

Operational Manual

Medical and Health Research and Ethics Committee

MINISTRY OF HEALTH
Brunei Darussalam

REVISION IN PROGRESS - FOR REFERENCE ONLY

1. Mission

The mission of the Medical and Health Research & Ethics Committee (MHREC) is to conduct scientific and ethical assessment of all studies pertaining to all aspects of human health research conducted by both Ministry of Health (MOH) and non MOH researchers in Brunei Darussalam.

2. Responsibility / Authority

- 2.1 The MHREC is directly responsible to the Permanent Secretary of MOH, Brunei Darussalam who is the Chairperson of the Ministry of Health Research Committee (MHRC).
- 2.2 The MHREC operates under the authority of the Permanent Secretary, MOH, Brunei Darussalam.
- 2.3 The MOH shall indemnify all appointed members of the MHREC against any and all legal issues and claims arising from decisions of the MHREC.

3. Membership / Composition

3.1 The MHREC will comprise the following members:

- 3.1.1 Director of MHREC who is a senior clinician and also as the Chairman/chairperson. This appointment is to the person holding the post.
- 3.1.2 Two (2) deputy chairman/chairpersons who are senior clinicians/senior officers based at MOH, Brunei. This is a personal appointment. The person should have at least an MRCP, FRCS/MRCS, MRCOG, MRCGP or equivalent, and with at least 10 years of experience in the clinical sector.
- 3.1.3 Eleven (11) clinicians based at MOH, Brunei, comprising of eight (8) hospital and three (3) community or public health based clinicians. This is a personal appointment. The person should have at least an MRCP, FRCS/MRCS, MRCOG, MRCGP or equivalent, and with at least 10 years of experience in the clinical sector.
- 3.1.4 One (1) Dental Officer from MOH, Brunei Darussalam. This is a personal appointment. The person should have at least an FRCS Dentistry or equivalent, and with at least 10 years of experience in the clinical sector.
- 3.1.5 Five (5) Medical Researchers based at MOH, Brunei Darussalam who may be Allied Health Professionals, Senior Scientific Officers and Medical Statisticians. This is a personal appointment. The person should have a basic science degree with at least MSc or its equivalent, and with at least 5 years of experience in health services.
- 3.1.6 One (1) Pharmacist employed by MOH, Brunei Darussalam. This is a personal appointment. The person should have a basic science degree with at least MSc or its equivalent, and with at least 5 years of experience in health services.

- 3.1.7 One (1) lay person whose primary interest is in a non-scientific area. This is a personal appointment.
- 3.1.8 One (1) representative from the Department of Policy and Planning, MOH as an ex-officio member.
- 3.1.9 One (1) representative, namely the chairperson from the PAPRSB Institute of Health Science Research Ethics Committee (IHSREC) as an ex-officio member.
- 3.1.10 One (1) representative from the PAPRSB Institute of Health Science with interest in research. This is a personal appointment.
- 3.1.11 Three (3) Secretaries who have participatory but non-voting role and serves the role of taking the minutes of the meetings.
- 3.1.12 One (1) Secretariat who have non-participatory and non-voting roles and serves the role of managing the clerical work for the committee.
- 3.2 The chairman will make recommendations to the Permanent Secretary, MOH, Brunei Darussalam on the appointment of MHREC members. The letter of appointment shall be signed by the Permanent Secretary, MOH stating the terms of reference of the MHREC, tenure of membership and other relevant matters.
- 3.3 On appointment, each member will abide to the preservation of confidentiality and shall not disclose to any other person any information relating to the affairs of the committee.
- 3.4 The Chairman will appoint one member as Alternate Chairman to conduct meetings in the absence of the Chairman.
- 3.5 Appointment to the MHREC is for renewable 3-year term commencing from the date of the appointment letter.
- 3.6 Any member, who is appointed due to the post held at MOH, Brunei Darussalam, shall automatically cease to be a member when the person no longer holds the post. Such person shall notify the Chairperson as soon as possible when he/she no longer holds the post. The Chairperson on receiving the notification or receive confirmed information on the change in status of any member, shall inform the Permanent Secretary as soon as possible to appoint a replacement. A replacement will only be made if there is more than six months remaining of the term of the current sitting board.
- 3.7 All members who are appointed on a personal basis are not allowed to send representatives to participate on their behalf at MHREC meetings.
- 3.8 The Secretary shall notify at least two (2) months before the end of the year 3-year term of any member. The chairman shall consider renewal of the membership of such members based on: (a) the member should have attended not less than 50% of the MHREC meetings held during his/her term, and (b) have actively participated in the meetings attended. If the chairman is satisfied the member qualifies for renewal, the chairman shall submit a recommendation to the

Permanent Secretary, MOH and a new letter of appointment will be issued as per item 3.2 above.

