Ministry of Health and Social Welfare
Directorate of Health Planning and Statistics

Guidelines for Submitting a Research Proposal

Section 1. General

A. Submission

The investigator must submit the proposal to The Director General (DHS), Chairperson, Ethics Committee, Ministry of Health and Social Welfare (MOHSW).
The documents to be attached:

1. Forwarding letter
2. Curriculum vitae
3. The protocol for the research/ study
4. Approval of the concerned university or institute or organization (if relevant)

1. Forwarding letter

The letter must encompass the following:

- Title of study
- Purpose of the study (e.g. fulfillment of the Master of Science in Family Medicine; For the interest of the Garment Factory, As Part of Multi-country study from SADC)
- Signature of the PI

2. Curriculum Vitae

The Curriculum Vitae (brief) and contact address & numbers of the Principal Investigator (PI) must be mentioned.
The list of members of the study team must be attaché (if relevant).

3. The protocol for the research/ study

The protocol should generally be submitted in both a hard copy and electronic version. Studies that involve the use of questionnaires or guides for data collection should attach copies of the instrument as annexes. A basic outline for writing a research protocol is herewith mentioned. These are guidelines which should not necessarily be rigidly applied. How they are applied will depend on the type of study and the methodological approach of each study.

4. Approval of the concerned university or institute or organization (if applicable)

This is self explanatory.
If the approval process is on-going in the respective institute/organization, the investigator can submit the proposal to save time. However, it is necessary to mention in the forwarding that the approval will follow. The ethical committee (MOHSW) will start the review but will response only when the necessary documents are complete.

B. MOHSW process for ethical approval

The estimated duration for the ethical committee to assess a proposal is estimated to be one month from the date of submission for Descriptive/ Historical/ Comparative research and three months for Experimental/ Clinical research.

C. Enquiry/follow-up for the progress

The time for applicants/researchers to enquire for the progress of the ethical review process is one month after the date of submission at M & E and Research Unit, Directorate of Health Planning and Statistics (DHPS), First Floor MOHSW headquarters office.

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D. Basic outline of a research protocol

1. Title of the Research Project

2. Introduction
    a. Project Summary
    b. Statement of the Problem (scientific justification)
    c. Justification and Use of the Results (objectives, applicability)
    d. Theoretical Framework (justification, possible answers, hypothesis)
    e. Literature if relevant

3. Research Objectives (general and specific)

4. Research design and Methods
    a. Operational definitions
    b. Type of study and study design
    c. Study population, sample size and selection criteria,
    d. Unit of analysis
    e. Proposed intervention (if applicable)
    f. Data collection procedures, instruments used, quality control, confidentiality

5. Plan of Analysis

6. Model of proposed analysis, dummy tables Software

7. Limitations of Study

8. Ethical considerations with all required forms (English and local language)

9. Timetable

10. Budget (fully itemized and justified)

11. References

12. Annexes

Presentation of proposals may vary according to the style and preference of each investigator. However, the scientific community has agreed that all proposals should at least contain the problem statement, justification for the research, general and specific objectives, design and methodology, plan of analysis, timetable and budget.

Note: The content under sub-titles (1 to 12) must be for the particular research per se. It means that if the investigator wants to elaborate any definition or concept or reference for any sub-titles (e.g. study design, sampling, ethics), it is suggested to mention under the "Literature Review".

For details for each sub-title: refer to section 2.

Section 2. Terms and definitions

1. Title of the Research Project

A good title should be short, accurate, and concise. It should make the central objectives and variables of the study clear to the reader (reviewer). The title provides the key words for the initial classification and indexing of the project. If it is possible, without undue length, the title can give a preview of the protocol. It is important to specify what population to be investigated. For example: Effects of a programme for nutritional supplementation on malaria morbidity: Longitudinal study of children under 5 years in hyper-endemic area for malaria in Sudan.

2. Abstract or project summary

The project summary or abstract should give a clear idea to the reader of the central question that the research is intended to answer and its justification. It should specify the hypotheses (if applicable) and the research objectives. In addition, the abstract should briefly describe the methods and procedures to be used in the project.

