

# Role of the Medical Health Research and Ethics Committee (MHREC) in Brunei Darussalam

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## BACKGROUND

Applying ethical principles to medical research is an important safeguard for patients and researchers. In the most simplistic way, medical research is focused on finding cures for medical illnesses and improving patient care. The fundamental dilemma in medical research is whether it is acceptable to expose some individuals to risk for the benefit of others. Much research if not done well, can cause harm to individuals and institutions and may impact on time, resources and morale. Therefore, there is a need to regulate research activities to ensure compliance to basic research principles.

The Medical health Research and Ethics Committee (MHREC) aims at instilling an ethos of good research practice to all researchers. In addition, it aims to safeguard patients' and the health services' interests to ensure that no harm is caused by the act of

research. This is achieved by strict adherence to the basic research principles of autonomy, non-maleficence, beneficence and justice.<sup>1</sup>

Autonomy refers to the rights of individuals to make decisions on personal matters. Non-maleficence is embodied by the phrase, '*first, do not harm*' which means that it is more important not to harm the subjects ahead of trying to do them good. Beneficence is defined as the act of promoting well-being to others. Justice concerns the fair distribution of healthcare resources and the decisions of who gets preferential treatment. Ethical decision making is done in accordance with the rules of Principlism whereby potential conflicts within the four basic research ethical domains can be resolved by the use of the Analytic Hierarchy Process which weighs up and arranges the different domains in a hierarchy, so that one of the principles always overrides the others.<sup>2, 3</sup> This approach ensures that decision-making can be flexible and pragmatic and take into account not only ethical but theological, social and environmental factors.

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## **Operational Aspects of the MHREC**

The MHREC was established under the auspices of the Ministry of Health (MOH) in 2009. The committee comprises of two chairpersons, 19 members, three secretaries and a secretariat. Quorum for decision-making meetings is set at six (including chairpersons but excluding secretaries and secretariat). The MOH appoints the chairpersons and committee members for biennial terms with an emphasis on representation from all the medical and healthcare fields. The chairpersons may make the overriding decision in the event of tied decisions and can refer difficult cases to the ministerial level if there are situations where decisions cannot be made at the committee level, or when endorsements are needed to consolidate decisions. Both scientific and ethical components of research are analysed and evaluated by the committee. All individual decisions undertaken by the committee members are confidential and will not be disclosed to researchers under any circumstances. Additionally, the committee also has lay and university representatives from non-medical fields to ensure unbiased ethical judgements. Subject experts may occasionally be invited to provide expert analysis and opinion on matters that may not be familiar to committee members. These experts will, however, not be given the right to vote.

MHREC meetings are held every month and dates are usually set at least six months in advance. The deadline for submission is two weeks before the date of the next meeting. All research with health themes or requiring the use of healthcare facilities and personnel can be reviewed by the committee. If there are excessive numbers of applications

to be reviewed on a scheduled date, the committee reserves the right to forward the research proposals to the next scheduled meeting. Similarly, decisions to fast track certain research proposals can be made by the committee if there are compelling reasons to do so. Researchers are required to adhere to submission guidelines which include a research proposal, updated curriculum vitae and necessary supporting documents. In addition, the primary investigator will be invited to do a PowerPoint presentation of his/her research to the committee. Full details of the submission guidelines can be obtained from the MHREC secretariat.

The MHREC can only give approval for research lasting up to one year. Research of longer duration will need annual approval renewal but this will not necessitate attendance or presentation at a full MHREC review meeting. Approval can be granted for extension of research provided that a satisfactory annual report is provided and there are no substantial deviations from the original proposal. Any changes in research methodology or personnel in an existing approved project must be validated by the MHREC. The committee reserves the right to invalidate existing approvals if these conditions are breached. Furthermore, the committee may forward any cases of serious breach or misconduct to the Ministry of Health for disciplinary action. Retrospective approval for completed or on-going research cannot be given by the committee.