- 3.9 The Chairman will determine which members shall vote on the scientific and/or ethical approval of an application.
- 3.10 The Chairman will recommend to the Permanent Secretary, MOH the disqualification of a member if the member is found to have professional or personal misconduct not conducive to the mission of the MHREC. As soon as possible the Chairman will recommend an appropriate replacement to the Permanent Secretary, MOH and a new appointment letter will be issued as per item 3.2.
- 3.11 Member who feels they can no longer contribute or participate in the MHREC can submit formal application to the Chairman for termination of their membership; the reasons for request for termination should be clearly stated. The Chairman will decide on the application. If request for termination is accepted, the chairman should recommend a replacement as soon as possible. A letter of appointment should be issued at per item 3.2 above and the same applies with the six months time frame as per item 3.6 above.
- 3.12 The chairman may submit application for any increase in membership to the Permanent Secretary, MOH stating number, justification and qualification.
- 3.13 The Chairman may invite other individual/s to attend meetings for purpose of providing expert advice. Such individual/s shall not vote in the approval of research.
- 3.14 The Secretary shall maintain a register of current members to include the following information:
 - (a) Name
 - (b) Date of appointment
 - (c) Date of expiry of membership
 - (d) Contact information
 - (e) Highest academic/professional qualification
 - (f) Name of Employer and position held
 - (g) Professional/Research experience
 - (h) Function in MHREC (see item 3.9)

4. Secretaries and Secretariat

- 4.1 The Secretary is appointment by the Permanent Secretary as Chairman of the MHRC. This is a personal appointment. The person should be a staff of the MOH. The appointment is for a 3-year renewable term. The Chairman stating the duties of the Secretary and tenure of appointment shall sign a letter of appointment. Renewal of appointment of the Secretary is decided by the Chairman of MHREC who will advise the Permanent Secretary.
- 4.2 The Permanent Secretary as Chairman of MHRC shall appoint these Secretariat members for a renewable 3-year term. The Permanent Secretary stating the duties of the Secretariat members and tenure of appointment shall sign a letter of appointment. Renewal of appointment of the Secretariat members is decided by the Chairman of MHREC.

- 4.3 The Secretary or Secretariat members who feel that they can no longer contribute or participate in the MHREC can submit a formal application to the Chairman of MHREC for termination of their membership; the reasons for request of termination should be clearly stated. The Chairman will decide on the application. If the request for termination is accepted, the Chairman should advise the Permanent Secretary to appoint a replacement as soon as possible; the Secretary should recommend replacements for Secretariat members.

5. **Standing Operating Procedures**

5.1 Meeting

- 5.1.1 The MHREC will meet at least once every two months and more often if necessary.
- 5.1.2 The Secretariat in consultation with the Chairman will notify all members of the coming meeting. The Secretariat will inform members of meetings in the calendar year not later than the end of January each year.
- 5.1.3 The Secretariat will notify members of a meeting not later than 1 week before scheduled date.
- 5.1.4 Document for a meeting must be circulated to members at least 1 week before scheduled date.
- 5.1.5 The Secretariat will notify members as soon as possible, of any change in dates or times of scheduled meetings.
- 5.1.6 The quorum for the meeting is not less than 5 members. The quorum for scientific or ethical review shall be not less than 3 voting members (see item 3.9)
- 5.1.7 Only members who are independent of the principal investigator or sponsor (for clinic studies) of an application, or has no conflict of interest, shall attend the meeting to provide opinion or vote on that application. Members should declare any conflict of interest to the Chairman before any application is reviewed.
- 5.1.8 Members whose research applications are being reviewed should only attend the meeting to present their application and shall not provide opinion or vote in the approval of the application. Such member should not be present during deliberations or voting by other members on the approval of the application.
- 5.1.9 The Secretary will take notes the proceedings of a meeting and prepare the minutes of the meeting. The minutes shall be verified by the Chairman and filed in members' personal file that are kept in a locked cabinet not later than 3 weeks after the meeting.