3. Problem statement

This constitutes the scientific justification for the study; i.e., the basis of the need for research to generate further knowledge that will contribute to existing knowledge. The statement must be written in a way that gives an empirical basis to describe the situation and also clearly specifies the gaps in existing knowledge and/or controversy and inconclusive evidence. It is at this point the investigator defines the objective of study and conveys the questions or broader issues motivating the research. A logical sequence for presenting the statement would be

- Magnitude, frequency and distribution: Affected geographical areas and population groups affected by the problem. Ethnic and gender considerations.
- Probable causes of the problem: What is the current knowledge of the problem and its causes? Is there consensus? Is there controversy? Is there conclusive evidence?
- Possible solutions: In what ways have solutions to the problem been attempted? What has been proposed? What are the results?
- Unanswered questions: What remains to be answered? What areas have not been possible to understand, determine, verify, or test?

The problem statement should make a convincing argument that there is not sufficient knowledge available to explain the problem and its determine possible solutions, or it should make a convincing argument for the need to test what is known and taken as fact if it is called into question by new findings or conditions.

The discussion in this section should show that the investigator has documented this problem and performed an exhaustive bibliographic review of the subject.

4. Justification and application of results

This describes the type of knowledge expected to be obtained upon completion of the project and the intended application of the results. It should indicate the strategy for disseminating and implementing the research. The justification should answer the following:

- How does the research relate to the national priorities or those of the Region?
- What knowledge and information will be obtained?
- What is the ultimate purpose that the knowledge obtained from the study will serve?
- How will the results be disseminated?
- How will the results be used and who will be the beneficiaries?

The justification, which can be included as part of the statement of the problem or in a separate section, should make a convincing argument that the knowledge generated will have a practical value.

5.Theoretical framework (Background)

This is derived from the statement of the problem (presentation of empirical evidence and central question) and is the argument that the research question has a basis (grounds) for providing a probable answer(s) to the question.

- Establishment of relationships (identification of the relationships between the independent variable and the response variables). What is known and how has it been explained? Are the results conclusive? What are the bases for the question?
- How are the possible answers to the question explained and defended? What are the assumptions? What are the relationships? What are the working hypotheses?

The theoretical framework, considered the grounds that support the central question of the study, states the investigator's reasoning and arguments for the project to find the evidence that will answer the research question and/or hypothesis. It requires an exhaustive bibliographic review.

6. Research Objectives (General and Specific)

These should be defined after the theoretical framework, research question and hypothesis is clear. This is recommended because the objectives are the how the answers will be determined. They are the intellectual activities that the investigator will perform throughout the research process.

- **General Objective**: This should specify what kind of knowledge the study is expected to obtain. It should give a clear notion of what is to be described, determined, identified, compared and, in the cases of studies with working hypotheses, confirmed.
  Example: To verify the differences in the malaria morbidity in children under 5 when they participate in the nutritional supplementation programme as compared to those who do not participate.

- **Specific Objectives:** These disaggregate and follow logically from the general objective. They are a preliminary view of the research design.
  Examples: To estimate the incidence of malaria in children covered by the nutritional supplementation programme and the incidence of malaria in that receive standard nutrition.
  To determine the existence of statistically significant differences in the incidence of malaria in the group of children who receive standard nutrition and the group receiving nutritional supplementation.
  To identify the protective factors that help to explain the differences in the incidence of malaria according to the type of supplementation received.

7. Research design and methods

The design and methods section describes the procedures that will be used to achieve the objectives. In this section the operational definition for the variables used should be specified in detail along with the type of variables and the means to measure them. In addition, the methodology should describe and justify the study design including any techniques and procedures used to achieve the proposed objectives. A description is given below of what the investigator is expected to specify in the methodology.

7.1 Operational definition of variables

Based on the concepts that may be made explicit in the theoretical framework, the variables should be made operative; i.e. the investigator should clearly describe what is understood by each variable, what type of variable is being considered and the way its values are to be reported (quantitatively, when the variable is numerical and qualitatively, when the variables do not have numerical values).

Operationalization is a process that will vary in accordance with the type of research and research design. However, the variables should be clearly defined.

