Ministry of Health
Republic of Maldives

Guidelines for Submitting Research Proposals

To

National Health Research Council

Health Research Section
Health Information Management and Research Division

2022

Background Information

The National Health Research Council (NHRC) was formed on 20th May 2019 under the Health Services Act (29/2015) and Health Research Regulation (R-1006/2019), with the responsibility of undertaking the scientific and ethical review of all types of health research proposals. The Health Information Management and Research Division of the Ministry of Health is the secretariat of this council. Prior to the formation of the National Health Research Council, the National Health Research Committee was established in 1999 as per a strategy outlined in the Health Master Plan 1996-2005 in order to strengthen the development and implementation of research relating to the health sector. With the establishment of the NHRC, all heath related research projects had to be submitted to the committee to obtain approval before implementation. The implementation of the establishment of NHRC came with the issuance of the Ministry of Health's circular number 23-C3/99/C-24 dated 15 August 1999 effective from 1 September 1999. In addition, the Maldives National Health Research Policy (Policy /23-MoH/2017/03) was established in 2017 with the main goal of implementing an effective national health research system that promotes research culture, addresses national health priorities using highest scientific and ethical standards and is used for improving the health of the people of Maldives.

This guideline was developed to assist health researchers in writing research proposals for submission to NHRC and to facilitate the work of the NHRC in reviewing health research proposals. Regular revisions have been brought to these documents to cater to continuing developments in health research.

Definition of health research as stipulated in the Health Research Regulation (R-1006/2019)

Health research is defined in clause 75 of the Health Research Regulation (R-1006/2019) as using scientific principles to obtain new knowledge on health and diseases. This includes:

- Research and surveys done to obtain information on biological, clinical, technological, psychological and social aspects related to health and well-being of humans
- Research and surveys related to communicable and non-communicable diseases
- Research and surveys related to environment health
- Research and surveys done to improve the health system
- Research and surveys related to new medicines, medical devices and procedures
- Research and surveys to identify the role of new technologies in improving health and health services
- All types of research related to health

Eligibility for submission to NHRC

A research will require NHRC review if it involves the following:

1. Health related research at postgraduate and higher levels
2. Collection of health-related data/health information from health facilities and other institutions
3. Recruitment of human participants as:
    a. Consumers of health or disability support services
    b. Relatives of caregivers of such consumers
    c. Volunteers in clinical trials
4. Human tissue

If you are still unsure whether your research project requires NHRC approval, please read the Health Research Regulation (R-1006/2019) or email the Ministry of Health at nhrc@health.gov.mv

NHRC conducts expedited reviews of health research proposals under the following conditions:

a) Involves only minor changes to the proposal otherwise fully approved within the research period.
b) Requires international or local funding and must receive approval of the council within a certain time period in order to acquire the funding.
c) Is based on a public health emergency or related to outbreak, disaster or time bound event.
d) Any other special situations

Application for Research Registration and Approval

1. Email the research proposal (in Microsoft Word format) with completed application form and other required documents to the Ministry of Health at nhrc@health.gov.mv. This guideline and application form is available from the Ministry of Health website www.health.gov.mv/Downloads. Please ensure that all the required documents as listed in the checklist (Annex 1) are submitted with the research proposal.
2. The secretariat will check if the proposal fits the guidelines. Researcher will be informed whether the proposal is accepted or not via email.
3. NHRC members will review the proposal in order of submissions and comments will be shared with researcher. The normal duration of the entire review process is 1-2 months. NHRC meetings are held weekly every Tuesday.
4. NHRC members will review re-submissions of proposals:
    a. Proposals can be submitted maximum three times (two re-submissions). If it is rejected on third submission, it must be submitted as a new proposal with the application form.
    b. Researchers are requested to submit amended proposals within 2-4 weeks

after receiving feedback from NHRC.

c. If a proposal is re-submitted after 3 months of receiving feedback from NHRC, the proposal will be reviewed as a first submission.

5. Researcher will receive the approval letter when approval is granted by NHRC.
6. If the council deems it necessary to meet with researchers, council may call researchers for a meeting with a minimum of three members.