University based research is reviewed by an expedited subcommittee who hold joint meetings with the university equivalent of MHREC (UREC or IHREC). The main role of the subcommittee is to expedite the approval

of simple university-initiated research. The MHREC subcommittee representatives have the right to bring a university-initiated project to the main MHREC committee if a unanimous decision cannot be agreed in the joint meetings. As student research is mainly geared towards research training, scientific methodologies may generally not be as robust as other research.

### Activities of the MHREC

Since its inception, the MHREC has reviewed 183 proposals, of which 63 were evaluated in the main committee and 120 through the subcommittee (Table 1). Tables 2 and 3 show the specialties and institutions which submitted proposals to the MHREC.

From 183 proposals reviewed in the past three years, only one was rejected. The remainder were usually granted conditional approvals subject to fulfilment of specific requirements laid out by the committee. The usual problems that require corrections are issues relating to consent forms and patient information sheets, rectifications of methodology and anonymisation of subjects. The median time from receipt to review of proposal is two months.

### CONCLUSION

The MHREC in Brunei is still in its infancy and

**Table 1: Number of MHREC meetings held between 2008-12.**

Year	Number of meetings held*
2008	3
2009	7
2010	11
2011	12
2012	11
<b>Total</b>	<b>44</b>

**Table 2: Proposals evaluated by MHREC.**

Year	Number of proposals
2008	4
2009	49
2010	45
2011	64
2012	21 *
<b>Total</b>	<b>183</b>

\* Data up to July 2012 (Not including an expected influx of about 40 Universiti Brunei Darussalam Special Study Module proposals in the second half of the year).

more work is needed to develop the committee to adapt to local needs, and at the same time, to comply with international standards. Our research and ethics principles are moulded by guidelines set by the International Conference on Harmonisation on Good Clinical Practice which focuses on protection of human rights as a subject in clinical trial and assurance on the safety and efficacy of newly developed compounds. <sup>4</sup> Acceptance and embracing of these basic ethical principles are crucial for the optimal evolution of healthcare in Brunei and this will require co-operation and understanding from all the relevant stakeholders.

We believe that generally research is

**Table 3: Proposals submitted by specialties.**

Specialties	Number of proposals
Obstetrics & Gynaecology	8
Oncology	6
Dental	6
Public / Occupational Health	5
Renal	4
Cardiology	4
Ophthalmology	4
General Practice	4
Psychiatry	3
Others	19
<b>Total</b>	<b>63</b>

**Table 4: Breakdown of University-led research submitted to the MHREC.**

Affiliations	Number of submissions
Universiti Brunei Darussalam (UBD); Pengiran Anak Puteri Rasidah Sa'adatul Bolkiah Institute of Health Science	83
Dental School (Brunei Darussalam)	18
United Kingdom based universities	9
UBD Social Sciences	3
UBD Biomedical Sciences	3
Australian based universities	2
New Zealand based universities	2
<b>Total</b>	<b>120</b>

done with sound and valid interest to benefit researchers, institutions and patients. However as interest in research grows in the country, there is a need to ensure that strict adherence to research principles are met and researchers do not go beyond the realms of autonomy, non-maleficence, beneficence and justice to achieve their goals. Endorsement from MHREC can ensure credibility and respectability which will lend credence towards conducting of more robust and focussed research which can improve opportunities for publications and presentations. More importantly, it will ensure that we are practising research at an internationally recognised and accepted standard.

#### REFERENCES

- 1:** Beauchamp T, Childress J. Principles of Biomedical Ethics. Fifth Edition. 2001
- 2:** Gillon R. Philosophical medical ethics. Chichester; Wiley, 1986-derived from a 26-part series in *Br Med J* from 1985;290:1117 to 1986; 292:543-5.
- 3:** Page K. The four principles: Can they be measured and do they predict ethical decision making. *BMC Med Ethics.* 2012; 13:10. [Epub ahead of print]
- 4:** Guideline for good clinical practice. Available from [http://www.emea.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002874.pdf](http://www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf). (Accessed 22<sup>nd</sup> August 2012).