Protocols will be considered incomplete if their operational aspects are vaguely formulated; for example, "The pertinent and relevant variables will be studied," "demographic and social variables will be considered," or when the statement is so imprecise that it does not allow the relevance of the variables and their use to be appraised.

7.2 Study design

The type of study and its design should be decided on the basis of its appropriateness to the objectives, the availability of resources and, in some cases, ethical considerations. The investigator should clearly state the type of study that will be conducted and provide a detailed explanation of its design. In addition, the investigator should also state the strategies and mechanisms that will be used to reduce or eliminate threats to the validity of the results, i.e. the so-called confounding factors (in the selection and assignment of subjects, the loss of cases, and the control of instruments and observers, etc.). These factors can be elaborated on when they are taken up in greater depth in their respective sections.

Example: A longitudinal controlled study will be conducted with two groups of children; those who participate in the programme for nutritional supplementation, and those who only receive standard nutrition. Selection will be made of children who reside in the study area, have been screened in the local health centre, and whose parents or legal guardians have given their consent for their children's participation in the study. There will be two groups formed, which will be randomly assigned.

7.3 Study population

In this section the investigator should describe the population under study and all aspects of the selection procedures and techniques for determining the sample size (if this is not applicable, an explanation should be given). For both probability samples and non-probability samples (samples of convenience or grab samples) the investigator should indicate the procedure and criteria used and justify the selection and size.

In the case of studies using non-probability samples, in which subjects are selected for focus groups or as key informants, the investigator should specify the selection criteria, the type of group and its size and the procedures used to establish the group. Here too, it is necessary to mention the selection criteria for the subjects or units of observation and the procedures to control factors that may affect the validity of the results.

7.4 Proposed intervention (if applicable)

Generally, these are comparative studies intervention (educational program, vaccine, treatment, etc.) with experimental or quasi-experimental designs, before and after, where assessment is made of results attributable to the intervention. There should be a full description provided of the intervention and an explanation given of the activities in their order of occurrence. It is essential that the description of the intervention answer three fundamental questions: Who will be responsible for the intervention? Where will it take place? What activities will be performed, and with what frequency and intensity? All research that include human subjects require an ethical review. In these cases, the investigator will be required to include a section in reference to this area.

7.5 Data collection, management and quality control

The investigator must describe the procedures that will be used (population survey, in-depth interviews, non-participant observation, focus group, content analysis, etc.), how and when the procedures will be used and include the instruments that will be used to collect information (questionnaire, interview guide, observation recording form, guide for a focus group moderator, content analysis guide, etc.). Procedures or techniques that are standardized and/or documented in the literature should be described briefly and bibliographic references should be given to sources where the details of these procedures and techniques can be found.

This section must describe in detail the procedures to be used to control the factors that undermine the validity or reliability of the results (controls for observers or persons responsible for compiling the information, and controls for the instruments).

If the use of secondary data is required, the investigator will describe their sources, content and quality so that it will be clear that the information required for the study is available. If use is made of historical, journalistic or other similar types of documentary sources, indication should be provided of the sources and techniques that will be used to collect and analyze the information.

The protocol should have an annex containing the instruments that will be used (questionnaires, interview guides, moderator guides, registration forms, etc.).

7.6 Data analysis

Indications are given below of what is expected from a plan of analysis. In accordance with the proposed objectives and based on the types of variables, the investigator should specify how the variables will be measured and how they will be presented (quantitative and/or qualitative), indicating the analytical models and techniques (statistical, non-statistical, or analytical techniques for non-numeric data, etc.). The investigator should provide a preliminary scheme for tabulating the data (especially for variables that are presented numerically). It is recommended that special attention be given to the key variables that will be used in the statistical models. State what procedures will be used for data management, including data coding, monitoring, and verification. Also describe the administrative and computer procedures to be used, the type of staff available and whether any training will be needed to facilitate data management. In addition, briefly describe the software packages that will be used.