The Proposal

All proposals should contain the following sections;

1. Title page

The title page must contain the following information:

- Title of the research
- The name of the organization that is proposing to do the research
- The name of the researcher(s) and Designation /Position
- Duration of the project proposed

2. Introduction: **(word count: 250 – 300 words)**

Context or the Statement of the Problem: This section should provide a brief statement on the problem including background of the study to be researched. Information such as current prevalence, incidence and so forth may be included in this section.

3. Purpose of the study, objectives and research questions: **(word count: 200-300 words)**

This section should provide why the research is being proposed, what the study is expected to achieve, including overall and specific objectives. The purpose of the study should align with the broader social, economic and/or health concerns outlined in the introduction, and further focus on the context of the research down to an essential purpose. This section should also include the specific questions/hypotheses that the research is proposing to answer.

4. Significance of the study:

(word count: 150-200 words)

This section should contain a brief statement on why the proposed research is important and perceived benefits.

5. Definitions of terms

The major terms, including different variables and concepts used in the study should be defined in this section. Add operational definitions of all variables. Ensure that appropriate references are provided where necessary.

6. Review of the Literature **(word count: 500– 700 words)**

In this section researcher should write a critical summary and a synthesis of the literature giving insight into the problem at hand and also to the theory behind the topic of research and the work done so far by other researchers, including the local context. Add theoretical and conceptual framework if relevant.

Any references used in developing the review should be acknowledged intext as well as in the reference list and followed consistently throughout the proposal. The references used must be recent, relevant and mainly use primary references. All standard referencing styles used by academic institutions are acceptable. Use consistent referencing style.

7. Methodology **(word count: 700 - 1000 words)**

This section should provide details of the methods that would be used for the study. It should contain the following sub-sections;

7.1 Research design:

This part should give an account of the exact design of the study including a justification of why and how the chosen design inform the research objectives and research questions.

7.2 Sample, population or subjects:

This part should have an outline of the sampling methodology used for the study. Any perceived biases that may be posed due to errors in sampling should also be stated.

Where relevant, the complete sample calculation and the sampling frame must be included in this section. Determining the sample at the outset will help the researcher to calculate the budget and other administrative measures needed for the study.

7.3 Instruments and materials:

This part should outline the instruments that will be used for the study. Validity and reliability of the instruments must be included. If the instruments include questionnaires and/or data collection forms, these documents should be attached as appendices. If documents need translation, translated documents should be attached as appendices.

7.4 Data collection

This part should outline the data collection procedure. Include details on data collection method, administration of any questionnaires/surveys and who will be collecting the data.

7.5 Data Management and Data Analysis:

This part should account for the procedures planned for management and analysis. Any computer-based software that will be used should also be stated. Quality control measures that will be undertaken at all stages of the research should also be outlined. A description of exactly how researcher plans to compile the data collected and how results of the analysis will be organized, presented and interpreted should be included.

8. Ethical considerations **(word count: approximately 200 – 300 words)**

Ethical issues such as obtaining consent and respect for privacy, confidentiality and anonymity of the subjects under study and measures undertaken to ensure safety of the participants.

Include details on data storage, data security, anonymity and discarding of data.

If the research involves medical and/or investigative procedures, any ethical issues that might arise must be envisaged and measures taken to overcome these issues must be stated.

9. Dissemination

The arrangements for disseminating the preliminary and final reports should be outlined. Final report must be shared with NHRC (Annex 2).

10. Limitations and delimitations of the study

This section should include both, what is measured and what will not be measured. Any other limitations such as time frame, sample design and any perceived biases must also be stated.

11. Project costs and Timeline

Budget breakdowns and timeline to conduct the study should be presented in this section. This should include staff requirement, if any, contingency expenses, non-recurring grant for equipment, travel grant for transportation cost etc. It is advised that budget calculations be shown both in local currency (MVR) and in United States dollars (USD). If detailed budget calculations are available, it must be attached to the proposal as an appendix. Declare if no cost involved.

12. Conflict of interest.

Declare conflict of interest of author or any sub-authors.