5.1.10 Minutes of meeting will be endorsed at the start of the next meeting.

5.2 Submission of application

5.2.1 Principal investigator shall submit 3 hard copies and a soft copy of their applications which is written in English to the Secretariat of the MHREC, MOH. The Secretariat will enter all applications into the registry. The Secretariat will keep 1 copy for each application in the registry file.

5.2.2 The Secretariat will check the completeness of all applications received. Incomplete applications shall be returned to the principal investigator.

5.2.2 The Secretariat will open an MHREC file for each complete application. All correspondences and documents pertaining to any application shall be filed in the application's file. Files shall be closed by the secretary after a final decision by the MHREC.

5.3 Management of application files and related documents

5.3.1 All active files shall be kept in secured cabinets. Access to the files will be restricted to persons approved by the Chairman.

5.3.2 Closed files shall be sent to the Secretary to be kept together with the related project file maintained by the Secretariat. The relevant Brunei General Orders (GO) and circulars shall govern the storage and destruction of these Secretariat files.

5.3.2 The Secretary is fully responsible for the reproduction of any files and documents. Reproduced copies that are no longer in use shall be destroyed as soon as possible.

5.3.3 Application documents that are circulated to members prior to a meeting for purposes of review of applications should be returned to the Secretary at the end of the meeting. No member is allowed to retain any such documents after a meeting.

5.4 Review process

5.4.1 The Chairman and Deputy Chairman(s) will make a preliminary assessment and determine which application involves study participants and requires ethical review. These applications shall be clearly marked in the list of applications for review that are sent to members together with the copies of applications.

5.4.2 The Secretariat will inform principal investigators of the scheduled review of their applications at least 10 days before the scheduled date. The Secretariat will get confirmation of the attendance of the principal investigators for the scheduled meeting.

5.4.3 The Secretariat will arrange for a suitable venue and make available meeting facilities.

5.4.4 For the scientific and ethical review of each application, the MHREC will adhere to the following;

- (a) The objectives are relevant to prevailing institutional health needs and research priorities set by the MOH or the applied funding source;
- (b) The application has a valid design, appropriate methodology, originality and scientific merit;
- (c) The research is feasible within the proposed duration, cost, physical and human resources.
- (d) The findings of the research are utilisable and shall have a potential positive impact on the management of health problems.
- (e) There is indirect benefit such as human resource development, training, transfer of technology, linkages, etc; and
- (f) The research is conducted in accordance to the 'Brunei Darussalam Guidelines for Good Clinical Practice (ICH-GCP)' with some modifications to suit the local customs.

5.4.5 In conducting ethical review, members shall adhere to the basic principles safeguarding the involvement of study participants in health research. No investigator or supervisor, however, forfeits his/her responsibility to ascertain the same principles are adhered to. Those principles are as follows:

- (a) Where appropriate, informed consent should be obtained from each study participant in accordance with regulatory requirements as outlined in the 'Brunei Guideline for Good Clinical Practice' and the 'Declaration of Helsinki'. In brief, the study participants should have the legal capacity to give consent and must give consent freely without subjected to any force, duress or inducement. The study participants must have sufficient understanding of the implications of his/her participation and should be properly informed through a written fact/information sheet to enable him/her to make an informed decision. The study participants will be told the nature, duration and purpose of the research, the method and means by which it is to be conducted, and any inconveniences and hazards to be expected. The study participants will be fully informed of the effects upon his/her health or person that may arise from participation in the research. The study participants shall be informed that at any time during the course of the research, the study participants shall have the right to revoke consent and withdraw from the research without prejudice to the study participants.
- (b) Written informed consent should be obtained from each study participant. Both the person taking the consent and the study participant should personally sign and date the consent form. Copies of a sample consent form (not filled in) should be kept by the:
 - i. Secretariat and filed in the MHREC file;

ii. Principal Investigator

- (c) Each study participant should be given a signed copy of their consent form and a copy should be filed by the Principal Investigator.
- (d) The research must be able to contribute to knowledge and has reasonable prospect of yielding significant findings that are not obtainable by other methods or means of study, such as the use of animals.
- (e) The research will be conducted so as to avoid all unnecessary physical and mental suffering and injury.
- (f) Only appropriately trained and qualified persons shall conduct the research. The highest degree of skill and care will be required of persons who conduct or engage in the research. Researchers must adhere to the 'Brunei Guidelines for Good Clinical Practice'.

