National Health Research Council
Republic of Maldives

Standard Operating procedure (SOP):
Council meetings, documentation and record keeping

2022
Health Research Section
Health Information Management and Research Division

1. Objective

This SOP is established under the Health Research Regulation (R-1006/2019), clause 24 (ﻫ) to contribute to the effective functioning of the National Health Research Council (NHRC) in Republic of Maldives so that a quality and consistent scientific and ethical review mechanism for health and biomedical research is put in place. These guidelines are in consonance with the international requirements for quality scientific and ethical review. This SOP has to be reviewed and changed accordingly. It is necessary that researchers and policy makers are also aware of the provisions under this SOP.

2. Role of NHRC

The NHRC was formed under the Health Research Regulation (R-1006/2019) on 20th May 2019 with the following responsibilities:

- Undertake the scientific and ethical review of all types of health research proposals (including clinical trials) and give approval to research proposals that meet the scientific and ethical requirements.
- Monitor approved research throughout the study until and after completion by examining the annual reports and final reports. The council will also examine whether all regulatory requirements and laws are complied with or not.
- Establish a mechanism to determine health research priority areas and strategies in Maldives.
- Encourage the use of the results from health research in evidence-based policy making.
- Advise the Minister of Health on issues related to health research.
- Investigate issues and complaints received regarding health research and report to the relevant authorities.

3. NHRC Chair

The Chair is appointed by the Minister of Health and will bear the following responsibilities:

- Call NHRC meetings
- Chair NHRC meetings
- Provide oversight of the NHRC Secretariat; Coordinate with relevant agencies regarding the decisions made in NHRC meetings
- Implement the final decisions of NHRC
- When necessary, delegate certain responsibilities and authorities to the vice-Chair and members.
- Answerable to Minister of Health regarding NHRC

4. NHRC Vice-Chair

The Vice-Chair is appointed by the Minister of Health and will bear the following responsibilities:

- Perform the tasks delegated by the Chair.
- Act as a Chair in his/her absence

In the absence of chair/vice-chair, NHRC meetings will be chaired by any member chosen by the chair/vice-chair.

5. Quorum requirements

The minimum members necessary to compose a quorum should be at least 25% including the Chair. At least two members must be from the Ministry of Health. All decisions should be taken in meetings, except for expedited review as mentioned under “Review procedures”.

6. Application Process

- All proposals are to be submitted with the prescribed application form. Depending on the number of proposals submitted to NHRC, it might take 1-2 months to review and approve

the proposal. Therefore, it is advised for researchers to submit at least 2 months in advance.

- The application shall be made in electronic format and submitted to the secretariat of NHRC as a Microsoft word document.
- The secretariat will screen the proposal before it is shared with members of the council.
- Copies of the proposal with relevant documents will be sent electronically. The members will maintain confidentiality of all documents received for review.
- Where there is need for further clarifications from researcher, the details of meeting will be communicated to the researcher.

7. Review procedure

- The meeting of the NHRC will be held once a week and the dates will be intimated well in advance. However, if need be, meetings can be held as decided by the Chairperson.
- Independent consultants/experts may be invited to offer their opinion on specific research proposals. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the NHRC.
- Proposals will be reviewed in order of submission to NHRC. Re-submissions will be tabled first in subsequent meetings.
- Full council review is carried out by NHRC during weekly meetings with required quorum. All health researches and national researches with a health component will be reviewed by NHRC.
- Researcher is allowed maximum three submissions (two re-submissions). If the proposal is rejected on third submission, researcher must submit a new application.
- The decision will be communicated in writing. If revision is to be made, the revised documents are to be submitted before the next meeting.
- An expedited review may be carried out by the chair of NHRC or member assigned as chair in the absence of NHRC chair/vice-chair, with two or more members designated by chair under the following conditions:
    - Involves only minor changes to the proposal otherwise fully approved within the research period.

- Requires international or local funding and must receive approval of the council within a certain time period in order to acquire the funding.
- Is based on a public health emergency or related to outbreak, disaster or time bound event.

- For all undergraduate research with a health component, researchers must submit a copy of their institutional approval to NHRC before undertaking research for recording purposes. Undergraduate researchers are not required to submit the proposals to NHRC.

8. Scientific Review

The following areas will be reviewed:

- Scientific design and conduct of the study.
- Statement of problem
- Relevance of problem to national or local health activities
- Field of application of proposed results
- Review of literature and other existing information
- Statement of objectives
- Statement of research hypothesis
- Detailed Research methodology
- Sampling technique, sample design, study instruments
- Plans for data analysis, interpretation and reporting
- Questionnaire.

9. Ethical Review

The following areas will be reviewed:

- Examination of predictable risks/harms.
- Examination of potential benefits.
- Procedure for selection of subjects: Exclusion/ Inclusion criteria
- Management of research related injuries, side effects, ADRs/AEs
- Compensation provisions.

- Justification for placebo in control arm, if any.
- Availability of products after the study, if applicable.
- Patient information sheet and informed consent form in local language.
- Adequate care of the vulnerable participants, if any
- Plans for protection of privacy and confidentiality, ensuring anonymity of respondents
- Ethics related to data collection procedure
- Data management
- Involvement of the community, wherever necessary.
- Plans for dissemination of information to public/participants
- Conflicts of interest, if any, and plans for management of same.
- Budget and timeline
- Funding source

10. Communicating the decision

- Decision will be communicated by the Convener in writing.
- Time frame for resubmitting the revised proposal should be indicated along with mode of submission.

11. Archiving/Record keeping

- Bio data of all members of NHRC.
- Agenda of all meetings of NHRC.
- Copy of all study protocols with enclosed documents, annual reports, side-effects/ADRs/AEs etc.
- Minutes of all meetings with due signature of Chairperson.
- Copy of all existing national and international guidelines on research ethics.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Final report of the approved projects.
- Signed confidentiality document of NHRC members.
- Institutional approval of undergraduate researches.
- Annual monitoring forms of researches.

12. Professional development of NHRC members

All relevant new research guidelines need to be brought to the attention of the members. Members including convener should be encouraged to attend national and international training programs in research methodology and research ethics to improve awareness in latest developments for maintaining quality in scientific and ethical review.

13. Conflict of Interest

- If a member is a researcher, supervisor, advisor or immediate family (parents, children, sibling, spouse) of the researcher, then respective member shall declare conflict of interest to the chair/convener of council. Member will not participate in that discussion and decision making process.

If any council member feels that there is any conflict of interest, the member should self-declare for appropriate council decision.

14. NHRC Secretariat/Convener

The NHRC will establish a council secretariat. The responsibility of the council convener/secretariat is as follows:

- The Secretariat is responsible for organizing the meetings, and maintains the records and communication with all concerned.
- Secretariat will prepare the meeting minutes, share with members for comments and get it approved by the chairperson.
- Secretariat will report to the NHRC chair.
- Secretariat will be responsible for the smooth running of NHRC related activities.
- All relevant guidelines to be brought to the attention of the members by secretariat
- Secretariat will monitor attendance and share with NHRC members.