National Health Research Committee
Republic of Maldives

Standard Operating procedure (SOP)

1st January 2013
Ministry of Health
Policy Planning Division
Health Information& Research Section

1. Objective:

The objective of this SOP is to contribute to the effective functioning of the National Health Research Committee 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 and to be used by NHRC as its procedure when reviewing and evaluating proposals for research. This SOP has to be reviewed and changed accordingly. It is necessary that researches and policy makers are also aware of the provisions under this SOP.

2. Role of NHRC

Health research proposals require two types of evaluation viz. scientific and ethical reviews. Ideally there should be two separate committees to undertake this responsibility. However, in view of the fact that large scale health research of different categories is yet to be initiated in this country, it is proposed to have a single committee which will have the dual responsibility of undertaking scientific and ethical reviews to begin with. In the long run, when research load increases two different committees or multiple committees can be set up.

NHRC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual or potential research participants while reviewing scientific excellence and viability of these proposals. It will be always kept in mind that the goals of research, however important, shall not be permitted to override the health and well being of the research participants.

The NHRC will carefully examine the scientific merit of the proposal first. The proposed aims and objectives, literature review, study design, methodology, sample size, statistical planning of the analysis and interpretation, testing of hypothesis, ethical considerations, plans for dissemination of research results, proposed budget, source of funding etc. The committee will also ascertain the investigator/s has the necessary expertise and training to take up the proposed research. Once the scientific rationale is acceptable then the committee will examine the ethical component of the proposed research.

The NHRC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-malificience and Justice are taken care of in research protocols. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start

of the studies as well as monitor the research throughout the study until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not.

This will be the highest body at the National level for Scientific and Ethical Review of health research proposals under Ministry of Health in the Republic of Maldives. It may delegate this responsibility to regional committees in future if adequate competence is developed.

3. Structure and Composition of NHRC

The National Health Research committee's role is to protect the safety and human rights of the community which it serves while approving the scientific merit of the proposed research. Hence the members are to be drawn from various walks of the society such as medical experts, scientists, legal experts, policy makers, statisticians, social scientists, philosophers, theologians etc. so that it can be broad based, multisectorial and multidisciplinary.

4. Appointment of members.

- The members are appointed by the Government of the Republic of Maldives.
- The members are drawn from different departments and specialties to give a multisectorial, multidimensional structure.
- A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.
- Member can tender resignation from the committee with proper reasons to do so, which should be acceptable to the Ministry of Health.
- All members should maintain absolute confidentiality of all discussions during the meeting. Each member should sign a Confidentiality Agreement.

5. A model committee suggested for the new NHRC is as follows.

- Chairperson
- Deputy chairperson
- Convener/Member Secretary: from MoH
- Permanent Members

Permanent members

- 3 Representatives from Ministry of Health (PPD, CCHDC)
- 1Representative from Department of National Planning.
- 1 Representative from Faculty of Health Sciences.
- 1 Representative from IGMH
- 1 Representative from Ministry of Gender, Family and Human Rights
- 1 Representative from Ministry of Education
- 1 Representative of Ministry of Islamic Affairs
- 1Representative from Attorney General's Office

6. NHRC Chair

The Chair will bear the following responsibilities:

- Call NHRC meetings
- Chair NHRC meetings
- Propose and seek approval of the agenda of each NHRC meeting;
- When necessary, make decisions between NHRC and/or Executive Committee meetings;
- Seek the opinion of the Vice-Chair on all important matters;
- Serve as spokesperson for the NHRC;
- Provide oversight of the NHRC Secretariat; Coordinate with relevant agencies regarding the decisions made in NHRC meetings
- Finalize minutes with the Secretariat before submission to NHRC
- When necessary, delegate certain responsibilities and authorities to the vice-Chair and members.
- Inform NHRC of the decisions of sub-committees
- Update and inform the NHRC of relevant issues and decisions of GF
- Organize orientation of new members on NHRC roles and responsibilities.

7. NHRC Vice-Chair

The Vice-Chair will bear the following responsibilities:

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

8. Selection of NHRC Chair and Vice-Chair

- NHRC chair will be the Director General of Health Services from the Ministry of Health.
- Vice- chair will be from permanent members excluding members representing Ministry of Health (departments and divisions).
- Vice – chair will be elected by simple majority of votes among permanent members.

Term of vice chair is as follow;

- The term of Vice-Chair will be for 2 calendar years starting from January
- At the end of the 2 year term the Vice-Chair may stand for re-election.
- However, no person may serve more than two consecutive terms as Vice-Chair.
- If Vice Chair resigns during the term, another Vice Chair will be elected for the remainder of that term.