5.4.6 For clinical studies involving study participants, the contact information of the MHREC office shall be included in the patient information sheet for the perusal of subjects to submit complaints pertaining to participation or conduct of the clinical study. On receiving such complaint, as soon as possible within 72 working hours, the Secretariat or Secretary will bring the matter to the attention of the Chairman. The Chairman or members appointed by the Chairman will investigate the complaint and if there is merit to the complaint, will request the principal investigator to submit a written explanation. If the explanation is deemed unsatisfactory, the Chairman will take the necessary corrective actions, which may include termination of the research.

5.4.7 Principal investigators shall attend MHREC meetings to present their applications and to respond to queries raised by MHREC members. If the principal investigator is unable to attend a meeting, he/she should be represented by one of the key investigators in the research. Individuals not involved, as investigators in an application shall not be allowed to participate in the presentation and defense of an application.

5.4.8 For student (both undergraduate and postgraduate) research, the supervisors must be present at the MHREC meeting. If the university is based outside Brunei Darussalam, a Brunei based co-supervisor should be appointed and present at the meeting.

5.4.9 Designated members (see item 3.9) shall vote on the scientific and/or ethics approval come to an outcome of either "full approval", "approval with amendments", "rejection of an application" or "abstention". The decision will be based on a simple majority. In the event of a tie, the Chairman will cast the deciding vote.

5.4.10 The MHREC may and will recommend amendments to an application. Approval for the application will only be given if the amendments are incorporated into the application. Investigators however may argue for such amendments to be voided with valid and acceptable reasons.

5.5 Informing applicant of MHREC decision

The Secretariat will inform the principal investigator of the outcome of an application in writing within three (3) weeks of a final decision by the MHREC. The letter should include: (a) clear and precise statement of decision reached; (b) clearly defined reasons for rejection (if applicable); (c) conditions for approval; and (d) list of materials reviewed at MHREC meetings. The letter must be signed by the Chairman or Deputy Chairman(s). Each section of the documents reviewed and approved must be clearly stamped with the date of decision and initialled by the Chairman or Deputy Chairman(s). For applications which are approved by MHREC, the letter to the will be copied ("cc" carbon copied) to the Permanent Secretary and Deputy Permanent Secretary (Professional) for their information. A copy of these letters and documents shall be kept at the MHREC for filing.

5.6 Appeals on decisions of the MHREC

Appeals on decisions of the MHREC should be made in writing by the principal investigator and submitted to the Chairperson. The Secretary will bring any appeals to the attention of the Chairman as soon as possible. The Chairman will conduct a preliminary evaluation of the appeal and will bring up the appeal for discussion and endorsement at the next MHREC meeting. The decision of the Chairman will be final. Any further appeal should be addressed directly to the Permanent Secretary as the Chairman of the MHRC.

5.7 Modifications of approved research

- 5.7.1 Investigators are not allowed to modify approved research protocols without prior approval from the MHREC.
- 5.7.2 Investigators are not allowed to conduct a research using a modified protocol that is not approved by the MHREC. The approval will automatically be withdrawn for any research found to be conducted using a modified protocol not approved by the MHREC.
- 5.7.3 Principal investigators who intend to modify an approved research protocol shall submit an application to the MHREC Secretary stating what are the modifications and reasons for modifications.
- 5.7.4 The Secretariat will forward such applications to the Chairman as soon as possible. The Chairman can decide on the application or refer to the next MHREC meeting for a decision.
- 5.7.5 The Secretariat will inform the applicant of the decision of the Chairman or MHREC within 4 weeks of the decision. The letter will be prepared as per item 5.5 above.