8. Ethical considerations in research with human subjects

When the research involves human subjects, this section should explicitly provide for the following aspects:

- The known benefits and risks or disadvantages for the subjects in the study.
- Exact description of the information to be delivered to the subjects of the study and when it will be communicated orally or in writing. Examples of this information include: the objectives and purposes of the study, any experimental procedures, any known short- or long-term risks, possible discomforts, expected benefits of the

procedures used, duration of the studies, alternative methods for treatment if the study is a clinical trial, suspension of the study if a finding is made of negative effects or if there is sufficient evidence of positive effects that do not justify continuing with the study, and the freedom of subjects to withdraw from the study whenever they want.

- When appropriate, indicate any special incentive or treatment that subjects will receive through their participation in the study. If there is any type of remuneration, specify the amount, method of delivery, time and reason why payment is required.
- Indicate how the information obtained from participants in the study will be kept confidential.
- List the drugs, vaccines, diagnoses, procedures, or instruments to be used, whether they are registered, unregistered, new or currently in use in the country.

Moreover, responses are required for other ethical aspects such as:

- In studies where personal information will be obtained from the subjects, indicate how the information will be kept confidential.
- For studies involving the participation of subjects in an experiment (experimental or quasi-experimental trials, studies of interventions, etc.), information should be provided on the free and informed consent of the participants and the strategy that will be used to obtain it.
- Brief synopsis of how the research findings will be reported and delivered to the subjects involved in the study or to other interested parties.
- Indicate and justify the inclusion, as appropriate, of children, the elderly, physical challenged, and pregnant women. Justify the non-inclusion in the study group, if appropriate, of women (of any age), an ethnic minority, racial group, etc.
- When appropriate, indicate how the appropriate balance of the two sexes will be ensured in the study groups. In addition, indicate, when appropriate, how gender inequities and discrimination and disadvantages can affect women's involvement in the research.

When studies involve human subjects, an institutional ethics committee in the country or institution where the research will be conducted should evaluate and endorse the research, before it is funded. For this purpose, the form for research involving human subjects should be filled out and care should be taken to attach the informed consent form that will be signed by the subjects involved in the study.

9. Budget

Generally, funding agencies, especially WHO programmes, will meet only the costs specifically incurred by the institution for conducting the project. The support is only for the purpose of research conducted under the project and usually short-term and time limited. Funds are not for general institution strengthening whether for equipment, supplies or training beyond the need of the specific project.

The budget must be itemized and be fully justified. Budget items include personnel costs, operating expenses, subject costs, minor equipment, local travel, and other specified expenditure. Budget items must not include "miscellaneous" or "contingency" items or an overhead payment to the institution.

9.1 Personnel costs

Generally not provided however some costs may be allocated for personnel time spent on the project by individuals not employed on a regular salary. Payments provided to personnel should not be considered as an incentive to conduct research. Funds requested for personnel costs should reflect actual labour costs. As an expression of spirit of collaboration in WHO-supported projects, principal investigators salary will not be supported

9.2 Supplies

For supplies, budget justification must relate chemicals, glassware, stationary, or other disposable items and other supplies to the number of procedures expected to be performed in the project.

9.3 Patient/subject costs

Subject costs must be reasonably related to time lost and/or actual transportation expenses. Costs for investigations and/or laboratory procedures may be included in the budget proposal if they are not a part of the routine medical care for the subjects and are performed only for the sake of the project. The costs shall not exceed the local fees normally charged for such tests.

9.4 Minor equipment

Only requests for minor equipment are generally considered and must be fully justified.

9.5 Local travel of project personnel

Justifiable travel expenses (local per diem) of personnel involved in the study may be included in the budget. No vehicles can normally be provided as part of project support, although vehicle rental can be considered.

9.6 Other costs

If the conduct of the project will necessitate additional support such as investigators' meetings, training workshops and external consultant inputs, this should be costed and an estimate provided under this budget item. Data analysis costs, costs of printing or photocopying forms, mail, telephone and telefax charges, etc., should also be specified and justified under this item.

Provide full justification for the amounts stated under each budget item. It is important to relate the total budget to the scope of the project or number of subjects to be included in the study. Remember, the better justified the budget, the more difficult it is for fenders to reduce it.

References

1. National Health and Social Welfare Research Policy (2008), MOHSW
2. Guidelines for protocol (WHO)