MINISTRY OF HEALTH

Guidelines for submission of a health research proposal
Version 3
DRAFT

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Introduction, preparations to submit, submission procedure, requirements, main narrative of the protocol, definition of terms.

For Research and ethics clearance in Lesotho

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Ministry of Health

Guidelines for submission of a protocol for Research and ethics clearance in Lesotho:

Chapter 1. Introduction

Initial counsel

It is advisable that investigators (researchers) familiarize themselves with provisions of the National Health and Social Welfare Research Policy and always consult the MOH –Research Coordinating Unit (RCU) to get in tune with the national research agenda for consideration and guidance in developing their research protocols. Before submitting a protocol an investigator should be satisfied that it tries to address at least one or more of the following research policy objectives:

- To conduct priority research whose result gets utilized in policy and program development and implementation.
- To establish and strengthen structures and mechanisms to enhance development and coordination of health research systems at all levels.
- To stimulate the generation of information and knowledge that facilitates policy analysis, improves understanding of health systems and guide policy development.
- To develop skills of health and health related staff as well as researchers in health research and in integrated disease surveillance and response to guide decision making.
- To promote the utilization of research recommendations and surveillance results to support evidence based policy and all decision-making.
- To mobilise resources to support the development and implementation of health research nationally.
- To develop and facilitate research and epidemiological advocacy, collaboration, information exchange and learning within Lesotho and externally.

For the purposes of these Guidelines, Health Research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, any records under the health system and biological samples, as well as epidemiological, social, population based studies and psychological investigations; and clinical trials are excluded.

According to current arrangements the Principal Investigator (PI) must submit the proposal to the Director General Health Services (DGHS), in her capacity as Chairperson, Ethics Committee, Ministry of Health (MOH) via the Research Coordination Unit (RCU) of the MOH. The documents to be submitted are mentioned under 3.2.

Introduction of new governing bodies, i.e an independent National Health Research Ethics Committee (NH-REC) and the National Health Institutional Review Board (NH-IRB) shall come with considerable changes to the current arrangement.

A strengthened Research Coordinating Unit (RCU) at the Ministry of Health will be a key central action point facilitating linkage between Principle Investigators and the two governing bodies on matters of research protocol submission for review and clearance.

In the immediate to intermediate term the PIs shall submit their protocols to the RCU and the latter shall make these available to reviewers and subsequently to the NH-IRB before engaging the REC.

Chapter 2. Preparing to submit a health research proposal

It is essential that the research protocol is submitted only when it has been fully developed. The PI therefore has a responsibility to ensure the protocol has been written up fully following the standard agreed format (see section 3.2 below). The PI (and the rest of the research team) is advised to familiarize themselves with the content of the research protocol clearance procedures and requirements so that they already satisfy themselves that all the essential information the reviewers will be looking for in the protocol is included and conditions for approval can be met.

The PI is advised to get a copy of the clearance procedures document and study it carefully: going through the tools annexed to the document shall enable the PI to check that the protocol can provide answers to listed review questions/ elements well in advance.

Upon encountering difficulties in comprehending what is needed the PI is welcome to ask for clarifications at either the RCU or from competent individuals at own institution (University etc).

This preparatory phase is intended to reduce the incidence of incomplete protocols and enhance the chances for successful clearance. It has the advantage of enhancing efficiency and minimize back and forth in queries and responses.

Chapter 3. Submitting the proposal

3.1 Submission procedure

The PI shall clear his/her protocol at the local IRB where one has been established then submit it to the RCU with a cover letter indicating the status of local IRB clearance. Where the local IRB does not exist the protocol shall be submitted directly to the RCU. It is preferable that the PI presents the protocol in person or through an agent to ensure that at the RCU the requisite registration and payment of due levy are accomplished. Steps for submission are as follow:

1) Prepare the proposal
2) Get approval from the LIRB (If applicable)
3) Screening at the RCU for completion and categorization
4) Payment to the REC account as guided by the RCU
5) Submit the proposal
6) Get the registration number for the proposal that is used as tracking number

The submission shall observe the deadlines of the application in relation to review dates as outlined by the RCU calendar for NH-IRB and NH-REC.