13. References

All references used in the development of the proposals should be properly acknowledged both in the text and in a reference list using an approved referencing system. Except for seminal articles references should be recent, preferably within five years. All standard referencing styles used by academic institutions are acceptable as long as it is used consistently.

14. CV and training:

Information about the primary investigator of the study and CVs of the primary investigator and co-investigators must be included in the appendix.

15. Appendices

All appendices including approval/no objection letter from data collection institute/organization should be attached. Any other additional documents deemed necessary may be included.

Monitoring of approved research

All approved research will be monitored by NHRC as stipulated in the Health Research Regulation (R-1006/2019). Principal investigator of approved research should submit monitoring form (Annex 3) to nhrc@health.gov.mv by end of December each year until completion of research.

Reminders will be sent to researchers to submit the monitoring form. If the monitoring form is not received after the third reminder, the council has the discretionary power to take action against the researcher.

Annex 1

Please ensure that the following documents are submitted in addition to the research proposal:

1. Application form with signatures
2. Supervisor's letter (for students)
3. Approval letter from university ethics review committee (for students)
4. No objection letters from all institutes of data collection
5. Information sheet, consent form and data collection instruments (including translations if relevant)
6. CV of primary investigator and co-investigators

Annex 2

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Ministry of Health
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FINAL REPORT SUBMISSION TO NATIONAL HEALTH RESEARCH COUNCIL

All research given approval from National Health Research Council (NHRC) should submit this form to NHRC after completion of research.

Part A: Research Details:	
1. Title of the study:	
2.Date of NHRC approval:	
3. NHRC registration number:	
4.Duration of the study (as per the submitted proposal):	

Part B: Researcher/ Investigator Details:	
1.Organization/Individual who applied for approval:	
2.Contact Address (if different from previous):	Contact Address:
	Mobile:
	Email Address (personal email address):

Part C: Details of the research		
1. Background *(Aim of the research /description of what is to be achieved by the study/Objectives/Research questions/Justification)*		
2. Methodology *(specific models or approaches used in the study eg: study design/ sampling technique used to select the participants).*		
3. Results/ findings of the research and implications *(Specific data that indicates the results of the project. What changes should be implemented as a result of the findings of the work? How does this work add to the body of knowledge on the topic?)*		
4. Conclusion *(The overall impact this research could have on the health sector)*		
5. Has the study abstract/ research article been published in a website or journal or disseminated?	Yes ☐	No ☐
5 .a. If yes, please specify in detail:		
6. Would you like to present your findings to NHRC?	Yes ☐	No ☐

Health Information Management and Research Division, Ministry of Health, Maldives,
Contact 332887/Ext:147 Email: nhrc@health.gov.mv

Part E: Declaration: I (Full name and NID Number (_____) hereby declare that all the information provided in this form are accurate, up-to-date and true.	
Sign:	
Date	DD/MM/YYYY

For official Use	
Form received by	Name of staff: Designation of staff:
Form received date	

Health Information Management and Research Division, Ministry of Health, Maldives,
Contact 332887/Ext:147 Email: nhrc@health.gov.mv

Annex 3

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Ministry of Health
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Monitoring Form for National Health Research Council Approved Research Proposal

All research given approval from National Health Research Council (NHRC) should submit this form to NHRC by end of December each year. This form must be submitted till completion of the research.

Part A: Research Details:	
1. Title of the study:	
2.Date of NHRC approval:	
3. NHRC registration number:	
4.Duration of the study (as per the submitted proposal):	

Part B: Researcher/ Investigator Details:	
1.Organization/Individual who applied for approval:	
2.Contact Address (if different from previous):	Contact Address:
	Mobile:
	Email Address (personal email address):

Part C: Status of Research	
1. Current stage/phase of the study:	
2. Specify any change to the study, after approval:	
3. If any changes have been made to study, was it approved by NHRC:	
4. Specify any major challenge faced or reasons for delay:	
5. Estimated date of completion of the study:	DD/MM/YYYY

Part D: Declaration: I (Full name and NID Number (_____) hereby declare that all the information provided in this form are accurate, up-to-date and true.	
Sign:	
Date	DD/MM/YYYY

For official Use	
Form received by	Name of staff: Designation of staff:
Form received date	

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