9. Membership requirements:

Minimum requirement for membership include good understanding of research. Familiarity of each member with the international regulations/standards for health research and ethics is imperative.

10. Quorum requirements:

The minimum members necessary to compose a quorum should be at least 50% including the Chair. All decisions should be taken in meetings and except for expedited review as mentioned under "Review procedures".

11. Independent consultants

NHRC may call upon subject experts as independent consultants who may provide special review of selected research protocols in writing or in person, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, Thalassaemia cases, HIV/AIDS positive persons etc. 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.

12. Applications Procedures:

- All proposals are to be submitted in the prescribed application form, at least 2 months before the proposed study.
- The application may be made in electronic format and submitted to the secretariat of NHRC with one hard copy for record duly forwarded by the head of the Department or Institution / Organization as the case may be.
- The members will be sent copies of the proposal with relevant documents electronically unless specified. The members will maintain confidentiality of all documents received for review.
- All relevant documents to be enclosed with application form
- The date of meeting will be communicated to the researcher, to be present, if necessary to offer clarifications.
- The decision will be communicated in writing. If revision is to be made, the revised documents to be submitted before the next meeting.

13. Review procedure.

- The meeting of the NHRC will be held once in every one month and the dates will be intimated well in advance. However, if need be, meetings can be held earlier as decided by the Chairperson.
- Taken for expedited review will be brought to the notice of all members for ratification of the decisions made.
- Researchers will be invited to offer clarifications if need be.
- Independent consultants/Experts will be invited to offer their opinion on specific research Proposals. The decisions will be recorded in the minutes by the Convener and communicated to the researchers after taking Chairperson's approval in writing.
- Student proposal with limited schedule as the criteria below shall be decided by chairperson.
- Student Research proposals done in undergraduate studies will be reviewed only for invasive, affecting patient/client safety, clinical, behavioural & other research with ethical implications.
- All other health researches (other than undergraduate health researches) shall be submitted to be reviewed by NHRC. All national research with a health component should be submitted to NHRC.

14. Updating NHRC members

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

16. Scientific Review

- 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
- Funding source
- Funds requested for with all components

17. Ethical Review

- 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.
- 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.
- Questionnaire.

18. Expedited review

- All revised proposals, unless specifically required to go to the main committee, will be examined by a sub-committee along with Chairperson and Convener to expedite decision making.
- In emergency situations, if enough time is not available for a full committee meeting, similar sub-committee as above may take the decision.
- Minor protocol variations can be examined in a similar way as above.
- Minor protocol variations can be examined through expedited review

19. Rule of decision making.

- Members will discuss the various issues before arriving at a consensus decision.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decision may be to approve, reject or modify the proposals. Specific suggestions should be given for modifications/revision.
- Modified/revised proposals may be reviewed by expedited review through identified sub-committee members. The recommendation should be ratified by the full committee at the next meeting.
- Negative decisions should always be substantiated by appropriate reasons.

20. Communicating the decision

- Decision will be communicated by the Convener/Member secretary in writing.
- Suggestions of NHRC, if any, should be sent.
- Time frame for resubmitting the revised proposal should be indicated along with mode of submission.

21. Follow up procedures should be as follows.

For specific researches as decided by committee, annual reports should be submitted for review by committee. For such research projects, committee members will review the annual report and look for the following:

- Any serious side effects, adverse drug reactions /adverse events etc undertaken to be intimated.
- Protocol deviation, if any, to be informed with adequate justifications.
- Major protocol revision should be resubmitted to the NHRC for fresh approval) any new information related to the study should be communicated.
- Premature termination of study should be notified with reasons and summary of the studies done so far.
- If published, a copy of research article should be submitted to the committee secretariat
- If research proposal is not published, then final report of research to be submitted at the end of study with a summary of the major findings.

22. 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.

23. 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.

24. Conflict of Interest

- If the researcher for a research proposal is a committee member, then respective member will not participate for that discussion & decision making process.
- If any committee member feels that there is any conflict of interest, the member should self declare for appropriate committee decision

25. NHRC SECRETARIAT/Convener

The NHRC will establish a committee secretariat. The responsibility of the committee convener/secretariat is as follow.

- The Secretariat is responsible for organizing the meetings, and maintains the records and communication with all concerned.
- Secretariat will prepare the minutes of the meetings and get it approved by the chairperson before communicating to the researcher.
- Secretariat will be 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.