In line with the government financial year the calendar of RCU showing timing of the review meetings is as follows:

Quarter 1 (April-May-June) REC session 1 in April, Resource mobilization in May

Quarter II (July-August-Sep.) IRB session 1 in July, REC session 2 in August

Quarter III (Oct-Nov-Dec) IRB session 2 in November, REC session 3 in December

Quarter IV (Jan-Feb-Mar) Planning & budget session in January, IRB session 3 in March.

Table 1: Annual Plan for RCU Activities

Ser #	Item of Activity	Q1			Q2			Q3			Q4		
		Apr	May	J	Jul	Au	S	O	N	D	Jan	F	M
1	Planning & Budget Meeting										x		
2	Resource Mobilization Meeting		x										
3	Receive the proposals from PIs		x				x				x		
4	Institutional Review Board (IRB) Meeting				x				x				x
5	Research Ethics Committee (REC) Meeting	x				x				x			
6	Supervision & Monitoring			x				x				x	
7	Research Forum						x						x
8	Participate in the Annual Joint Review		x										

3.2 Submission requirements

The PI is required to submit the hard copies and the soft copy of the whole proposals The contents of a proposal are:

- The submission letter
- Main narrative of the protocol
- Form for Material Transfer Agreement where relevant
- Bank receipt for registration and review

(Go to 3.2.1 to 3.2.3 for details)

Notes:

1) A Soft copy for complete protocol must be submitted (The Microsoft word 2007 and Excel 2007 software are recommended)

2) Payment of a levy shall be required for all proposals. Levels of fees shall be determined with due consideration to equity between categories of applicant: Lower for Basotho students, medium for students of other citizen and higher for other researchers (table 3). The levy shall be for registration and review for the respective category of applicant and the charges for printing of proposal per page (if necessary). When a Principal Investigator (PI) submits the proposal, the RCU staff will screen the proposal for completeness by using the checklist (attached as annex 2). For an acceptable proposal, the RCU will give a form for payment of levy. Getting the completed proposal and the bank receipt an ID number will be issued from RCU and that will be used as a tracking number for the proposal. Then, the RCU in consultation with the NH-REC chairperson will categorize the proposals and prepare for review.

For the proposals under "Exemption" the RCU will manage in consultation with REC chairperson. If the proposal is satisfactory the letter of approval will be issued. Otherwise, the NH-REC chairperson will give letter of comments to the PI to improve the weaknesses or flaws identified in the proposal. The PIs have to modify the proposal as commented and resubmit to the NH-REC chairperson via RCU for final approval. For the proposals under "Expedite Review", the RCU will send hard copies proposals to 3 primary readers and forthose under Full Committee Review" RCU will sent to all members of NH-REC/IRB (the readers are requested to give feedback by 2 weeks).

The RCU will send soft copies of all proposals to all members of the NH-IRB and REC for information and transparency in which the reasons for exemption will be mentioned when necessary.

Table 2. Number of copies to be submitted

Stage	Category of Review		
	Exempted	**Expedited Review**	**Full Committee Review**
Initial screening	1	1	1
NH-IRB review	0	3	7
NH-REC review	0	3	10

Note: The PI has to submit only 1 copy initially. If necessary, the RCU will contact for modification. Then, if the proposal is categorized under **"Exempted"**, the RCU will issue the letter of approval.

For those who are categorized under **"Expedited Review"** the PI will need to submit 4 more copies of proposal for NH-IRB review. If the NH-IRB has comments, the PI has to edit accordingly and resubmit until it is approved by the committee. When the proposal is approved by the NH-REC, the RCU will inform the PI to submit 3 more copies for NH-REC review. Then, the PI has to modify as commented by the committee.

