugs to alleviate pain and distress.
c. If applicable, the method of euthanasia should be specified.

12. EXPECTED APPLICATION OF THE RESULTS: This section summarizes the importance of expected results and their potential application.

13. REFERENCES

The literature citations should be provided in full detail, preferably using the numbering style, however, each reference cited in the project proposal must be listed giving: the names of the authors, the full title of the publication, volume if it is a serial or authors and publishers if a book.

14. BUDGET

This section is written in three parts

I. Budget Summary which outlines a list of major components of the budget
II. Detailed Budget which outlines a breakdown of each sub section of the budge summary. The total in I. and II. Should be the same.
III. Justification of the Budget: A short paragraph should give a justification for the items intended for the project and cost estimates given

15. APPENDICES

I. State the role of each participating investigator

II. Attach the relevant documents:
    a. Curriculum Vitae of the investigators
    b. Case record and data collection forms
    c. Informed Consent advise and forms