For those under **"Full Committee Review"**, the PI has to submit 7 more copies for NH-IRB review and modify as commented. When approved by the committee, it will be again submitted to the NH-REC. The RCU will inform the PI to submit 10 more copies for review by all committee members. The PI needs to modify as commented by the committee.

For all proposals, submission of the soft copy to the RCU is essential.

Table 3: Payment structure

Category of applicant	Fees for registration and review
1. Students of Basotho citizen attending the Universities/colleges in Lesotho	M 200
2. Students of Basotho citizen attending the University abroad	TBD
3. Students of other citizen (attending the University in Lesotho or abroad)	US$ 100
4. National institutes and organizations	3% of total estimated budget
5. International institutes and organizations	5% of total estimated budget
Notes: 1. Clinical trials and pharmaceutical interventions are not included 2. If the hard copies proposals are not submitted the applicant has to pay additional 1 M per page for printing	

3.2.1 The submission 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)
- Declaration of clearance by local IRB (if there is one)
- Expected research commencement and ending dates
- Signature, e-mail address and contact number of the PI

3.2.2 Letter of recommendation from respective University/Institutions or organization

3.2.3 Main narrative of the protocol

Format of the research protocol shall be adhered to taking into account type and scope of the study, so that the following is presented:

i. Title of the Research Project: a concise title is preferable.

ii. Institutional affiliations (if relevant) and CV of the investigator: The Curriculum Vitae and contact address and telephone numbers of the Principal Investigator (PI) must be mentioned. CVs of other investigators should also be attached in addition to their being listed as members of the study team.

iii. Introduction/ background

a. This should be a 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, the title of the publication, the journal/book, the year, volume, beginning and end pages of the article. Also to be included here:
b. Statement of the Problem (Including a problem analysis) and research question should enable the reader to make sense of justification and objectives.
c. Rationale and justification and Use of the Results (objectives, applicability) should reflect on significance of the proposed research, emphasizing how the results will provide new knowledge in the particular field, and why it will be important for national or international development.
d. Hypothesis (as applicable)

iv. Literature review
The literature related to the topic from national, regional and international studies, text book and international sources should be mentioned.

v. Research Objectives (general and specific)

vi. Research design and Methods

a. Operational definitions
b. Type of study and study design (e.g. Cross sectional/retrospective/prospective; Descriptive/analytic/experimental) should be spelled out
c. Study population & sample, sampling method, sample size and determination of sample size
d. Place of study
e. Data collection procedures, instruments used, confidentiality
f. Plan of Analysis

vii. Plan for distribution and use of results

viii. Expected benefit from research

ix. Limitations of Study

x. Ethical considerations with informed consent for and forms for data collection (English and translate to Sesotho when the subjects do not understand English)

xi. Timetable for the study

xii. Budget (fully itemized and justified) – A budget summary which should list the major components of the budget, e.g. Travel, Staff emoluments, Equipment, etc. should have an elaborate detailed budget giving the breakdown of each of the sub-sections of the budget summary. Source of budget must be indicated.

xiii. References

xiv. Annexes: Data collection tools, Informed consent forms should be attached. When the study is related to non-English speaking community, the tools and forms must be translated to Sesotho. Material transfer form must be attached if relevant.

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 a problem statement, justification for the research, general and specific objectives, design and methodology, plan of analysis, timetable and budget. It is to the advantage of the investigator(s) to have a protocol that is elaborated clearly and in sufficient level of detail as possible since this will tend to minimize questions and comments from reviewers and increase the chances of approval.

xv. The soft copy of the protocol

xvi. Summary proposal (suggested format attached as annex 1)

3.3 Enquiry/follow-up for the progress

The time for applicants/researchers to enquire for the progress of the review process is two months after the date of submission at the RCU. After NH-IRB and NH-REC sessions respectively the RCU shall communicate results to the PIs as a matter of regular procedure. (Refer to the table 1 on page 5)

Chapter 4. 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. 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 program 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 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 hypothesis (where applicable) and the research objectives. In addition, the abstract should briefly describe the methods and procedures to be used in the project, a brief on work planned, nature of results expected, and their significance.

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 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 and should meet criteria of being realistic and applicable.

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 targeted study units 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. For sensitive personal data the protocol must clarify how confidentiality of the data will be observed and who will have access.
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 and personal information from the subjects 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:
- 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

Funds are usually not for general institution strengthening whether for equipment, supplies or training beyond the need of the specific project. But an investigator may have indications from prospective funders as to what is possible to include and what is not possible.

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. Consideration should be made for compensation to research participants and other costs related to the subjects as long as these are kept reasonable and appropriate to the setting.

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.

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. Again through negotiations exceptions to the rule occur.

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

Annex 1

Protocol Reg. number (for RCU): …….

Summary of Proposal

(To the applicants: please mention briefly, bullet points are encouraged.)

1. **Title**

……

……

2. **Authors and institutional affiliations**

Status in the study	**Name**	**Institutional/organizational affiliations**
Principal Investigator (PI)		
Co-Principal Investigator (CoPI)1		
Co-Principal Investigator (CoPI) 2		
Co-Principal Investigator (CoPI) 3		

2a. Are the CV/s attached with the protocol? Y/N

3. **Problem statement/ Reason for the study**

4. **Research questions and Hypothesis (if applicable)**

5. **Objective/s of the study**

   (a)

   (b)

   (c)

   (d)

   (e)

6. **Expected output/outcome of study**

7. **Methodology**

   a. Study area and population:

   b. Sample Size:

   c. Determination of sample size:

   d. Sampling method:

   e. Type of data:

   f. Study design;

   g. Variables:

h. The data collection method:

i. Data management:

j. Proposed procedures and interventions (if applicable:)

k. Data management:

l. Are the instrument for the study attached with the protocol?
Yes/No/NA

7. Limitation of the study

8. Ethical consideration (Recruitment, Informed consent form, Privacy, Confidentiality of data, Role of the sponsor (if applicable)

8a. Are the informed consent form/s attached with the proposal? Yes/No

9. Time line for the study

10. Dissemination plan

11. Source of budget, estimated budget total and by component

12. Other supporting documents attached

a. Approval from respective IRB/REC Yes/ No

b. Recommendation from respective University/Organization Yes/No

Annex 2

CHECKLIST FOR RECEIVING A PROPOSAL, RCU, MOH (Final Draft)

Title_____

_____

_____

_____

Date_____

Sr. #	Item	Yes (√)
1	Application letter (with the contact number & email of PI)	
2	Letter from the University/organization/IRB approval	
3	CV of the PI and Co-PI as annex	
4	Soft copy of the proposal	
5	Main protocol	
5.1	Title	
5.2	Table of content	
5.3	Study team	
5.4	Introduction: background, Problem statement, justification of study	
5.5	Literature review	
5.6	Research objectives	
5.7	Research Method	
5.7.1	Study type/design	
5.7.2	Operational definition/s	
5.7.3	Population, sample, sample size & its determination, Sampling method, selection criteria	
5.7.4	Independent and dependent variables (if applicable)	
5.7.5	Place of study	
5.7.5	Data collection methods, tools for the study, translate if necessary- attached as annex	
5.7.6	Plan for analysis	
5.7.7	Plan for use of results and distribution of report, expected benefit of study	
5.8	Limitation of study	
5.9	Ethical issues- privacy for respondent, confidentiality of data/ information (informed consent (or) waiver for consent (translate the form if necessary)	
5.10	Time table for the study	
5.11	Budget and source of budget/sponsor	
5.12	List of acronyms	
5.13	References	
5.14	Annexes	
5.15	Numbering of pages	
6	Summary of proposal	

Notes:_____
_____
_____

When complete fill the following: ID#

PI category

Registered by-